



medical technology
ASSOCIATION OF NEW ZEALAND

**MTANZ DENTAL
CODE OF PRACTICE
5th EDITION**

2009

CONTENTS

PAGE

1	BACKGROUND AND PURPOSE OF THE CODE AND AMENDMENTS	4
2	DEFINITIONS	7
3	GENERAL PRINCIPLES	13
4	OBJECTIVES AND SCOPE OF THE CODE	13
5	ADVERTISING AND PROMOTION TO HEALTHCARE PROFESSIONALS.....	14
5.1	General	14
5.2	Claims and endorsements	16
5.3	Comparative Advertising.....	17
5.4	Advertisements to Healthcare Professionals - general.....	18
5.5	Company Commissioned Articles	19
6	INTERACTIONS WITH HEALTHCARE PRACTITIONERS AND OTHER PROFESSIONALS	19
6.1	General interactions	19
6.2	Company-sponsored Training and Education and Medical Technology Demonstrations	19
6.3	Third Party Educational Conferences	21
6.4	Arrangements with Healthcare Professionals acting as Consultants	26
6.5	Hospitality and Entertainment	28
6.6	Market research	29
6.7	Gifts to Healthcare Professionals.....	30
6.8	Competitions for Healthcare Professionals.....	31
6.9	Research and educational grants and charitable donations	31
6.10	Fellowships.....	34
6.11	Provision of reimbursement and other information	34
7	COMPANY Representatives	34
7.1	General	34
7.2	Requirement for training.....	35
8	INTERACTIONS WITH CONSUMERS	36
8.1	General	36
8.2	Competitions for Consumers	37
9	ADMINISTRATION OF CODE OF PRACTICE	37
9.1	Code of Practice Committee - general	37
9.2	Composition of CPC.....	37
9.3	Role of CPC.....	38
9.4	CPC procedures	39
9.5	Reviews	40
9.6	Publicising the Code.....	41
9.7	Education on the Code.....	41
9.8	Reporting	42
10	COMPLIANCE MECHANISMS	42
10.1	General	42
10.2	Code Monitoring Committee - composition and procedures.....	43
10.3	Code Complaint Committee - composition and procedures	46

11	Complaint handling procedures	49
11.1	General	49
11.2	Complaints by Consumer or Non-Industry Complainant	49
11.3	Complaints by an Industry Complainant	50
11.4	Complaints General	50
11.5	Referral by Code Monitoring Committee	53
11.6	Withdrawal	55
12	SANCTIONS	56
12.1	Classification of Breaches	56
12.2	Available Sanctions	57
12.3	Failure to comply with sanctions	59
13	APPEAL PROCEDURES	60
13.1	Appeals - general	60
13.2	Abuse of Code	61
13.3	Appeals Committee - composition and procedures	61
14	REPORTING BY CCC	63
15	MEDIATION.....	63
15.1	General	64
15.2	Mediator	64
16	INTERPRETATION	65

Preamble

(This preamble, comprising clause 1 does not form a part of the Code)

1 BACKGROUND AND PURPOSE OF THE CODE AND AMENDMENTS

- 1.1 The Medical Technology Association of New Zealand (MTANZ), in conjunction with the Medical Technology Association of Australia (MTAA) introduced a Code of Practice for member companies in September 2001¹. This served to formalise legal and ethical business practices for member companies and promote socially responsible conduct required of companies in this industry sector. The Code carried punitive measures whereby defaulting member companies could be disqualified from MTAA/MTANZ membership. It did not seek to address advertising issues.
- 1.2 The Code was revised in 2005² to:
- a. address advertising issues;
 - b. give more in-depth guidance on interactions with health care practitioners;
 - c. take into account the anticipated Australia and New Zealand Therapeutic Products

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. The Explanatory Notes will be developed further over time and updated to reflect input from Companies, and other users of the Code.

The Code sets out standards which industry participants are urged to observe. The Code is compulsory for members of MTAA and MTANZ but extends to all companies in the medical technology industry if they agree to observe the Code.

The purpose of the Code is to ensure high standards of integrity of behaviour across the medical technology industry to enable 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 MTAA/MTANZ 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.

¹ Edition 1

² Edition 2, implemented March 2006

(ANZTP) legislation, which was expected to be implemented in late 2007.

1.3 The Code was further amended in May 2008 for a number of reasons, including the following:

- a. To facilitate the possible acceptance of the Code by the Regulator in Australia and/or New Zealand for mandatory application in Australia and/or New Zealand.
- b. To provide greater clarity and a more comprehensive understanding of issues confronting the industry.
- c. To further develop and facilitate best practice by members in their daily business undertakings, so as to comply with all Australian and New Zealand laws, ethical business practices and socially responsible industry conduct.
- d. To set out mandatory information guidelines for advertising and promotion to Healthcare Professionals.
- e. To restructure the complaints and appeals committees and provide operative provisions for their functions and activities.
- f. To refine and develop the complaints resolution and appeals mechanisms.

1.4 The 4th Edition of the Code incorporated amendments to clarify language and meaning

following implementation of the 3rd Edition.

- 1.5 The 5th Edition of the Code reflects changes in global therapeutic industry codes and business practices in the medical technology industry.

2 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, and the requirements of the Advertising Standards Authority in New Zealand, as amended or replaced from time to time.

Appeals Committee means the Code Complaint Appeals Committee.

Association means MTAA and MTANZ or either of them as the context requires.

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 and MTANZ or either of them as the context requires.

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.

EXPLANATORY NOTES

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

Code means the MTAA and MTANZ Code of Practice as amended from time to time.

Code Complaint Committee (CCC) means the committee established in accordance with clause 10.3 to hear Complaints brought under the Code.

Code Monitoring Committee (CMC) means the committee established in accordance with clause 10.2 to proactively review an activity or a Promotion by a Company.

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

- a. Sponsors, in relation to any Medical Technology the subject of a licence requiring the Sponsor to comply with the Code; and
- b. any other relevant person from the Industry who submits to the Complaints process and outcomes in accordance with the provisions of the Code.

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

Complaint means a complaint lodged with MTAA or MTANZ under the Code.

Complaints Secretary means the person from the MTAA or MTANZ secretariat, as applicable for each Complaint, responsible for administration of a Complaint under the Code.

Conference Sponsor means a Professional Association or Training Organisation with a genuine educational purpose or function, or a bona fide third party conference organiser which is independent of the Company.

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

Consulting Arrangement means any relationship in which services are provided to a Company by a Healthcare Professional in exchange for remuneration.

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

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

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

Entertainment includes sporting events, musical and other entertainment.

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

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

Healthcare Professional includes any individuals or entities involved in the provision of health care services and/or items to patients; which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Medical Technologies in Australia and/or New Zealand.

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 or New Zealand (as applicable to the relevant Association) to which any act or omission the subject of the Code applies,

including the *Therapeutic Goods Act (Cth) 1989*.

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 (Cth) 1989 / New Zealand Medicines Act 1981*, as amended from time to time.

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.

MTANZ means Medical Technology Association of New Zealand Inc.

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.

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 (Cth) 1989 / New Zealand Medicines Act 1981*

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

Third Party Educational Conference means a conference sponsored or conducted by or on behalf of a Professional Association that is:

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

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

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

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

3 GENERAL PRINCIPLES

- 3.1 Companies at all times must comply with provisions of all relevant legislative requirements.
- 3.2 Companies must not engage, directly or indirectly, or be knowingly concerned in any unethical behaviour, misleading or deceptive conduct, or unfair or unconscionable practice.
- 3.3 Companies must place the highest priority on the safety and welfare of users of their Medical Technologies.
- 3.4 Companies must always respect ethical requirements and codes of practice which apply to Healthcare Professionals and their business associates within the Industry.

4 OBJECTIVES AND SCOPE OF THE CODE

- 4.1 The Associations are 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.
- 4.2 To this end the Associations will provide a framework and mechanisms for setting minimum 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.
- 4.3 The Code is a fundamental part of the framework and mechanism provided by the Associations. Companies recognise and accept the importance of compliance with the

EXPLANATORY NOTES

The Code reflects the commitment of industry to adherence to legal principles and ethical and transparent behaviour. Companies must have regard to applicable legislative obligations including those found in the *Fair Trading Act*, the *Medicines Act* and others. Companies should have regard to the requirements of the various codes of ethics and codes of practice that apply to the members of the many professional bodies with which companies have dealings.

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.

Code and the significant benefits to be derived through its application and use across the Industry.

EXPLANATORY NOTES

4.4 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 each Association, to accept and observe all provisions of the Code. In accepting and observing the Code, Companies must comply with both the letter and the spirit of the Code. As the Code provides guidance to a minimum standard, a Company should also have regard to its own company code which might provide for a higher standard.

4.5 Companies that are not members of an Association but which are engaged in the Industry are encouraged to accept and observe the Code.

4.6 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.

5 ADVERTISING AND PROMOTION OF PRODUCTS

5.1 General

An Advertisement must:

- a. comply with the Advertising Code and all other

Advertisements for medical technology products must comply with the current Advertising Code. The Advertising Code is the standard applied to all advertisements for therapeutic products including advertisements on the internet. Compliance with the code does not absolve sponsors and other advertisers from the need to comply with other common law and

EXPLANATORY NOTES

- b. relevant Laws and Regulations;
 - c. not be misleading or deceptive, or likely to mislead or deceive;
 - d. reflect a high standard of social responsibility and conform to generally accepted standards of good taste;
 - e. be readily recognisable by the target audience as an Advertisement;
 - f. not claim that a Medical Technology is unique or has some special merit, quality or property unless the claim can be substantiated;
 - g. not use the term “safe” without appropriate qualification;
 - h. 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;
 - i. 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;
 - j. 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
- statutory requirements, in particular the trade practices 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

Scheduled Medicine; and

- k. 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.

5.2 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 20 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.

EXPLANATORY NOTES

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 device/IVD 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

EXPLANATORY NOTES

professionals, industry members and, where

appropriate, consumers within 20 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.

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 practitioners 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.

5.3 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 5.3b arises from separate studies then a qualifying statement must be included to the effect that substantiating data arise from separate studies.
- 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.

5.4 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 20 days.
- c. Despite the terms of this clause 5, Brand Name Reminder Advertisements do not need to contain any mandatory statements unless otherwise required by law.

5.5 Company Commissioned Articles

- 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.

EXPLANATORY NOTES

6 INTERACTIONS WITH HEALTHCARE PRACTITIONERS AND OTHER PROFESSIONALS

6.1 General interactions

In all dealings with Healthcare Professionals:

- a. a Company must comply with this clause 6; and
- b. without limiting this clause 6, 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.

6.2 Company-sponsored Training and Education and Medical Technology Demonstrations

The following applies to Training and Education, and Medical

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, lease, recommend, use or arrange 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

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.
- 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 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.
- e. 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;

EXPLANATORY NOTES

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.

The 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 consideration in choice of a venue for any training should be whether it provides an environment that is conducive to the effective transmission of knowledge. The physical attractiveness of the venue or available sporting or leisure facilities should not determine the venue. A venue of an exclusively resort nature would not be appropriate.

Hospitality (ie the provision of food and beverages) may be provided but as an ancillary offering. It must not be the main focus of the training event.

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

- (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.
- f. 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.
- g. The Company must not provide to attending Healthcare Professionals any gifts, rewards or free products other than in compliance with clause 6.7.

EXPLANATORY NOTES

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 6.7. This means that small thank you gifts to a healthcare professional who has presented at a training session must be modest in value (less than NZD100), and of an educative nature.

6.3 Third Party Educational Conferences

6.3.1 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 6.3.5; and
- b. the Company complies with this clause 6.3.

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 that is independent, of an educational, scientific or policy-making nature and for

EXPLANATORY NOTES

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 Sponsor. The Conference Sponsor can be a professional association, a Training Organisation (ie. 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.

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 (eg. 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.

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

6.3.2 Sponsorship or grants for Third Party Educational Conferences

- a. A Company may provide sponsorship or a grant to the Conference Sponsor 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 Sponsor selects the recipient of the sponsorship or grant, who may be a Faculty Member;
- (iv) the Conference Sponsor makes the arrangements, and pays for, the travel and accommodation of the recipient;
- (v) the Conference Sponsor 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 Sponsor; and
 - (D) does not give rise to, or facilitate any breach of the Code;
- (vii) the Conference Sponsor and the Company enter into a written agreement specifying the nature and conditions of the sponsorship or

EXPLANATORY NOTES

speaker but if requested by the organiser a company may suggest names 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 organiser.

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

grant; and

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

6.3.3 Hospitality at Third Party Educational Conferences

- a. A Company may provide funding to the Conference Sponsor to support Hospitality at a Third Party Educational Conference provided the Conference Sponsor and the Company enter into a written agreement:
 - (i) specifying the nature and conditions of the Hospitality; and
 - (ii) which requires the Conference Sponsor 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;
- c. All Hospitality at Third Party Educational Conferences funded by, or supplied by, a Company, must comply with the provisions of clause 6.5.

EXPLANATORY NOTES

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 (ie. 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.

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.

6.3.4 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 or facilitate the symposium;
- b. any Hospitality complies with the provisions of clause 6.5; and
- C.** a Company does not pay the costs of attendees to attend the symposium, other than those referred to in paragraph a.

6.3.5 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 5 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

EXPLANATORY NOTES

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.

Where a company takes a booth at a third party 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 5 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.

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 Sponsor 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.

6.4 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 may pay the Healthcare Professional reasonable compensation for performing services as a Consultant.
- c. Consulting arrangements between a Company and a Consultant must comply with the following:
 - (i) the arrangement must be documented in

EXPLANATORY NOTES

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 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 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

- writing between the Company and the Consultant, specifying all services to be provided and compensation to be paid;
- (ii) the compensation paid to a Consultant must be consistent with fair market value for the services provided;
 - (iii) selection of the Consultant must be on the basis of the Consultant's qualifications and expertise in dealing with the subject matter of the engagement, and must not be on the basis of volume or value of business generated or potentially generated by the Consultant;
 - (iv) when a Company contracts with a Consultant to conduct clinical research services there should be a written research protocol;
 - (v) Consulting Arrangements should only be entered into where a legitimate need for the services 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,

EXPLANATORY NOTES

healthcare professional must be based on objective factors such as the amount of effort of the healthcare professional reflected in the product development.

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; 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.

EXPLANATORY NOTES

6.5 Hospitality and Entertainment

- a. Members may provide reasonable and modest travel, accommodation, meals and receptions with education and professional development for healthcare professionals to facilitate the safe and effective use of their products and services.
- b. The provision of such educational opportunities shall neither construe nor create any obligation on the relevant professional to purchase or cause to

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

purchase any goods or services associated with the training

EXPLANATORY NOTES

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.

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 6.8.

6.6 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 6.8.

EXPLANATORY NOTES

6.7 Gifts to Healthcare Professionals

- a. A Member may not give a gift to a Healthcare Practitioner or Other Professional which is beyond the level of what is reasonable and customary in the circumstances of the relationship within the industry.
- b. Any gift provided shall not encourage or likely to encourage excessive purchase or use of products or services

A company may provide a gift of appreciation to a healthcare professional or other product purchaser in very limited circumstances to ensure that there can be no perception that the company is using the gift as a means of persuasion or influence.

EXPLANATORY NOTES

6.8 Competitions for Healthcare Professionals

- a. In the course of business activity, members may provide competitions to Healthcare Professionals.
- b. The competition prize(s) shall not be beyond the level of what is reasonable and customary in the circumstances of the relationship
- c. Any competition prize shall not encourage or likely to encourage excessive purchase or use of products or services. The conduct of a competition must comply in all respects with 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. Entry must not be dependent on ordering or using a particular product.

6.9 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

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

products; and

- (iii) 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 6.4 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 may not make an educational grant directly to a Healthcare Professional or a Practitioner in Training (whether to attend a Third Party Educational Conference or not).

EXPLANATORY NOTES

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.

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. **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.

f. 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.

g. The Company must fully document every donation made by the Company.

EXPLANATORY NOTES

6.10 Fellowships

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

6.11 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 COMPANY REPRESENTATIVES

7.1 General

- 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

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

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.

EXPLANATORY NOTES

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.

7.2 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

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

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 than once every three years.

EXPLANATORY NOTES

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 MTANZ or reviewed by MTANZ.

8 INTERACTIONS WITH CONSUMERS

8.1 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. The Associations recognise and support relationships between Industry and Health Consumer Organisations 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.

8.2 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 5 of the Code.
- c. Entry into a Competition must not, as a condition of entry, require a Consumer to use or purchase a Medical Technology.
- d. The conduct of a Competition must comply in all respects with all relevant Laws and Regulations.

9 ADMINISTRATION OF CODE OF PRACTICE

9.1 Code of Practice Committee - general

The Code of Practice Committee (**CPC**) is established to supervise the administration of the Code and is responsible to the Boards.

9.2 Composition of CPC

EXPLANATORY NOTES

The requirement in paragraph c. that entry into a competition must not, as a condition of entry, require a consumer to use or purchase a product does not apply to non-invasive Class I devices, Class I sterile and Class IIa medical devices intended for consumer supply and use, and Class IIa contact lenses, where the marketing of the product is directed only to consumers.

The structure of the administrative provisions of the Code is to provide for a series of committees established for complementary purposes:

- Code of Practice Committee - member-based committee which reviews Code implementation and education and reports annually on Code complaints and outcomes. Each Association has its own CPC but with cross-representation

CPC shall be made up of:

Full Members:

- a. an independent Chair;
- b. six representatives from MTAA elected from among the Authorised Representatives or a senior delegate of an Authorised Representatives;
- c. one representative from MTANZ; and
- d. one Consumer Representative.

Observers:

- a. a representative of the secretariat of each of MTAA and MTANZ; and
- b. the secretary to CPC, provided by MTAA.

9.3 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 and external reviews of the Code in accordance with clause 9.5 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;

EXPLANATORY NOTES

- Code Monitoring Committee - has a proactive role to request material from a company related to either promotion or dealings with healthcare professionals. The Committee has the capacity to refer a possible breach to the Code Complaints Committee
- Code Complaints Committee - initial complaints review body which is drawn from a cross-section of representatives of healthcare professionals, healthcare institutions, consumers and industry
- Code Appeal Committee - similar cross-section of representatives, established to hear an appeal from findings of the Code Complaint Committee.

- c. submit all proposed amendments to the Boards for approval;
- d. publicise all amendments in accordance with clause 9.5;
- 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 Boards.

9.4 CPC procedures

CPC must operate in accordance with the following procedures:

- a. The independent Chair and the Consumer Representative have an initial term of two years. The Boards may reappoint the independent Chair and the Consumer Representative for one further term each of two years.
- b. In its first year, all CPC members elected by each of MTAA and MTANZ have an initial term of one year. One half of those members, to be determined by lot, are eligible for re-election for one further term of one year and the other half for one further term of two years. In subsequent years each elected member of CPC has a term of two years and may stand for re-

election for one further term of two years.

- c. 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.
- d. A quorum consists of the Chair, and three other members.
- e. CPC must meet at a minimum twice per year. The Chair may request more frequent meetings on an as needs basis.
- f. Decisions of CPC must be made unanimously or by a majority vote of its members.

9.5 Reviews

- a. External reviews of the Code must be carried out once every three years or more frequently if so determined by CPC.
- b. 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.
- c. For the purposes of conducting an internal review, CPC may seek comment or submissions from Companies and other relevant stakeholders.

9.6 Publicising the Code

- a. CPC must identify and recommend to the Associations the optimal means for the Associations to promote the Code to Companies, the Industry, Healthcare Professionals, Regulators and other relevant stakeholders and participants in the healthcare industry.
- b. The Associations must undertake a publicity campaign upon the commencement of the Code and every time more than minor changes are made, and provide opportunities to raise awareness of the Code through media and other outlets.
- c. The Associations must ensure that the Code is available on the MTAA and MTANZ websites at all times and encourage Companies to reference and provide links to the Code on their own websites.
- d. The Associations must encourage Companies to promote the Code on a regular basis.

9.7 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 upon the commencement of the Code and each and every time that more than minor changes are made and at least once every three years.

9.8 Reporting

Each year, CPC must provide a written report on the administration of the Code, for inclusion in the Annual Reports of each Association.

10 COMPLIANCE MECHANISMS

10.1 General

- 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.
- c. A Complaint regarding:
 - (i) an Advertisement (other than an Advertisement directed to Consumers which is dealt with in clause 10.1d), 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 2.
- d. Subject to clause 10.1e, a Complaint regarding an

Advertisement directed to Consumers must be forwarded to the bodies listed in Appendix 1.

e. Notwithstanding the provisions of clause 10.1d 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.

f. All Complaints and responses must be in writing.

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

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

i. Notwithstanding the obligations on MTAA and MTANZ 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 and MTANZ until all avenues of appeal are exhausted and outcomes of appeals known.

10.2 Code Monitoring Committee - composition and procedures

a. To support compliance with the Code the Code Monitoring Committee will proactively monitor

EXPLANATORY NOTES

The Code Monitoring Committee has been established with authority to require companies to supply promotional material and material identifying interactions with healthcare professionals for review. This ensures that industry behaviour is reviewed

Promotions and activities of Companies on a regular and ongoing basis.

- b. The Code Monitoring Committee may request a Company to submit a copy of the selected Promotions and activities from a specified period during the past 12 months, or other evidence of compliance with the Code, for review by the Code Monitoring Committee.
- c. The Authorised Representative must provide a signed written statement that the material provided to the Code Monitoring Committee constitutes all the relevant material or that no such material exists.
- d. The Company must provide the material within the time specified in the request being not less than 7 days from the date of the request. The Code Monitoring Committee may request additional material from a Company to clarify or expand on the material before it.
- e. The membership of the Code Monitoring Committee will comprise 8 members, drawn from the following areas to ensure sufficient spread of knowledge and experience:
 - (i) Independent Chair with knowledge of the Industry, marketing and the Code and who may be legally qualified;
 - (ii) Two representatives of Professional Associations;
 - (iii) Two representatives of Institutions;
 - (iv) Two representatives of Industry, one with experience in marketing and the other with

EXPLANATORY NOTES

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

The Code Monitoring Committee 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.

experience in technical issues;

- (v) One Consumer Representative.
- f. Membership of the Code Monitoring Committee will be for a period of two years, with members eligible for reappointment for a further two years. The members of the Code Monitoring Committee are appointed by each Board.
- g. A member of the Code Monitoring Committee 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 continue to participate in the deliberations of the CMC, but not in any vote on a matter before it.
- h. If, the Code Monitoring Committee determines that a breach of the Code may have occurred the Code Monitoring Committee 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 verify if that determination is correct and to receive any further material that the Company deems relevant to the process.
- i. Where clause 10.2h(ii) applies, the Code Monitoring Committee must consider the response and, if appropriate, refer the matter to the Code Complaint Committee as a Complaint, if any.

10.3 Code Complaint Committee - composition and procedures

- a. No later than the end of January in each year the secretariats of MTAA and MTANZ must each prepare for approval by the relevant Boards, a list of 12 panelists from whom members of the CCC will be drawn as and when required.
- b. Where the subject matter of the Complaint occurred:
 - (i) in New Zealand the CCC will be drawn from the New Zealand panel;
 - (ii) in Australia the CCC will be drawn from the Australian panel; and
 - (iii) in both countries, the MTAA Complaints Secretary may determine the panel to hear the Complaint.
- c. If the subject matter of the Complaint took place in both Australia and New Zealand, or its location is not clear, the panel from which the CCC will be formed shall be determined by the MTAA Complaints Secretary.
- d. The panelists must be drawn from the following groups to ensure appropriate expertise across relevant disciplines and activities:
 - (i) Professional Associations;
 - (ii) Institutions;
 - (iii) Consumer Representatives;

- (iv) Industry; and
 - (v) Lawyers who are not from one of the groups in paragraphs (i) to (iv) to sit as the independent chair.
- e. Australian panelists must be:
 - (i) resident or available to sit on the CCC in Australia, and
 - (ii) approved by the Board of MTAA.
- f. New Zealand panelists must be:
 - (i) resident or available to sit on the CCC in New Zealand, and
 - (ii) approved by the Board of MTANZ.
- g. Each Board may add or remove panelists during the year.
- h. The selection of particular panelists to form the CCC to hear a Complaint will be determined by the secretariat of MTAA or MTANZ as applicable, having regard to the nature of the Medical Technology and potential conflicts of interest.
- i. Each CCC must comprise:
 - (i) an independent Chair; and
 - (ii) three other members of the approved panel from either Australia or New Zealand as applicable, with a spread of representation

from the members of the panel.

- j. The Chair of the CCC:
 - (i) must be a person experienced in the regulation of advertising and marketing and dispute resolution, and familiar with trade practices and fair trading legislation;
 - (ii) will be determined by the secretariat of MTAA or MTANZ as applicable; and
 - (iii) may be a person not included on a CCC panel.
- k. The MTAA or MTANZ secretariat, as applicable, must ensure prior to the empanelment of the CCC that there are no conflicts of interest for a proposed panelist. No panelist may sit on a CCC if he or she has a conflict of interest or perceived conflict of interest in the subject matter or with a party before the CCC.
- l. The quorum for the CCC is the Chair and two other members.
- m. Decisions of the CCC must be made unanimously or by a majority vote of its members.
- n. The MTAA or MTANZ secretariat, as applicable, must provide the Complaints Secretary to manage the material relating to the Complaint and to minute and report on the outcomes of the hearing of the Complaint.
- o. Neither the Complainant nor the respondent, nor a representative of either of them, may be present

during the hearing of the Complaint. The CCC must determine the outcome of the Complaint based on the material submitted by the parties.

- p. The deliberations of the CCC are confidential and must not be disclosed by a party, or a member of the CCC. All panellists and each Chair of the CCC must enter into a confidentiality agreement in a form approved by the relevant Board prior to appointment.

11 COMPLAINT HANDLING PROCEDURES

11.1 General

- 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.
- b. A party to a Complaint must notify the Complaints Secretary immediately upon becoming aware of any court proceedings concerning the substance of the Complaint.
- c. The Complaints Secretary must acknowledge a Complaint, whether concerning a Company or a non-member, in writing within seven working days of its receipt and deal with the Complaint expeditiously.

11.2 Complaints by Consumer or Non-Industry

EXPLANATORY NOTES

Complainants are encouraged to first approach the company whose behaviour is complained of to attempt to address the behaviour. If the complainant is not satisfied that the behaviour has been addressed then a complaint may be lodged with MTAA or MTANZ, depending on the location of the behaviour.

The Code requires industry participants to attempt to resolve issues before resorting to the complaints process. Non-industry complainants are also encouraged to raise issues with a company before lodging a complaint. However as it might be more difficult for a non-industry person to raise a matter directly with a company (whether as a consumer, healthcare professional or other healthcare participant), the Code provides that a non-industry complainant may bring a complaint without first taking the step of contacting the company whose behaviour is complained of.

The Code also provides for a mediation process which may be more appropriate in some situations than a formal complaint process. It is open to the parties to a complaint to request mediation as the means to resolve the issue.

While the Code Monitoring Committee may be viewed as a Non-Industry Complainant under the Code, a

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 behaviour 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.

EXPLANATORY NOTES

complaint referred by the Code Monitoring Committee is not subject to the requirements in the Code for intervention or mediation prior to consideration of the complaint.

11.3 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.

11.4 Complaints General

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 Complainant)

Secretary and one for the Respondent) and:

- (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 11.3.
- b. If the Complaint is brought under clause 5.2(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.
- c. 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. The Respondent must respond in writing to the Complaints Secretary within 10 working days.

- d. The Complaints Secretary must provide the Complainant with a copy of the Respondent's response and invite the Complainant to reply in writing within 10 working days. The Complaints Secretary must provide the Respondent with a copy of the Complainant's reply within 5 working days.
- e. 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,provided that:
 - (iv) any person consulted by the CCC is bound to maintain confidentiality under a written non-disclosure agreement; and
 - (v) the parties are provided with a record of all information obtained pursuant to clauses 11.4e(i), (ii) or (iii), and are afforded a period of 10 working days within which to respond in writing.
- f. Neither the Complainant nor the Respondent, nor a representative of either of them, may be present during the hearing of a Complaint.
- g. 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.

- h. If the CCC considers that a breach of the Code has occurred, it must determine the appropriate sanction as provided under clause 12.2 of the Code.
- i. 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.
- j. If a Complaint is upheld, the Respondent must reimburse MTAA or MTANZ, as applicable, 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 12. 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.
- k. 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.

11.5 Referral by Code Monitoring Committee

If in the course of undertaking a review in accordance with clause 10.2, 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 11.5a(i), 11.4e(ii) or 11.4e(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 12.2 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 or MTANZ, as applicable, 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 12.

11.6 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 11.6b, the Complaints Secretary must inform the Complainant and the Respondent in writing, detailing

the reasons.

- d. Termination of the Complaints handling procedure under clause 11.6a will not prevent the CCC from referring to the relevant 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 or MTANZ, as applicable, its secretariat costs and out-of-pocket expenses associated with the Complaint, unless the CCC determines otherwise.

EXPLANATORY NOTES

12 SANCTIONS

12.1 Classification of Breaches

Where a breach of the Code has been established, before determining any sanction under clause 12.2, 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 will adversely impact on the perceptions of Healthcare Professionals or the general public regarding the Medical

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.

Technology the subject of the Complaint, similar products or the Industry.

Severe Breach: a breach of the Code that has safety implications or will 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.

12.2 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 13 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 \$20,000
Severe Breach:	Maximum \$40,000
Repeat Breach:	Maximum \$50,000
Serial Breach:	An amount not less than \$5,000 and

not more than \$75,000.

- b. Subject to clause 13.2, 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 \$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 or MTANZ, it must make such a recommendation to the relevant Board. The Board may deal with the recommendation under the provisions of its constitution.
- d. In the event that the 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.

12.3 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; and
 - (ii) in addition to any further sanctions imposed pursuant to clause 12.2, entitles the CCC to direct MTAA and/or MTANZ 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 and/or MTANZ 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 12.2 above, the CCC may direct MTAA and/or MTANZ to notify the Regulator of the continued breach of the Code.

13 APPEAL PROCEDURES

13.1 Appeals - general

- a. A Company who has been found under clause 12 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 five working days in which to lodge material in support of its appeal with six copies (one for each member of the Appeals Committee, one for the Complaints Secretary and one for the other party).
- 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 or MTANZ, as applicable, its secretariat costs and out-of-pocket expenses associated with the determination of the appeal, unless the Appeals Committee determines otherwise. This payment is separate from and in addition to any fine payable under clause 12. In the case of a Complaint by an Industry Complainant, the Appeals Committee may require such costs to be shared by the parties in proportions determined by the Appeals Committee.

13.2 Abuse of Code

A Complainant company which has had a fine imposed under clause 12.2b 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.

13.3 Appeals Committee - composition and procedures

- a. The Code Complaint Appeals Committee (Appeals Committee) must comprise the following:
 - (i) an independent Chair who must be a qualified lawyer; and
 - (ii) three other members drawn from the panel established under clause 10.2 but who did not sit on the CCC which heard the original Complaint.

- b. Prior to selection of members of an Appeals Committee the Complaints Secretary must establish that a proposed member has no conflict of interest with a party or the subject matter of an appeal. No panelist may sit on an Appeals Committee if he or she has a conflict of interest or perceived conflict of interest in the subject matter or with a party before the Appeals Committee.
- c. The quorum for the Appeals Committee is the Chair and two other members.
- d. The Appeals Committee must make decisions by consensus and/or a majority of its members.
- e. The Appeals Committee must consider only:
 - (i) the material that was considered by the CCC in the matter;
 - (ii) the appeal papers and any response from the Complainant; and
 - (iii) any additional material which the Appeals Committee reasonably believes will assist it in its deliberations.
- f. The Complaints Secretary must provide a copy of any additional material before the Appeals Committee to each party no later than five working days before the date of the appeal hearing.
- g. A party is entitled to attend at, or be heard by, the Appeals Committee, in person on prior arrangement with the Complaints Secretary.
- h. The findings of the Appeals Committee are final and

binding on the parties. The Complaints Secretary must provide the outcome of the deliberations of the Appeals Committee to each party no later than five working days after the Appeals Committee reaches its decision.

- i. The deliberations of the Appeals Committee are confidential and must not be disclosed by a party, or a member of the Appeals Committee.

14 REPORTING BY CCC

- a. The CCC must provide an annual written report to the Boards 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.
- b. To ensure transparency of procedures, MTAA and MTANZ must each publish on its website the outcome of every upheld Complaint and appeal finalised during the year. The website publication may be removed once it is published in the Annual Report of the Associations. 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 and MTANZ must not publish in any form the name of a Complainant if it has been withheld in accordance with clause 11.2b.

15 MEDIATION

15.1 General

- a. Either Association may invite a Company, a Consumer, 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.
- b. The Complaints Secretary may appoint an independent mediator to assist the parties to discuss, negotiate and achieve a resolution.
- c. Where the parties consent to a mediation, the Complaints Secretary must arrange the mediation session in consultation with the parties and mediator.
- d. 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.
- e. The parties may be present in person at the mediation. It is not expected that the parties will be legally represented at mediation.
- f. Any agreement reached as a result of mediation shall be confidential, binding, in writing and signed by the parties and the mediator. The agreement must remain confidential to the parties and the Mediator, unless the parties agree it be made available to MTAA or MTANZ, as applicable.

15.2 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.

16 INTERPRETATION

16.1 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 or New Zealand currency as applicable in the

circumstances;

- 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.

16.2 This edition of the Code replaces and supersedes all previous editions of the Code.

Appendix 1

Complaints on Advertisements directed to Consumers

Complaints about Advertising directed to Consumers must be directed to:

Australia:

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

Complaints Resolution Panel
PO Box 764
North Sydney NSW 2059
Australia

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

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

Complaints Secretary
Medical Technology Association of Australia
PO Box 2016
North Sydney NSW 2059
Australia
Ph: +61 2 9900 0650
Fax: +61 2 9900 0655
Email: reception@mtaa.org.au

New Zealand:

Advertising Standards Authority
PO Box 10 675
Wellington New Zealand
Ph: +64 - (0)4 - 472 7852 or
0800 ADHELP (0800 234357) from New Zealand.
Email: asa@asa.co.nz

Information on the procedure to make a complaint can be found at <http://www.asa.co.nz/Procedure.htm>

Appendix 2

Complaints on Advertisements to and interactions with Healthcare Professionals

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

Australia:

Complaints Secretary
Medical Technology Association of Australia
PO Box 2016
North Sydney NSW 2059
Australia
Ph: +61 2 9900 0650
Fax: +61 2 9900 0655
Email: reception@mtaa.org.au

New Zealand :

The Secretary
Advertising Standards Complaints Board
Box 10-675
Wellington NZ
Ph: +64 – (0)4 – 472 7852
Fax: +64 – (0)4 – 471 1785
Email: asa@asa.co.nz

OR

MTANZ
PO Box 8378
Symonds Street
Auckland
New Zealand
Ph: +64- (0)9 - 917 3645
Fax: +64- (0) 9 -917 3651
Email: admin@mtanz.co.nz