Submission No 42

THE PROMOTION OF FALSE OR MISLEADING HEALTH-RELATED INFORMATION OR PRACTICES

Organisation: Medical Technology Association Australia

Name: Ms Susi Tegen

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MTAA submission

Inquiry into the promotion of false or misleading health-related information or practices

7 February 2014

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Medical Technology
ASSOCIATION OF AUSTRALIA

www.mtaa.org.au

Level 12, 54 Miller St, North Sydney
NSW 2060 Australia
PO Box 2016 North Sydney
NSW 2059 Australia
P (+612) 9900 0650
F (+612) 9900 0655
E reception@mtaa.org.au

a) Executive Summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to make a submission to the Inquiry into the Promotion of False or Misleading Health-Related Information or Practices.

b) About MTAA

MTAA is the national association representing companies in the medical technology industry. MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. MTAA members distribute the majority of the non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia.

c) Response to the Inquiry's terms of reference

General

The Committee on the Health Care Complaints Commission (HCCC) is inquiring into possible measures to address the promotion of unscientific health-related information or practices which may be detrimental to individual or public health.

MTAA agrees that health-related recommendations should be consistent with available clinical evidence. In the medical technology context, individuals and organisations should only make claims about medical technology that can be substantiated.

There is a particular risk associated with individuals or organisations that promote unproven medical technology, particularly in place of proven technology. For example, in 2011, the Australian Competition and Consumer Commission (ACCC), Cancer Council Australia and Therapeutic Goods Administration (TGA) issued a warning for Australian women not to rely on unproven commercial breast imaging technologies to detect breast cancer.[1]

HCCC powers

The Inquiry's terms of reference include the adequacy of the HCCC's powers to investigate organisations or individuals that are promoting unscientific health-related information. MTAA considers that the 2013 amendments to the NSW *Health Care Complaints Act* 1993 to allow the HCCC to initiate own motion complaints are appropriate so that the HCCC can investigate matters that:

- raise a significant issue of public health or safety;

[1] "Beware of unproven breast imaging technologies, say ACCC, Cancer Council and TGA" Joint media release, http://www.accc.gov.au/media-release/beware-of-unproven-breast-imaging-technologies-say-accc-cancer-council-and-tga (last accessed 28 January 2014)

- raise a significant question regarding a health service that affects, or is likely to affect, the clinical management or care of an individual client.

In relation to the HCCC's ability to take enforcement action where necessary, section 42 of the *Health Care Complaints Act* allows the HCCC to make recommendations or comments to a health organisation on the subject of a complaint at the end of the investigation of that organisation. However, if a health organisation does not implement the HCCC's recommendations, the misinformation may not be rectified in a timely manner. While section 94A allows the HCCC to issue a warning about unsafe treatments or health services, the health service's false or misleading information may remain in the public domain.

Other applicable regulatory schemes

Complaints about false or misleading information about medical technology may be outside the HCCC's jurisdiction where they are made by a person or organisation that is not a health service or health practitioner in New South Wales. In such a case, there are other government agencies that may have jurisdiction. For example:

- Therapeutic Goods Administration: where the individual or entity is the sponsor of a therapeutic good on the Australian Register of Therapeutic Goods;
- Australian Competition and Consumer Commission: for consumer law concerns.

In addition, the therapeutic goods industry has various industry codes that may apply. For example, the Medical Technology Industry Code of Practice, which is administered by MTAA, is the voluntary industry code for the medical technology industry. The Code of Practice has provisions regarding advertisements or promotion to healthcare professionals. For example, it prohibits misleading or deceptive advertisements to healthcare professionals. Members of the public can lodge a complaint under the Code of Practice if they are concerned that it has been breached.

Medical Technology Industry Code of Practice

(Administered by the Medical Technology Association of Australia)

8th Edition

2012

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Medical Technology
ASSOCIATION OF AUSTRALIA

www.mtaa.org.au

Medical Technology Association of Australia Limited

Level 12, 54 Miller Street
North Sydney NSW 2060 Australia

P (02) 9900 0650
E code@mtaa.org.au

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1 STATEMENT OF PRINCIPLES

1.1 The Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products which is based on genuine consumer health needs and supported by the ethical conduct of all parties. The quality use of therapeutic products means:

a. selecting diagnostic and treatment options wisely based on the best available evidence and the consumer's needs;

b. choosing suitable therapeutic products if this is considered necessary; and

c. using therapeutic products safely and effectively.

1.2 Therapeutic industry codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant community.

1.3 Therapeutic products industry sectors will collaborate with relevant stakeholders in code creation, updating, education, monitoring and compliance.

2 BACKGROUND AND PURPOSE OF THE CODE

2.1 The Medical Technology Association of Australia Limited (MTAA) introduced a Code of Practice for member companies in September 2001. This served to formalise legal and ethical business practices for member companies and promote socially responsible conduct required of Companies in this industry sector.

2.2 The Code has been revised on several occasions, most recently through an independent review in 2011 as provided for in the Code. This edition of the Code is the result of that independent review and also incorporates the recommendations of the Working Group on Promotion of Therapeutic Products which reported to the Australian Government in March 2011.

2.3 The Code is a self-regulatory industry code applying to all Companies which operate in the Industry. A Medical Technology Company must:

a. Adhere to the ethical Promotion of therapeutic products;

b. Provide products that conform to the highest relevant standards of safety, efficacy and quality as established by the Therapeutic Goods Administration (TGA);

The Medical Technology Industry Code of Practice has two columns on each page. The provisions of the Code are on the left hand side of each page. Further guidance on the Code wording can be found in the right hand column under the heading "Explanatory Notes". The Explanatory Notes have been provided to assist with understanding and implementing the Code at an operational level. They do not form part of the Code itself. Additional guidance can be found through the Frequently Asked Questions pages on the MTAA website which can be accessed www.mtaa.org.au

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

The purpose of the Code is to ensure high standards of integrity of behaviour across the medical technology industry to ensure patient and healthcare professional confidence in dealings with the industry and its products.

There are several industry codes applying to different therapeutic sectors. It is the intention that the Medical Technology Industry Code of Practice apply to the supply of medical technology products. Where there is another therapeutic industry code that is more relevant then that code will generally be the more appropriate code.

The Code is but one part of a wider framework for encouraging compliant behaviour by industry. It is complemented and supplemented by a range of training and related programs to assist awareness of the ethical responsibilities of industry.

Many companies in the medical technology industry have their own internal codes of behaviour. The Code aims to set a best practice approach to behaviour but to the extent that a company might require a higher standard of behaviour through its internal code, the provisions of the internal code do not reduce or compromise the standards set out in the Code.

The Code is a self-regulatory code with the consequence that industry assumes the responsibility for maintaining and enforcing the agreed standards of behaviour set out in the Code.

c. Maintain trust and confidence in the Industry through transparency and accountability;

d. Respect ethical requirements and codes of practice which apply to Healthcare Professionals;

e. Uphold not just the letter of the Code but also the spirit of the Code;

f. Have in place a comprehensive process to monitor behaviour and deal with complaints;

g. Remedy behaviour if found to be in Breach of the Code.

2.4 A Medical Technology Company is entitled to fair and equitable treatment under the Code.

3 OBJECTIVES AND SCOPE OF THE CODE

3.1 MTAA is committed to promoting the interests of the Industry by assisting Companies to abide by business standards and engage in behaviours which will enhance the reputation and continuously maintain the integrity of the Industry.

3.2 To this end MTAA provides a framework and mechanisms for setting standards of behaviour, educating Companies, monitoring Industry activities and development, providing self-regulation and disciplinary functions and interacting with governmental, professional and other industry bodies and associations and Consumers.

3.3 The Code is a fundamental part of the framework and mechanism provided by MTAA. Companies recognise and accept the importance of compliance with the Code and the significant benefits to be derived through its application and use across the Industry. Companies also recognise the importance of not only acting, but being perceived by the community to act, with integrity.

3.4 The Code provides guidance to industry best practice standards which shall apply to business practices of Companies. Companies are obliged, as a condition of membership of MTAA, to accept and observe all provisions of the Code.

3.5 A Company should always have regard to its own company code which might provide a higher standard.

3.6 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.

3.7 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 DEFINITIONS

In the Code:

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

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

Association means MTAA.

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

Board means the board of directors of MTAA.

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

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 Complaint Appeals Committee (CCAC) means the committee established in accordance with clause 11.1 to hear an appeal from findings and any imposed sanctions of the Code Complaint Committee.

Code Complaint Committee (**CCC**) means the committee established in accordance with clause 11.1. to hear Complaints brought under the Code.

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

The members of MTAA can be found at the following web address: www.mtaa.org.au

Code of Practice Committee (CPC) means the committee established in accordance with clause 11.1 to review and evaluate the Code and its administration.

Code Monitoring Committee (**CMC**) means the committee established in accordance with clause 11.1 to proactively review activities and Promotions of Companies on a regular basis.

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

a. Sponsors, in relation to any Medical Technology the subject of a licence requiring the Sponsor to comply with the Code;

b. Any person or entity within the Industry which agrees to abide by the Code, however that agreement is expressed; and

c. Any other relevant person or entity from the Industry who submits to the Complaints process and outcomes in accordance with the provisions of the Code.

The definition of company includes any person or entity which agrees to abide by the Code, however that agreement is expressed. 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 healthcare services and/or items to patients; which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Medical Technologies in Australia and/or New Zealand. 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 products, 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.

Regulator means a government agency performing a statutory regulatory function.

Resort Location means a venue that promotes itself or may be reasonably perceived by the public to be a resort with an emphasis on leisure and recreation.

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.

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

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; and

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.

5 INTERPRETATION

5.1 In the Code:

a. the singular includes the plural and vice versa, and a gender includes other genders;

b. another grammatical form of a defined word or expression has a corresponding meaning;

c. a reference to a clause, paragraph, schedule or annexure is to a clause or paragraph of, or schedule or annexure to, the Code and a reference to the Code includes a reference to any schedule or annexure;

d. a reference to A$, $A, dollar, or $ is to Australian currency;

e. the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions; and

f. headings are for ease of reference only and do not affect interpretation.

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

6 ADVERTISING AND PROMOTION OF PRODUCTS

6.1 General

An Advertisement that is directed exclusively to Healthcare Professionals as defined in the Therapeutic Goods Act must:

a. comply with the Code and relevant Laws and Regulations;

b. not be misleading or deceptive, or likely to mislead or deceive;

c. reflect a high standard of social responsibility and conform to generally accepted standards of good taste;

d. be readily recognisable by the target audience as an Advertisement;

e. not claim that a Medical Technology is unique or has some special merit, quality or property unless the claim can be substantiated;

f. not use the term “safe” without appropriate qualification;

g. not imitate the branding, names, logos, get-up or graphic design, copy, slogans, or general layout adopted by a competitor in a way that is likely to mislead, deceive or confuse;

h. not use, the term “new”, or any other term having the same connotation in an Advertisement to describe a Medical Technology after one year from the date of the product’s launch, unless appropriately qualified;

i. comply with the 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.

This section of the Code applies to advertisements directed exclusively to healthcare professionals and those with responsibility for the purchasing of medical devices. However, advertisements directed to consumers are regulated by the Advertising Code rather than the Code.

Compliance with the Code does not absolve sponsors and other advertisers from the need to comply with other common law and statutory requirements, in particular competition and consumer legislation.

Advertisers have a responsibility to ensure the content and presentation of their advertisement and promotional material promotes the quality use of medical technology products through encouraging the healthcare professionals to select, for their patients, appropriate management options, suitable products and then to use those products safely and effectively.

All claims, not just therapeutic claims, which are made, must be truthful, valid and not misleading. While “unique” may be used to describe some special feature of a device it may be taken as implying general superiority. This is unacceptable unless the claim can be supported.

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

6.2 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.

b. A Company must not use the name or photograph of a Healthcare Professional without their written permission nor in any way that is:

(i) contrary to the ethical guidelines of the Professional Association of which the Healthcare Professional is a member; or

(ii) likely to mislead, deceive or confuse.

Advertisers/sponsors are required to hold appropriate balanced comprehensive and credible evidence to substantiate advertised/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 be aware not to 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.

6.3 Comparative Advertising

a. An Advertisement must not unfairly denigrate a competitor’s Medical Technology.

b. 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.

c. If the comparative data that supports a claim referred to in clause 6.3b arises from separate studies then a qualifying statement must be included to the effect that substantiating data arise from separate studies.

When comparative claims are made there should be unequivocal evidence to support the claim. Given the potential commercial impact of comparative claims members should ensure that claims are current accurate and balanced and do not mislead by implication or omission. The intent of any comparison should be that it provides 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.

“Hanging“ comparatives are those that merely claim that a product is better, stronger, more widely used must not be used.

d. A Company must not use Advertisement claims that describe or show a competitor product as broken or defaced, inoperative or ineffective, unless based upon the outcome of comparative testing.

e. An Advertisement must not contain, whether expressly or by implication, exaggerated or unqualified superlative claims.

6.4 Advertisements to Healthcare Professionals – general

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

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

(ii) the name and contact details of the Sponsor;

(iii) claims consistent with the intended purpose of the Medical Technology; and

(iv) all such other information as may be required by law or as a condition of grant of a licence.

b. If a third party requests information on the intended purpose then the Company must provide the information to the third party within 10 working days.

c. Despite the terms of this clause 6, Brand Name Reminder Advertisements do not need to contain any mandatory statements unless otherwise required by law.

6.5 Company Commissioned Articles (CCA)

a. A CCA must be clearly identified as a company commissioned article.

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 referenced.

6.6 Social media in Promotions to Healthcare Professionals

a. 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, MySpace, YouTube, blogs, Twitter, LinkedIn, wikis and similar communication tools.

b. All use of social media by Companies in the Promotion of products to Healthcare Professionals must comply with the requirements of clause 6.1 and clause 6.4.

7 INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.1 General interactions

In all dealings with Healthcare Professionals:

a. a Company must comply with this clause 7; and

b. without limiting this clause 7, a Company must undertake and encourage 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.

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

The following applies to Training and Education, and Medical Technology Demonstrations, conducted by or on behalf of a Company and provided to Healthcare Professionals.

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 leisure or recreational facilities. The choice of venue must be able to successfully withstand professional and public standards of ethics and good taste. Training and Education should not be held at a Resort Location.

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.

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

d. A Company may pay for modest Hospitality for attending Healthcare Professionals.

The overarching purpose of the Code is to encourage, educate on and reinforce the need for ethical dealings by industry with healthcare professionals. Specifically industry needs to determine with each interaction 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.

A healthcare professional is an individual or entity involved in the provision of healthcare services or items to patients, or which purchases, leases, recommends, uses or arranges for purchase or lease of medical technology.

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 that they use the products in the optimal manner.

To this end there is extensive training and education conducted by companies for the benefit of healthcare professionals and ultimately for enhanced patient outcomes. However in conducting the education and training companies need to ensure that the focus of the relationship is educative and not an opportunity to provide 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 product and patient benefit to be derived from the product.

Training should not be held at a resort location. It must be at an appropriate location for education purposes and in a clinical setting where there is ‘hands on’ or instructional training. The primary considerations in choice of a venue for any training should be whether it provides an environment that is conducive to the effective transmission of knowledge and would be perceived by an ordinary member of the public to be conducive to learning. The physical attractiveness of the venue or available sporting or leisure facilities should not determine the venue. If a venue promotes itself or may be perceived by the public to be a resort with an emphasis on leisure and recreation, it is not an appropriate location for education and training, regardless of whether it has adequate conference facilities.

e. A Company must not pay for the Hospitality, travel, or other expenses of any guest of a Healthcare Professional, or for any other person who does not have a genuine professional interest in the information being shared at the program.

f. In the interests of transparency and accountability:

   (i) subject to paragraph (iii), the Company must enter into a simple written agreement with each Healthcare Professional attending the program, which sets out the nature of the program and the services to be provided by or on behalf of the Company;

   (ii) the agreement must require the Company and the Healthcare Professional to make all necessary disclosures to any relevant Professional Association or Institutions; and

   (iii) where the event is modest in nature, the requirement to enter into an agreement may be satisfied by the provision of a detailed program or agenda outlining the services to be provided to the Healthcare Professional.

g. The Company must not impose any requirement on any 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. The Company must not provide to attending Healthcare Professionals any gifts, rewards or free products other than in compliance with clause 7.7.

Hospitality (i.e. 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.

Gifts and other inducements are not permitted except in compliance with clause 7.7. This means that small thank you gifts to a healthcare professional who has presented at a training session must be modest in value (less that AUD$100), and of an educative nature.

7.3 Third Party Educational Conferences

7.3.1 General

A Company may participate in and support a Third Party Educational Conference provided:

a. the Company's participation and support is not provided for the purposes of Promoting a Medical Technology, except in accordance with clause 7.3.5; and

b. the Company complies with this clause 7.3.

7.3.2 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;

An aspect of the relationship between industry and healthcare professionals is the financial support provided to ensure the success of healthcare conferences conducted by the professional associations and conference organisers on behalf of groups of healthcare professionals. This section sets out the parameters within which a company must operate to provide financial support to a conference aimed at healthcare professionals and others in the healthcare sector with responsibility for purchasing decisions.

A third party educational conference is a conference sponsored or conducted by or on behalf of a professional association or a training organisation with a genuine educational purpose or function and which meets certain criteria. The criteria are that the conference is independent, of an educational, scientific or policy-making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.

The relationship regulated under the Code is between the company and the conference organiser. The conference organiser is the entity organising the conference and 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.

The overall aim of this section is to ensure that there are no direct payments to individual healthcare professionals that might be regarded as an inducement to make a recommendation on product selection.

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.

A company may provide sponsorship for a broad range of purposes - to contribute generally to reduce the cost of the conference to participants, to provide grants or direct support by the conference organiser to a healthcare professional or trainee, or provide support for a participating speaker.

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.

(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;

(vi) the sponsorship or grant:

(A) is not conditional on any obligation to or by the recipient;

(B) is not offered or provided in a manner or on conditions that would interfere with the independence or professional obligations of a Healthcare Professional or Practitioner in Training;

(C) is consistent with guidelines established by the Conference Organiser; and

(D) does not give rise to, or facilitate any Breach of the Code;

(vii) the Conference Organiser and the Company enter into a written agreement specifying the nature and conditions of the sponsorship or grant; and

(viii) the agreement requires the Conference Organiser to account to the Company for the use of the sponsorship or grant, without being required to disclose the identity of recipients.

The focus of the conference must be educative, medical or scientific. A company may not direct the conference organiser to select a particular attendee or speaker. If requested by the organiser a company may suggest names of possible speakers or attendees for consideration. A company may not direct the organiser on content but again may suggest possible content if requested by the organiser.

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.

The Code requires that a company and the conference organiser enter into an agreement that sets out the terms of the arrangement.

7.3.3 Hospitality at Third Party Educational Conferences

a. A Company may provide funding to the Conference Organiser to support Hospitality at a Third Party Educational Conference provided the Conference Organiser and the Company enter into a written agreement:

(i) specifying the nature and conditions of the 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 Conference provided the Hospitality is available to all attendees at the conference who are Healthcare Professionals, or a specialty sub-group of Healthcare Professionals;

Any hospitality supported by or provided by a company must be looked at carefully to ensure that it meets community expectations of appropriate behaviour of both industry and healthcare professionals.

A company may provide hospitality (i.e. food and beverages) at a conference either by providing funds to the conference organiser for the purpose or by itself sponsoring an event. In each case the nature of the hospitality must not be the central focus of the event and must comply generally with the other provisions of the Code.

Where a company itself provides hospitality it must be open to all healthcare professional attendees at the conference (or a sub-group). This ensures that a company is not selecting a small number of healthcare professionals to whom it will provide hospitality. At large conferences it is acceptable to provide hospitality to a smaller sub-group such as a clinical sub-group rather than all attendees where the cost might be significant.

c. All Hospitality at Third Party Educational Conferences funded by, or supplied by, a Company, must comply with the provisions of clause 7.5.

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 however the company must determine if the event is lavish or excessive, even if the company has not itself organised the event.

7.3.4 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 7.5; and

c. a Company does not pay the costs of attendees to attend the symposium, other than those referred to in paragraph a.

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 company 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 as a means of avoiding the restrictions on direct individual sponsorship. A company may invite its employees to participate.

7.3.5 Advertisements and Trade Displays at Third Party Educational Conferences

a. A Company may purchase an Advertisement, at transparent and commercially sensible rates, and lease booth space for a Trade Display at a Third Party Educational Conference.

b. A Trade Display must:

(i) not display Advertisements that do not comply with clause 6 of the Code;

(ii) prominently identify the Sponsor of the Medical Technology that is the subject of the Trade Display;

(iii) where the Medical Technology is not yet registered with the Regulator, and is displayed for the purposes of a Medical Technology Demonstration, a notice must indicate that the Medical Technology is not yet registered and be consistent with the intended purpose assigned by the manufacturer;

(iv) comply with requirements of the Conference Organiser that are lawful and do not conflict with any provision of the Code; and

(v) carry out only activities that can withstand public scrutiny and conform to professional and community standards of good taste.

Where a company takes a booth at a third party educational conference or takes out an advertisement, it is required to meet certain conditions, including the general provisions that regulate an advertisement set out in clause 6 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.

7.4 Arrangements with Healthcare Professionals acting as Consultants

a. A Company may engage a Healthcare Professional to serve as a Consultant to provide valuable genuine consulting services, including research, participation on advisory boards, presentations at Company-sponsored training, and product collaboration, provided that such an engagement may take place only where 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. 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.

c. 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 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. Companies should disclose their involvement in both the research and the development of research or scientific publications and require external authors to disclose all relevant competing interests when submitting a publication or making a presentation.

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;

Where a company has a consulting arrangement with a healthcare professional it must set out the terms and conditions of that arrangement in an agreement. Any payment is required to be consistent with “fair market value” which will vary depending on the medical speciality and the seniority of the healthcare professional. However regardless of these criteria the arrangements must reflect fair payment for fair input and be proportionate to the effort involved. The consultant must be selected by reference to objective criteria such as the skills and appropriateness of experience, not on the basis of recommendation of volume of product or value of business.

Arrangements with consultants who are clinical trial investigators may include attendance at third party educational conferences to present clinical trial results. The clinical research services should be addressed in a clinical research protocol. The basis for the arrangements should be set out clearly in the contract with the healthcare professional. The amount of any royalties to be paid for the intellectual property input of the healthcare professional must be based on objective factors such as the amount of effort of the healthcare professional reflected in the product development.

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

The intention of clause 7.4(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.

(ii) the compensation paid to a Consultant must be consistent with fair market value for the services provided;

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

(iv) when a Company contracts with a Consultant to conduct clinical research services there should be a written research protocol;

(v) Consulting Arrangements should only be entered into where a legitimate need for the services relevant to the Company's products is identified in advance and documented;

(vi) the calculation of royalties payable to a Healthcare Professional in exchange for intellectual property arising from the Consulting Arrangements should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence;

(vii) the location and circumstances for any meetings between the Company and the Consultant must be appropriate to the subject matter of the engagement and the meeting must be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of information;

(viii) Company-sponsored Hospitality that occurs in conjunction with a Consultant meeting or a meeting with a prospective Consultant must be modest in value and subordinate in time and focus to the primary purpose of the meeting;

(ix) the Company may pay for reasonable and actual expenses incurred by a Consultant in carrying out the engagement, including reasonable and actual travel, modest Hospitality and lodging costs in attending meetings with, or on behalf of, the Company. The Company may not fund or facilitate personal or private side trips from a consulting engagement which the Company has engaged the Consultant for; and

(x) the written agreement documenting the Consulting Arrangement must require the Company and the Consultant to make all necessary disclosures to any relevant Professional Association or Institutions concerning any existing or potential conflict of interest.

7.5 Hospitality and Entertainment

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 that the Hospitality:

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

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

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

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. 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.

7.6 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 7.8.

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

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

7.7 Gifts between Healthcare Professionals and Companies

a. A Company occasionally may provide a Healthcare Professional with an item that benefits patients or serves a genuine educational function for the Healthcare Professional provided that the item has a fair market value of less than A$100, except in the case of medical textbooks or anatomical models.

b. A Company may not give a Healthcare Professional any type of non-educational branded promotional item, even if the item is of minimal value and related to the Healthcare Professional's work or for the benefit of patients. This restriction does not apply to Medical Technology marketed only to Consumers.

c. A Company may not accept a gift from a Healthcare Professional which is beyond the level of what is reasonable and customary in the circumstances of the relationship.

d. A Company must ensure that sales of Medical Technology are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a Healthcare Professional receiving payments, gifts or Hospitality.

e. For the avoidance of doubt, this clause does not preclude the legitimate practice of providing to Healthcare Professionals appropriate sample Medical Technologies for genuine Training and Education or Medical Technology evaluation purposes.

A company may provide a gift to a healthcare professional of an item that benefits patients or serves a genuine educational purpose.

Any gift must have a fair market value of no more than A$100 and be of an educative nature. The limit of A$100 does not apply if the gift is a medical textbook or anatomical model given that these invariably cost more than the limit. Nonetheless they should not be extravagant. Branded promotional items are not permitted.

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.

7.8 Competitions for Healthcare Professionals

a. A Company may conduct a Competition for Healthcare Professionals that complies with the following limited 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 A$100) and directly relevant to the practice of medicine or area of healthcare. This means that e.g. a prize of cinema tickets or wine would not be appropriate.

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

7.9 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) ensures that the recipient of the funds makes an independent decision on application of the funds or selection of any beneficiary of the funds; and

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

b. Research grants

A Company may provide research grants to support independent medical research with scientific merit provided that such activities have well-defined objectives and milestones (and subject to clause 7.4 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 7.9 are met.

A company may provide research and educational grants and charitable donations in prescribed circumstances. Criteria for making a grant or donation must not depend on volume or value of purchases.

All grants must be 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 7.9(a)(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.

A company may make a charitable donation provided that the donation is directed to the charitable or philanthropic purpose. 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.

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 genuine charitable organisations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission.

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.

7.10 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.

7.11 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.

7.12 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.

8 COMPANY REPRESENTATIVES

8.1 Company representatives

a. A Company must:

(i) ensure that its Company Representatives are fully aware of the provisions of the Code; and

(ii) provide ongoing training to Company Representatives on compliance with the provisions of the Code.

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; and

(iv) act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.

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.

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.

It is preferable that all employees within the medical technology industry receive at least broad training on the Code and the need for ethical and professional dealings.

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

8.2 Company Representatives - requirement for training

a. A Company must ensure that every Company Representative undertakes an education program on the Code approved by the Association:

(i) within the first six months of employment in the role of Company Representative; and

(ii) as a refresher program at no less frequency than once every three years.

b. A Company must ensure that every employee employed in a role which involves Promotional activities on behalf of the Company undertakes an education program on the Code approved by the Association:

(i) within the first six months of employment in the role; and

(ii) as a refresher program at no less frequency that once every three years.

In support of the requirement to ensure adequate knowledge of the Code, every employee who works in a role with a direct relationship with healthcare professionals must undertake an education program on the Code within six months of commencing employment with the company and then a refresher program at least once every three years. If there are significant changes to the Code it is expected that these employees will have a refresher on the changes.

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

8.3 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.

9 INTERACTIONS WITH CONSUMERS

9.1 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.

9.2 Competitions for Consumers

a. A Competition must not be directed to Consumers in relation to any Restricted Medical Device.

b. To the extent a Competition comprises an Advertisement, it must comply with clause 6 of the Code.

c. Entry into a Competition must not, as a condition of entry, require a Consumer to purchase a Medical Technology during or after the Competition period. This restriction does not apply to non-invasive Class I devices, Class I sterile and Class IIa medical device intended for consumer supply and use, or Class IIa contact lenses, where the marketing of the product is directed only to Consumers.

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

9.3 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.

9.4 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, alist of health consumer organisations to which it provides financial supportand/or significant direct/indirect non-financial support. The list could be updated on an annual basis.

10 INTERESTS HELD BY HEALTHCARE PROFESSIONALS IN MEDICAL TECHNOLOGY COMPANIES

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

b. A Healthcare Professional who owns an interest in a Medical Technology Company must disclose that interest to a Consumer where the Healthcare Professional recommends a product that is marketed by that Company.

11 ADMINISTRATION OF CODE OF PRACTICE

11.1 General

Four committees are established for complementary Code administration purposes:

a. Code of Practice Committee- member-based committee which is responsible for overseeing regular reviews and evaluation of the Code and its administration (including complaints and their outcomes), promotion of the Code and education on the Code.

b. Code Monitoring Committee- has a proactive role to request material from Companies related to either Promotion to or dealings with Healthcare Professionals. The Committee has the capacity to refer a possible Breach to the Code Complaints Committee.

c. Code Complaints Committee- initial complaints review body which is drawn from a cross-section of representatives of Healthcare Professionals, Institutions, Consumers and Industry.

d. Code Complaint Appeals Committee- appeals body established to hear an appeal from findings and any imposed sanctions of the Code Complaints Committee.

The meeting procedures for each Committee are in Appendices 1-4 of the Code.

11.2 Role of CPC

CPC is responsible for the review and evaluation of the Code and its administration. To achieve this, CPC must:

a. conduct regular internal reviews in accordance with clause 11.3(a) of the Code and external reviews in accordance with clauses 11.3(b) and (c) of the Code to ensure it continues to reflect community, Industry and regulatory standards and values;

b. consult with key stakeholders if it is considered that more than minor amendments are required;

c. submit all proposed amendments to the Board for approval;

d. publicise all amendments in accordance with clause 11.4;

e. oversee the effective operation and administration of the complaints handling procedures;

f. collate statistical data of complaints received and their outcomes; and

g. conduct a regular review and analysis of complaints and Industry issues they may raise and make recommendations to the Board.

11.3 Reviews

a. For the purposes of conducting an internal review, CPC may seek comment or submissions from Companies and other relevant stakeholders.

b. External reviews of the Code must be carried out once every three years or more frequently if so determined by CPC.

c. External reviews may be conducted by:

(i) an independent, appropriately qualified and experienced, consultant; or

(ii) a panel of independent, appropriate qualified and experienced persons.

11.4 Publicising the Code

a. CPC 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.

b. MTAA must undertake a publicity campaign every time more than minor changes are made to the Code, and provide opportunities to raise awareness of the Code through media and other outlets.

c. MTAA must ensure that 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.

d. MTAA must encourage Companies to promote the Code on a regular basis.

The section outlines the MTAA's role in publicising the Code. Clause 8.2 outlines company requirements to train company representatives.

11.5 Education on the Code

a. CPC must ensure the regular provision of education on the interpretation and application of the Code to Companies, the Industry, Healthcare Professionals, Regulators and other relevant stakeholders and participants in the healthcare industry.

b. CPC must conduct education programs every time more than minor changes are made to the Code and at least once every three years.

This section outlines the CPC's role in educating stakeholders about the Code. Clause 8.2 outlines company requirements to train company representatives.

12 CODE MONITORING

12.1 Code Monitoring Committee

a. To support compliance with the Code the Code Monitoring Committee (CMC) will proactively monitor Promotions and activities of Companies on a regular and ongoing basis.

b. The CMC may request a Company to report on Promotions and activities from a specified period during the past 12 months, or other evidence of compliance with the Code, for review by the CMC.

c. The Company must report within the time specified in the request being not less than 15 working days from the date of the request. After reviewing the report, the CMC may request additional information and/or material from a Company to clarify or expand on the information before it.

d. The Authorised Representative must provide a signed written statement that the report and any additional material provided to the CMC constitutes all the relevant information and material or that no such material exists.

e. If the CMC determines that a Breach of the Code may have occurred the CMC 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

(ii) contact the Company to indicate its view that a Breach of the Code may have occurred and advise the Company that the CMC is giving consideration as to whether or not to prepare a Complaint for consideration by the CCC. The CMC 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.

f. Where clause 12.1(e)(ii) applies, the CMC 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 12.1(e)(i) or under clause 12.1(g).

The Code Monitoring Committee has been established with authority to require companies to report on and supply promotional material and material identifying interactions with healthcare professionals for review. This ensures that industry behaviour is reviewed proactively as well as a review of specific actions or material arising from a complaint.

The aim of the monitoring process is to encourage compliance with the Code, provide advice on compliance where necessary and to provide an ongoing mechanism for the identification of potential future amendments to the Code and any training and education requirements.

The CMC will also be able to analyse the extent to which companies have a compliance system in place for monitoring and reporting on compliance.

The CMC has the authority to refer any material or actions that appear to disclose a breach of the Code, to the Code Complaints Committee for further investigation. The failure to respond to a request to provide material may in itself constitute a breach of the Code.

g. Where the CMC having considered any response of the Company under clause 12.1(f), determines that it is appropriate to refer a matter to the CCC as a Complaint, it must:

(i) Formulate the Complaint in a manner consistent with the form of complaint set out in Appendix 7;

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

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

13 COMPLAINTS

a. A Complaint regarding:

(i) an Advertisement (other than an Advertisement directed to Consumers which is dealt with in clause 13(b)), or Promotional activities by a Company; or

(ii) an interaction with a Healthcare Professional,

must be dealt with by the Code Complaints Committee (CCC), contact details for which are listed in Appendix 6.

b. Subject to clause 13(c), a Complaint regarding an Advertisement directed to Consumers must be forwarded to the bodies listed in Appendix 5.

c. Notwithstanding the provisions of clause 13(b) of the Code, 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,

then the CCC may deal with any assertion in the Complaint insofar as it relates to the other conduct.

d. All Complaints and responses must be in writing.

e. In support of a fair and transparent complaints system, anonymous Complaints are not accepted.

f. The CCC must deal with all Complaints it receives in accordance with the provisions of the Code.

g. Notwithstanding the obligations on MTAA to report on the outcome of Complaints as provided in the Code, all information about a Company, a Complainant, and the subject matter of a Complaint, must be kept confidential by MTAA until all avenues of appeal are exhausted and outcomes of appeals known.

14 COMPLAINT HANDLING PROCEDURES

14.1 Complaints by Consumer or Non-Industry Complainant

The following applies to a Complaint to be made by a Consumer or Non-Industry Complainant.

a. Before lodging a Complaint, the party wishing to complain is encouraged (but not required) to seek to resolve the issue the subject of the Complaint with the Company whose behavior has given rise to the Complaint.

b. For privacy purposes, and to avoid any disincentive for making a Complaint, the Complainant may apply to the CCC to have the Complainant's name withheld from the Respondent and from public release.

14.2 Complaints by an Industry Complainant

Before lodging a Complaint, an Industry Complainant must seek to resolve the issue the subject of the Complaint, directly with the Company whose behaviour has given rise to the Complaint.

The Industry Complainant may not make a Complaint unless the parties have been unable to satisfactorily resolve the issue within 10 working days.

14.3 Mediation

MTAA may invite a Company, a Consumer or a Complainant (other than the Code Monitoring Committee) to participate in mediation as an alternative to participating in the Complaints process established under the Code.

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

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

The Code Complaints Committee considers complaints about alleged breaches of the Code.

Before making a complaint to the CCC, possible complainants should consider two issues:

1. Consider approaching the company who you are concerned about (this step is mandatory for industry complainants);

2. Consider whether mediation may be an appropriate avenue for resolving the matter;

In relation to step 1, the Code requires industry participants to attempt to resolve issues before resorting to the complaints process. If an industry complainant is not satisfied that the behaviour has been addressed after approaching the other company then a complaint may be lodged with MTAA. Consumer and non-industry complainants are encouraged, but not required, to raise their concerns with the company itself before making a complaint to the CCC.

While the Code Monitoring Committee may be viewed as a non-industry complainant under the Code, a complaint referred by the CMC is not subject to the requirements in the Code for intervention or mediation prior to consideration of the complaint.

Step 2 refers to the mediation process provided for under the Code. This may be more appropriate in some situations than a formal complaint process. MTAA may invite parties to participate in mediation. It is also open to the parties to a complaint to request mediation as the means to resolve the issue.

Where steps 1 and 2 are unsuccessful or not appropriate, a complaint may be lodged with the CCC.

14.4 Process for making a complaint to CCC

The following applies to all Complaints, other than those referred by the CMC.

a. A Complaint must be in writing with six copies of the Complaint and supporting material (one for each member of the CCC, one for the Complaints Secretary and one for the Respondent) 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;

(v) where the objection refers to other Advertising, provide sufficient detail to enable the CCC to obtain a copy of the Advertisement; and

(vi) in the case of a Complaint by an Industry Complainant, include evidence that the Complainant has complied with clause 14.2.

b. If the Complaint is brought under clause 6.2(a)(iii) by an Industry Complainant on the basis that the Company has not provided substantiation of a claim, the Complainant must provide evidence to support its allegations.

14.5 Steps to be taken following receipt of Complaint

a. When a Complaint is received, the Complaints Secretary must acknowledge the Complaint, whether concerning a Company or other entity in the Industry, 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

Where a complaint is made against a member of MTAA, the company is bound to participate in the complaints process.

Where a complaint is made against a non-member of MTAA, the company will be invited to participate in the complaints process.

MTAA will use best endeavours to:

- convene the CCC within 30 working days of receipt of complaint;
- convene the CCAC to hear the matter within 25 working days of receipt of appeal; and
- notify companies of the outcome of the CCC and CCAC deliberations within 10 working days.

14.6 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 CCC and asked to indicate whether it agrees to abide by the CCC'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 the invitation 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.

14.7 CCC consideration of Complaint

a. The CCC 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,

(iv) provided that:

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

(vi) the parties are provided with a record of all information obtained pursuant to clauses 14.7(a)(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 CCC must determine the outcome of the Complaint based on the material submitted by the parties.

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

d. The CCC 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 CCC 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 CCC must provide a written notice of its decision to the Complainant and the Respondent, within 10 working days of the CCC 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 CCC determines otherwise. This payment is separate from and in addition to any fine payable under clause 15. In the case of a Complaint by an Industry Complainant, the CCC may require such costs to be shared by the parties in proportions determined by the CCC.

14.8 If in the course of hearing a Complaint the CCC identifies a further possible Breach of the Code (not itself the subject of the Complaint) it may refer the matter to the Code Monitoring Committee for further investigation. Complaints about matters which are the subject of court proceedings

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

14.9 A party to a Complaint must notify the Complaints Secretary immediately upon becoming aware of any court proceedings concerning the substance of the Complaint. Referral by Code Monitoring Committee

If in the course of undertaking a review in accordance with clause 12.1, the CMC identifies a Breach of the Code and resolves to refer the matter to the CCC, the CCC must deal with the matter in accordance with the following procedures:

a. the CCC may inform itself of any matter by:

(i) seeking further information from the Respondent;

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

(iii) referring to publicly available information,

provided that:

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

(v) the Respondent is provided with a record of all information obtained pursuant to clauses 14.9a(i), 14.9a(ii) or 14.9a(iii), and is afforded a period of 10 working days within which to respond in writing;

b. the Respondent may not be present during the hearing of a Complaint, either in person or by a representative;

c. the CCC 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;

d. if the CCC considers that a Breach of the Code has occurred, it must determine the appropriate sanction as provided under clause 15.2 of the Code;

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

f. 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 CCC determines otherwise. This payment is separate from and in addition to any fine payable under clause 15.

14.10 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 CCC 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 CCC 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 14.10b, the Complaints Secretary must inform the Complainant and the Respondent in writing, detailing the reasons.

d. Termination of the Complaints handling procedure under clause 14.10a will not prevent the CCC 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 grave disrepute.

e. The Complainant must reimburse MTAA its secretariat costs and out-of-pocket expenses associated with the Complaint, unless the CCC 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 CCC must first classify the severity of the Breach, in accordance with the classification set out below.

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

The Code determines the outcome of a complaint in two parts. The first is to determine if there has been a breach and to classify the seriousness of the breach. The second part is to assess the applicable penalty or sanction for the breach that has been determined.

15.2 Available Sanctions

a. Where the CCC finds that a Company breached the Code, the CCC 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 CCC 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 CCC, within 10 working days of receipt of the decision, that it has taken the required action.

(iii) A requirement that the Company issue a retraction, including corrective letters and advertising. The retraction must comply with all directions of the CCC, including directions in relation to recipient, number, format, size, wording, mode of publication, prominence, timing and method of distribution. The Company must confirm in writing to the CCC, within 10 working days of receipt of the decision, that it has taken the required action and provide a copy of the retraction once published.

(iv) The imposition by the CCC of a fine in accordance with the following schedule. The Respondent must pay the fine to the Complaints Secretary within 30 days of being advised of the decision of the CCC.

Minor Breach: Nil

Moderate Breach: Maximum A$25,000

Severe Breach: Maximum A$50,000

Repeat Breach: Maximum A$75,000

Serial Breach: An amount not less than A$10,000 and not more than A$100,000.

b. Subject to clause 16.2, if the CCC resolves that a Complaint from a member of the Industry is frivolous or vexatious, the CCC 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 A$5,000 for abuse of the Code.

c. If the CCC 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 Board. The Board may deal with the recommendation under the provisions of its constitution.

d. In the event that the CCC requires a Respondent to cease a conduct or withdraw an Advertisement and the Respondent wishes to appeal the decision, the CCC'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 CCC to have breached the Code, fails to comply with any sanctions imposed on it by the CCC, 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 CCC 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 CCC 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 CCC may direct MTAA to notify the Regulator of the continued Breach of the Code.

In relation to clause 15.3(a), failure to comply with any sanction imposed by the CCC 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 PROCEDURES

16.1 Appeals - general

a. A Company who has been found by the CCC 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.

b. 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 with six copies (one for each member of the CCAC, one for the Complaints Secretary and one for the other party).

MTAA will use best endeavours to:

- convene the CCC within 30 working days of receipt of complaint;
- convene the CCAC to hear a matter within 25 working days of receipt of appeal; and
- notify companies of the outcome of CCC and CCAC deliberations within 10 working days.

c. 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.

d. 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, unless the CCAC determines otherwise. This payment is separate from and in addition to any fine payable under clause 15.

e. In the case of a Complaint by an Industry Complainant, the CCAC may require such costs to be shared by the parties in proportions determined by the CCAC. In all other circumstances the CCAC 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 CCAC must consider:

(i) the material that was considered by the CCC in the matter;

(ii) the appeal papers; and

(iii) any response from the Complainant.

b. The CCAC 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 CCAC to each party no later than five working days before the date of the appeal hearing.

d. The CCAC must consider whether findings of the CCC 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 CCC.

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

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

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

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.

b. The website publication will be removed after twelve months. 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.

c. MTAA must not publish in any form the name of a Complainant if it has been withheld in accordance with clause 14.1(b).

18 MEDIATION

18.1 General

a. Where the parties have consented to a mediation under clause 14.3, the Complaints Secretary 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 may be present in person at the mediation. It is not expected that the parties will be legally represented at mediation.

e. 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 mediator may seek the advice or participation of an expert, as required.

c. The mediator is responsible for arranging and conducting the mediation and, subject to confidentiality arrangement agreed between the parties, reporting to the CCC on progress and any outcome.

d. 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.

CODE OF PRACTICE COMMITTEE (CPC) PROCEDURES

CPC must operate in accordance with the following procedures.

1 **Composition of CPC**

CPC is made up of:

Full Members:

a) one chair who is independent of both MTAA and its members;

b) six representatives elected from among the MTAA Authorised Representatives or a senior delegate of an Authorised Representative; and

c) one Consumer Representative.

Observers:

d) a representative of the MTAA secretariat ; and

e) the Code Secretary.

CPC may from time to time second one or more experts to assist it in its deliberations. Experts and observers do not have voting rights.

2 **Appointments to Code of Practice Committee**

The Board appoints the independent chair and Consumer Representative, who have an initial term of two years. The Board may reappoint the independent chair and the Consumer Representative for one further term each of two years.

Each elected member of CPC has an initial term of two years and may stand for re-election for one further term of two years.

3 **Quorum**

A quorum consists of the chair and four other members.

4 **Frequency of meetings**

CPC must meet at a minimum twice per year. The Chair may request more frequent meetings on an as needs basis.

5 **Conflicts of interest**

A member of the CPC must disclose any conflict of interest or likelihood of a conflict of interest, in any matter under consideration. If a conflict is disclosed the member may not participate in the deliberations of the CPC regarding the matter nor any vote relating to it.

6 **Voting**

Decisions of CPC must be made unanimously or, where there is not a unanimous decision, by a simple majority vote of the attending CPC members, that is, more than 50% of the members in attendance at the meeting.

Experts and observers do not have voting rights at meetings.

7 **Reporting by the CPC**

Each year, CPC must provide a written report on the administration of the Code which addresses each of the sub-clauses in clause 11.2(a) to (g), for inclusion in the MTAA Annual Report .

CODE MONITORING COMMITTEE (CMC) PROCEDURES

CMC must operate in accordance with the following procedures.

1 **Composition of Code Monitoring Committee**

The membership of the CMC will comprise eight members, drawn from the following areas to ensure sufficient spread of knowledge and experience:

a) one independent chair with knowledge of the Industry, marketing and the Code and who may be legally qualified;

b) two representatives of Professional Associations;

c) two representatives of Institutions;

d) two representatives of Industry, one with experience in marketing and the other with experience in technical issues;

e) one Consumer Representative.

2 **Appointments to Code Monitoring Committee**

The Board appoints members of the CMC.

Membership of the CMC will be for a period of two years, with members eligible for reappointment for a further two years.

3 **Conflicts of interest**

Prior to selection of members of each meeting of the CMC, potential members must disclose to the CMC secretary any conflict of interest, or likelihood of a conflict of interest, regarding a party or the subject matters being reviewed. The CMC secretary will take the declarations into account when forming the panel for each meeting.

A member of the CMC must disclose any conflict of interest or likelihood of a conflict of interest, in any matter under consideration. If a conflict is disclosed the member may not participate in the deliberations of the CMC regarding the matter nor any vote relating to it.

4 **Voting by the CMC**

Decisions of CMC must be made unanimously or, where there is not a unanimous decision, by a simple majority vote of the attending CMC members, that is, more than 50% of the members in attendance at the meeting.

5 **Confidentiality**

All panelists and the Chair of the CMC must enter into a confidentiality agreement prior to appointment.

6 **Reporting by the CMC**

Each year, CMC must provide a written report providing an overview of reviews undertaken and issues identified, for inclusion in the MTAA Annual Report . The CMC report will not name individual Companies but will focus on general issues of note.

CODE COMPLAINT COMMITTEE (CCC) PROCEDURES

CCC must operate in accordance with the following procedures:

1 **Appointments to list of panelists for CCC**

The MTAA secretariat will maintain a list of panelists from which members of the CCC will be drawn as and when required. Panelists must be approved by the Board.

The panelists must be drawn from the following groups to ensure appropriate expertise across relevant disciplines and activities:

a) Professional Associations;

b) Institutions;

c) Consumer Representatives;

d) Industry; and

e) lawyers who are not from one of the groups in paragraphs (i) to (iv) to sit as the independent chair.

The Board may add or remove panelists during the year.

2 **Composition of Code Complaint Committee**

The selection of particular panelists to form the CCC to hear a complaint will be determined by the MTAA secretariat having regard to the nature of the Medical Technology and potential conflicts of interest.

Each CCC must comprise:

a) an independent chair; and

b) three other members of the approved panel with a spread of representation from the members of the panel.

The chair of the CCC:

a) must be a person experienced in the regulation of advertising and marketing and dispute resolution, and familiar with competition, consumer and fair trading legislation;

b) will be determined by the secretariat of MTAA; and

c) may be a person not included on a CCC panel.

3 **Quorum**

The quorum for the CCC is the Chair and two other members.

4 **Conflicts of interest**

Prior to selection of members of a CCC panel for a complaint, potential members must disclose to the Complaints Secretary any conflict of interest, or likelihood of a conflict of interest, regarding a party or the subject matter of the complaint. A panelist may not sit on a CCC panel if he or she has declared a conflict of interest or perceived conflict of interest in the subject matter or with a party before the CCC.

If a member of a CCC becomes aware of any conflict of interest, or likelihood of a conflict of interest, regarding a party or the subject matter of an appeal, after the CCC has been formed, they must declare the conflict of interest to the Complaints Secretary and withdraw from the CCC for that matter.

5 **Voting**

Decisions of CCC must be made unanimously or, where there is not a unanimous decision, by a simple majority vote of the attending CCC members, that is, more than 50% of the members in attendance at the meeting.

The Complaints Secretary is responsible for managing the material relating to the Complaint and for minuting and reporting on the outcomes of the hearing of the Complaint.

6 **Confidentiality**

All panelists and each chair of the CCC must enter into a confidentiality agreement in a form approved by the Board prior to appointment.

7 **Reporting by CCC**

The CCC must provide an annual written report to the Board detailing all Complaints and appeals dealt with during the year including the outcome of the CCC's determinations and any sanctions imposed on a Company.

CODE COMPLAINT APPEALS COMMITTEE (CCAC) PROCEDURES

1 **Composition of Code Complaint Appeals Committee**

The selection of particular panelists to form the CCAC to hear an appeal will be determined by the MTAA secretariat with regard to the nature of the Medical Technology and potential conflicts of interest.

The CCAC must comprise the following:

a) an independent chair who must be a qualified lawyer; and

b) three other members drawn from the panel established under clause 2 of Appendix 3 but who did not sit on the CCC which heard the original complaint.

2 **Quorum**

The quorum for the CCAC is the Chair and all three members drawn from the panel established under clause 2 of Appendix 3 but who did not sit on the CCC which heard the original Complaint.

3 **Conflicts of interest**

Prior to selection of members of a CCAC, potential members must disclose to the Complaints Secretary any conflict of interest, or likelihood of a conflict of interest, regarding a party or the subject matter of an appeal. A panelist may not sit on a CCAC if he or she has declared a conflict of interest or perceived conflict of interest in the subject matter or with a party before the CCAC.

If a member of a CCAC becomes aware of any conflict of interest, or likelihood of a conflict of interest, regarding a party or the subject matter of an appeal, after the CCAC has been formed, they must declare the conflict of interest to the Complaints Secretary and withdraw from the CCAC for that matter.

4 **Voting**

Decisions of CCAC must be made unanimously or, where there is not a unanimous decision, by a simple majority vote of the attending CCAC members, that is, more than 50% of the members in attendance at the meeting.

5 **Reporting by CCAC**

The CCC must provide an annual written report to the Board detailing all Complaints and appeals dealt with during the year including the outcome of the CCC's determinations and any sanctions imposed on a Company.

Appendix 5

COMPLAINTS ON ADVERTISEMENTS DIRECTED TO CONSUMERS

1 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

2 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: (+612) 9900 0650

F: (+612) 9900 0655

E: code@mtaa.org.au

Appendix 6

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: (+612) 9900 0650

F: (+612) 9900 0655

E: code@mtaa.org.au

Appendix 7

FORM FOR CODE MONITORING COMMITTEE TO USE WHEN MAKING A COMPLAINT TO THE CODE COMPLAINTS COMMITTEE

Complaint summary

Reference number for each alleged Breach of Code	Edition of Code alleged to have been breached (e.g. 8th edition)	Code provision alleged to have been breached (please use one row per Code provision)	Summary of conduct comprising alleged Breach of Code provision (use one row per Code provision)	Appendix number (if applicable)
1.				
2.				
3.				

Complaint particulars

Reference number for each alleged Breach of Code	Particulars of complaint
1.	
2.	
3.	

Appendices

Appendix reference	Description of material in the appendix (e.g. copy of advertisement, scientific data if applicable, and any other supporting documentation)
A.	
B.	
C.	

www.mtaa.org.au

Medical Technology Association of Australia Limited

Street Address
Level 12, 54 Miller Street
North Sydney NSW 2060 Australia

Postal Address
PO Box 2016 north Sydney
NSW 2059 Australia

P (02) 9900 0650
F (02) 9900 0655
E code@mtaa.org.au

MTAA Medical Technology
ASSOCIATION OF AUSTRALIA