



**Medical Technology**  
Association of Australia

**MTAA and MIANZ**  
**CODE OF PRACTICE**

**3<sup>rd</sup> EDITION**

**2008**

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Preamble	Explanatory Notes
<p>(This preamble, comprising clause 1 does not form a part of the Code)</p> <p><b>1 BACKGROUND AND PURPOSE OF THE CODE AND AMENDMENTS</b></p> <p>1.1 The Medical Technology Association of Australia Limited (MTAA) (formerly the Medical Industry Association of Australia Inc) introduced a Code of Practice for member companies in September 2001<sup>1</sup>. 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 MIAA membership. It did not seek to address advertising issues.</p> <p>1.2 The Code was revised in 2005<sup>2</sup> to:</p> <ul style="list-style-type: none"> <li>• address advertising issues;</li> <li>• give more in-depth guidance on interactions with health care practitioners;</li> <li>• take into account the anticipated Australia and New Zealand Therapeutic Products (ANZTP) legislation, which was expected to be implemented in late 2007.</li> </ul> <p>1.3 The Code now is being amended for a number of reasons, including the following:</p>	<p>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 Members, and other users of the Code.</p> <p>The Code sets out standards which industry participants are urged to observe. The Code is compulsory for members of MTAA and MIANZ but extends to all companies in the medical technology industry if they agree to observe the Code.</p> <p>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.</p>

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<sup>1</sup> Edition 1

<sup>2</sup> Edition 2, implemented March 2006

<ul style="list-style-type: none"><li>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.</li><li>b. To provide greater clarity and a more comprehensive understanding of issues confronting the industry.</li><li>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.</li><li>d. To set out mandatory information guidelines for advertising and promotion to Healthcare Practitioners and Other Professionals.</li><li>e. To restructure the complaints and appeals committees and provide operative provisions for their functions and activities.</li><li>f. To refine and develop the complaints resolution and appeals mechanisms.</li></ul>	
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## 2 DEFINITIONS

In the Code:

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

**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 MIANZ 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 MIANZ or either of them as the context requires.

**Brand Name Reminder Advertisement** means an Advertisement for a Product that:

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

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

**Code** means the MTAA and MIANZ 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 Member.

**Company Commissioned Article (CCA)** means an article or series of articles, which is

## EXPLANATORY NOTES

The definitions have been relocated to the front of the Code document to assist with interpretation. Where a word is used with a capital letter at the beginning then it has the meaning given to it in the definitions clause.

The members of each of MTAA and MIANZ can be found respectively at the following web addresses:

MTAA:

<http://www.mtaa.org.au/pages/page12.asp>

MIANZ: TBC

paid for by a Member 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 Member pursuant to any agreement, arrangement or understanding between that person or entity and the Member, 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.

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

**Complaints Secretary** means the person from the MTAA or MIANZ 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 Member.

**Consultant** means a Healthcare Practitioner who is engaged by a Member to act as a consultant to the Member.

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

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

**Demonstration** means demonstration of the operational use of Products.

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

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

**Faculty Member** means a Healthcare Practitioner 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 Practitioner** means any:

- a. chiropractor, dental practitioner, dietician, medical practitioner, nurse, optometrist, osteopath, pharmacist, physiotherapist, podiatrist, psychologist, scientist working in a medical laboratory or veterinary surgeon; or
- b. acupuncturist, herbalist, homeopathic practitioner, naturopath, nutritionist or practitioner of traditional Chinese medicine or other traditional medicines; or
- c. person who:
  - (i) has current membership of an Australian or New Zealand Professional Association; and
  - (ii) has the necessary or appropriate qualifications and training for membership of such a body.

**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 Products

**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 Products (other than the Member's contracted distributors), the administration or regulation of healthcare or medical products or the provision of information and education in relation to medical products.

**Institution Staff** means an employee or agent of an Institution who is not a Healthcare Practitioner.

**IVD** means any medical device that is a reagent, reagent product, calibrator, control

material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product (for *in vitro* use), intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of:

- a. giving information about a physiological or pathological state or a congenital abnormality; or
- b. determining safety and compatibility with a potential recipient; or
- c. monitoring therapeutic measures.

**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 as amended from time to time.

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

- a. Sponsors, in relation to any Product 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.

**MIANZ** means Medical Industry Association of New Zealand Inc.

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

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

**Other Professionals** means persons other than Healthcare Practitioners that a Member may deal with in relation to Products, including, but not limited to Institution Staff, and

Professional Associations and their staff.

**Practitioners in Training** means persons training to become Healthcare Practitioners.

**Product** means a Medical Device or an IVD, and related repair and maintenance services.

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

**Promotion**, in relation to a Product, means any activity that, directly or indirectly, promotes or encourages the use, acquisition or other supply of the Product, by purchase, sale or otherwise, or discourages such use, acquisition or supply of a competing Product, 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 Member 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 Practitioner.

**Scheduled Medicine** has the meaning given in the *Therapeutic Goods Act (Cth)* 1989.

**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 Product or an Advertisement or Educational Material

about a Product.

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

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

<p><b>3 GENERAL PRINCIPLES</b></p> <p>3.1 Members at all times must comply with provisions of all relevant legislative requirements.</p> <p>3.2 Members must not engage, directly or indirectly, or be knowingly concerned in any unethical behaviour, misleading or deceptive conduct, or unfair or unconscionable practice.</p> <p>3.3 Members must place the highest priority on the safety and welfare of users of their Products.</p> <p>3.4 Members must always respect ethical requirements and codes of practice which apply to Healthcare Practitioners, Other Professionals and their business associates within the Industry.</p>	<p><b>Explanatory Notes</b></p> <p>The Code reflects the commitment of industry to adherence to legal principles and ethical and transparent behaviour. Companies must have regards to applicable legislative obligations including those found in the <i>Trade Practices Act</i>, the <i>Therapeutic Goods Act</i> and others.</p> <p>Companies should have regard to the requirements of the various codes of ethics and codes of practice that apply to the members of many professional bodies with which companies have dealings.</p>
<p><b>4 OBJECTIVES AND SCOPE OF THE CODE</b></p> <p>4.1 The Associations are committed to promoting the interests of the Industry by assisting Members to abide by business standards and engage in behaviours which will enhance the reputation and continuously maintain the integrity of the Industry.</p> <p>4.2 To this end the Associations provide a framework and mechanisms for setting minimum standards of behaviour, educating Members, monitoring Industry activities and development, providing self-regulation and disciplinary functions and interacting with governmental, professional and other industry bodies and associations and Consumers.</p> <p>4.3 The Code is a fundamental part of the framework and mechanism provided by the Associations. Members recognise and accept the importance of compliance with the Code and the significant benefits to be derived through its application and use across the Industry.</p> <p>4.4 The Code provides guidance to minimum standards which shall apply to business practices of Members. Members are obliged, as a condition of membership of each Association, to accept and observe all provisions of the Code. In accepting</p>	<p>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.</p> <p>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.</p> <p>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.</p>

and observing the Code, Members must comply with both the letter and the spirit of the Code. As the Code provides guidance to a minimum standard, a Member should also have regard to its own company code which might provide for a higher standard.

4.5 Companies that are not Members 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.

<p><b>5 ADVERTISING AND PROMOTION OF PRODUCTS</b></p> <p><b>5.1 General</b></p> <p>An Advertisement must:</p> <ul style="list-style-type: none"> <li>a. comply with the Advertising Code and all other relevant Laws and Regulations;</li> <li>b. not be misleading or deceptive, or likely to mislead or deceive;</li> <li>c. reflect a high standard of social responsibility and conform to generally accepted standards of good taste;</li> <li>d. be readily recognisable by the target audience as an Advertisement;</li> <li>e. not claim that a Product is unique or has some special merit, quality or property unless the claim can be substantiated;</li> <li>f. not use the term “safe” without appropriate qualification;</li> <li>g. not imitate the branding, names, logos, get-up or graphic design, copy, slogans, or general layout adopted by a competitor in a way that is likely to mislead, deceive or confuse;</li> <li>h. not use, the term “new”, or any other term having the same connotation in an Advertisement to describe a Product after one year from the date of the Product’s launch, unless appropriately qualified;</li> <li>i. comply with the laws and regulations for both Medical Devices and Scheduled Medicines where the Product consists of both a Medical Device and a Scheduled Medicine; and</li> <li>j. conform with all requirements of the Code, except to the extent that any such requirement may be in conflict with any provision of the Advertising Code.</li> </ul>	<p><b>Explanatory notes</b></p> <p>Advertisements for medical devices and IVDs 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 statutory requirements, in particular the trade practices legislation.</p> <p>Advertisers have a responsibility to ensure the content and presentation of their advertisement and promotional material promotes the quality use of medical devices and IVDs through encouraging the Health Care Practitioners to select, for their patients, appropriate management options, suitable products and then to use those products safely and effectively.</p> <p>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.</p> <p>The term “new” cannot be used for a product that has been available and promoted for more than 12 months in Australia</p>
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## 5.2 Claims and endorsements

- a. A Member 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 Member must not use the name or photograph of a Healthcare Practitioner or Other 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 Practitioner or Other Professional is a member; or
  - (ii) likely to mislead, deceive or confuse.

Advertisers/sponsors are required to hold appropriate balanced comprehensive and credible evidence to substantiate advertised/ promotional claims. It is fundamental that any therapeutic claim made must be consistent with the intended purpose of the device/IVD and conform to current standards for clinical evidence.

In determining whether sufficient evidence is available to support a claim, members 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.

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

In response to a reasonable request, supporting evidence must be made available to healthcare professionals, industry members and, where appropriate, consumers within 20 working days. 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.

<p><b>5.3 Comparative Advertising</b></p> <p>a. An Advertisement must not unfairly denigrate a competitor's Product.</p> <p>b. A Member may report in an Advertisement, on the outcomes of comparative testing of Products, provided</p> <ul style="list-style-type: none"> <li>(i) the Products have been subjected to the same and appropriate testing;</li> <li>(ii) the outcomes are reported in a fair and balanced manner; and</li> <li>(iii) each outcome is referenced and consistent with the body of evidence.</li> </ul> <p>c. If the comparative data that supports a claim referred to in clause <b>Error! Reference source not found.</b> arises from separate studies then a qualifying statement must be included to the effect that substantiating data arise from separate studies.</p> <p>d. A Member 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.</p> <p>e. An Advertisement must not contain, whether expressly or by implication, exaggerated or unqualified superlative claims.</p>	<p>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.</p> <p>“Hanging“ comparatives are those that merely claim that a product is better, stronger, more widely used must not be used.</p>
<p><b>5.4 Advertisements to Healthcare Practitioners - general</b></p> <p>a. An Advertisement must contain the following mandatory information:</p> <ul style="list-style-type: none"> <li>(i) the brand name of the Product (where appropriate);</li> <li>(ii) the name and contact details of the Sponsor;</li> <li>(iii) claims consistent with the intended purpose of the Product; and</li> <li>(iv) all such other information as may be required by law or as a</li> </ul>	

<p style="text-align: center;">condition of grant of a licence.</p> <p>b. If a third party requests information on the intended purpose then the Member must provide the information to the third party without delay.</p> <p>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.</p>	
<p><b>5.5 Company Commissioned Articles</b></p> <p>a. A CCA must be clearly identified as a company commissioned article.</p> <p>b. The Sponsor must be clearly identified at either the top or the bottom of the article.</p> <p>c. Where a CCA is used solely for the purpose of supporting a claim, including a comparative claim, the claim must be referenced.</p>	

<p><b>6 INTERACTIONS WITH HEALTHCARE PRACTITIONERS AND OTHER PROFESSIONALS</b></p> <p><b>6.1 General interactions</b></p> <p>In all dealings with Healthcare Practitioners and Other Professionals:</p> <ul style="list-style-type: none"> <li>a. a Member must comply with this clause 6; and</li> <li>b. without limiting this clause 6, a Member 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.</li> </ul>	<p><b>Explanatory Notes</b></p> <p>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.</p> <p>A Healthcare Professional under the Code is a person who is any one of the listed professional specialities set out in the definition, or who has current membership of a Professional Association in Australia or New Zealand. A Professional Association is a clinical or other professional body representing healthcare professionals.</p>
<p><b>6.2 Member-sponsored Training and Education and Product demonstrations</b></p> <p>The following applies to Training and Education, and Product demonstrations, conducted by or on behalf of a Member and provided to Healthcare Practitioners or Other Professionals.</p> <ul style="list-style-type: none"> <li>a. The program must be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of knowledge.</li> <li>b. If the program requires “hands on” training in medical procedures or Product demonstration: <ul style="list-style-type: none"> <li>(i) it must be held at a training facility, medical institution, laboratory, or other appropriate facility; and</li> <li>(ii) the training staff must have the proper qualifications and expertise to conduct such training.</li> </ul> </li> <li>c. A Member may provide a Healthcare Practitioner or Other Professional attendee with Hospitality that is modest in value and subordinate in time</li> </ul>	<p>The development of, and further research into, medical technology products is often dependent on the feedback and information provided by a healthcare professional. That relationship is therefore fundamental to beneficial outcomes for patients. Industry also invests heavily in training and educating healthcare professionals to ensure that they use the products in the optimal manner.</p> <p>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.</p> <p>The training should not be held at a resort location. It must be at an appropriate for education purposes and in a clinical setting where there is ‘hands on’ training.</p> <p>Hospitality (ie the provision of food and beverages) may be</p>

<p>and focus to the educational or training purpose of the program.</p> <p>d. A Member may pay for reasonable travel and modest lodging costs incurred by attending Healthcare Practitioners and Other Professionals.</p> <p>e. A Member must not pay for the Hospitality, travel, or other expenses of any guest of a Healthcare Practitioner or Other Professional, or for any other person who does not have a genuine professional interest in the information being shared at the program.</p> <p>f. In the interests of transparency and accountability:</p> <p>(i) subject to paragraph (iii), the Member must enter into a simple written agreement with each Healthcare Practitioner and Other Professional attending the program which sets out the nature of the program and the services to be provided by or on behalf of the Member;</p> <p>(ii) the agreement must require the Member and the Healthcare Practitioner or Other Professional to make all necessary disclosures to any relevant Professional Association or Institutions; and</p> <p>(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 by the Healthcare Practitioner or Other Professional.</p> <p>g. The Member must not impose any requirement on any Healthcare Practitioner or Other Professional to purchase or cause to be purchased any Products or other goods or services associated with the training, in consideration for attending the program.</p> <p>h. The Member must not provide to attending Healthcare Practitioners or Other Professionals any gifts, rewards or free Products other than in compliance with clause 6.7.</p>	<p>provided but as an ancillary offering. It must not be the main focus of the training event.</p> <p>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.</p> <p>Companies should use simple agreements with healthcare professionals to ensure that everyone is clear on the purpose of the event and what will be provided. MTAA will develop standard form agreements that can be used for this purpose. 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.</p> <p>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 participated in a training session must be modest in value (less than AUD100), and either of an educative nature or branded with the company's logo. Where branded the gift must be consistent with the educative nature of the training.</p>
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<p><b>6.3 Third Party Educational Conferences</b></p> <p><b>6.3.1 General</b></p> <p>A Member may participate in and support a Third Party Educational Conference provided:</p> <ul style="list-style-type: none"> <li>a. the Member's participation and support is not provided for the purposes of Promoting a Product, except in accordance with clause 6.3.5; and</li> <li>b. the Member complies with this clause 6.3.</li> </ul>	<p>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.</p> <p>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 the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.</p> <p>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.</p>
<p><b>6.3.2 Sponsorship or grants for Third Party Educational Conferences</b></p> <ul style="list-style-type: none"> <li>a. A Member may provide sponsorship or a grant to the Conference Sponsor to: <ul style="list-style-type: none"> <li>(i) reduce conference costs;</li> <li>(ii) provide for attendance by a Healthcare Practitioner or a Practitioner in Training; or</li> <li>(iii) provide a reasonable honorarium, travel, lodging, and Hospitality expenses for a Faculty Member.</li> </ul> </li> <li>b. A Member may provide sponsorship or a grant provided:</li> </ul>	<p>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.</p> <p>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.</p> <p>It is recognised that some conferences are very large events with many attendees. Others may be quite small events</p>

<ul style="list-style-type: none"> <li>(i) it is proportionate to the overall cost of the conference;</li> <li>(ii) the conference is primarily dedicated to promoting objective medical, scientific and educational activities and discourse;</li> <li>(iii) the Conference Sponsor selects the recipient of the sponsorship or grant, who may be a Faculty Member;</li> <li>(iv) the Conference Sponsor makes the arrangements, and pays for, the travel and accommodation of the recipient;</li> <li>(v) the Conference Sponsor is responsible for and controls the selection of program content, Faculty Members, educational methods and materials;</li> <li>(vi) the sponsorship or grant: <ul style="list-style-type: none"> <li>(A) is not conditional on any obligation to or by the recipient;</li> <li>(B) is not offered or provided in a manner or on conditions that would interfere with the independence or professional obligations of a Healthcare Practitioner or Practitioner in Training;</li> <li>(C) is consistent with guidelines established by the Conference Sponsor; and</li> <li>(D) does not give rise to, or facilitate any breach of the Code;</li> </ul> </li> <li>(vii) the Conference Sponsor and the Member enter into a written agreement specifying the nature and conditions of the sponsorship or grant; and</li> <li>(viii) the agreement requires the Conference Sponsor to account to the Member for the use of the sponsorship or grant, without being required to disclose the identity of recipients.</li> </ul>	<p>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.</p> <p>The focus of the conference must be educative, medical or scientific. A company may not direct the conference organiser to select a particular attendee or speaker 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.</p> <p>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.</p> <p>The Code requires that a company and the conference organiser enter into an agreement that sets out the terms of the arrangement. MTAA will develop a standard agreement to assist members to comply with this requirement.</p>
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### 6.3.3 Hospitality at Third Party Educational Conferences

- a. A Member may provide funding to the Conference Sponsor to support Hospitality at a Third Party Educational Conference provided:
- (i) the Hospitality:
    - (A) is subordinate to, and does not divert from, the educational and technical purposes of the conference,
    - (B) is consistent with the Conference Sponsor's guidelines for the conference;
  - (ii) the funding:
    - (A) is appropriate in value; and
    - (B) does not give rise to, or facilitate any breach of the Code; and
  - (iii) the Conference Sponsor and the Member enter into a written agreement:
    - (A) specifying the nature and conditions of the Hospitality; and
    - (B) which requires the Conference Sponsor to account to the Member for the use of the funding.
- b. A Member may provide Hospitality at a Third Party Educational Conference provided the Hospitality:
- (i) is available to all attendees at the conference who are Healthcare Practitioners, a specialty sub-group of Healthcare Practitioners, or Other Professionals;
  - (ii) is subordinate to, and does not divert from, the educational and technical purposes of the conference;
  - (iii) is consistent with the Conference Sponsor's guidelines for the

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.

conference; (iv) is appropriate in value; and (v) does not give rise to, or facilitate any breach of the Code.	
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<p><b>6.3.4 Member-sponsored symposia with Faculty Members</b></p> <p>A Member may conduct a Member-sponsored symposium as part of a Third Party Educational Conference provided that the symposium:</p> <ul style="list-style-type: none"> <li>a. uses a Faculty Member or a Consultant of the Member to speak or facilitate the symposium; and</li> <li>b. complies with the provisions of clause 6.3.3a(i)(A).</li> </ul>	<p>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.</p>
<p><b>6.3.5 Advertisements and Trade Displays at Third Party Educational Conferences</b></p> <ul style="list-style-type: none"> <li>a. A Member may purchase an Advertisement, at transparent and commercially sensible rates, and lease booth space for a Trade Display at conferences.</li> <li>b. A Trade Display must: <ul style="list-style-type: none"> <li>(i) not display Advertisements that do not comply with clause 5 of the Code;</li> <li>(ii) prominently identify the Sponsor of the Product that is the subject of the Trade Display;</li> <li>(iii) where the Product is not yet registered with the Regulator, and is displayed for the purposes of a Demonstration, a notice must indicate that the Product is not yet registered and be consistent with the intended purpose assigned by the manufacturer;</li> <li>(iv) comply with requirements of the Conference Sponsor that are lawful and do not conflict with any provision of the Code; and</li> <li>(v) carry out only activities that can withstand public scrutiny and conform to professional and community standards of good taste.</li> </ul> </li> </ul>	<p>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.</p> <p>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.</p>

#### **6.4 Arrangements with Healthcare Practitioners and Other Professionals acting as Consultants**

- a. A Member may engage a Healthcare Practitioner or an Other Professional to serve as a Consultant to provide valuable genuine consulting services, including research, participation on advisory boards, presentations at Member-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 Product to the Healthcare Practitioner or Other Professional is not a purpose for the engagement.
- b. A Member may pay the Healthcare Practitioner or Other Professional reasonable compensation for performing services as a Consultant.
- c. Consulting arrangements between a Member and a Consultant must comply with the following:
  - (i) the arrangement must be documented in writing between the Member 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) the location and circumstances for any meetings between the Member and the Consultant must be appropriate to the subject matter of the engagement and the meeting must be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of information;
  - (v) Member-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

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.

<p>primary purpose of the meeting;</p> <p>(vi) the Member 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 Member; and</p> <p>(vii) the written agreement documenting the consulting arrangement must require the Member and the Consultant to make all necessary disclosures to any relevant Professional Association or Institutions concerning any existing or potential conflict of interest.</p>	
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<p><b>6.5 Hospitality and Entertainment</b></p> <p>a. Any Hospitality provided by a Member to a Healthcare Practitioner or Other Professional must be secondary to the educational content of the meeting, provided in an environment that enhances education and learning and reflect the professional standing of the audience.</p> <p>b. The venue and location at which a Member provides hospitality to Healthcare Practitioners and Other Professionals must be conducive to education and must not be chosen for its leisure or recreational facilities.</p> <p>c. Interaction between a Member and a Healthcare Practitioner or Other Professional must not include Entertainment.</p>	<p>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. There will be many day-to-day interactions between industry and healthcare professionals, including assistance 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.</p> <p>A meeting with a hospital buyer or procurement manager will have less of an educational focus than a meeting with a healthcare professional but nonetheless should include an element of instruction or advice on a product to ensure that the interaction is not simply a social interchange funded by the company.</p>
<p><b>6.6 Market research</b></p> <p>A Member may conduct Market Research with a Healthcare Practitioner or Other Professional provided that:</p> <p>a. the sole purpose is to collect data and the Market Research is not calculated to Promote to and/or reward the Healthcare Practitioner or Other Professional;</p> <p>b. the Market Research study is clearly identified as such to the Healthcare Practitioner or Other Professional;</p> <p>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 Practitioner or Other Professional. and</p> <p>d. where the Market Research includes a Competition or allows for the provision of any prize, it complies with clause 6.8.</p>	<p>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 speciality of the healthcare professional.</p> <p>If a company uses a competition as part of the participation it must meet the requirements for healthcare professional competitions in clause 6.8.</p>

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<p><b>6.7 Gifts to Healthcare Practitioners and Other Professionals</b></p> <p>a. A Member occasionally may provide a Healthcare Practitioner or Other Professional with:</p> <p>(i) a gift of minimal value other than medical textbooks or anatomical models used for education purposes provided:</p> <p>(A) it serves a genuine educational function for the Healthcare Practitioner or Other Professional; or</p> <p>(B) it serves to provide education to a Consumer; or</p> <p>(ii) a branded Promotional item of minimal value.</p> <p>b. A Member may not accept a gift from a Healthcare Practitioner or Other Professional which is beyond the level of what is reasonable and customary in the circumstances of the relationship.</p> <p>c. A Member must ensure that sales of Product are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a Healthcare Practitioner or Other Professional receiving payments, gifts or Hospitality.</p> <p>d. For the avoidance of doubt, this clause does not preclude the legitimate practice of providing to Healthcare Practitioners appropriate sample Products for genuine training, educational or Product evaluation purposes.</p>	<p>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.</p> <p>Any gift must be modest in value (ie. no more than AUD100) and either of an educative nature or a branded promotional item. The limit of AUD100 does not apply if the gift is a medical textbook or anatomical model given that these invariably cost more than the limit. Nonetheless they should not be extravagant. Branded promotional items should be appropriate - notepads, pens and the like are appropriate. Golf balls and bottles of wine are not appropriate.</p>
<p><b>6.8 Competitions for Healthcare Practitioners and Other Professionals</b></p> <p>a. A Member may conduct a Competition for Healthcare Practitioners or Other Professionals that complies with the following limited provisions:</p> <p>(i) the Competition must be based entirely on medical or other specialist healthcare knowledge or the acquisition of that knowledge;</p>	<p>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.</p> <p>The competition must be based on the participant's medical or other specialist knowledge. The prize must be modest (ie. no more than AUD 100) and directly relevant to the</p>

<p>(ii) all Competition prizes must be:</p> <p>(A) directly relevant to the practice of medicine or field of other specialist healthcare; and</p> <p>(B) of minimal monetary value or be an item of an educational nature; and</p> <p>(iii) entry into a Competition must not be dependent on the ordering, recommending, using or prescribing of a Product;</p> <p>b. The conduct of a Competition must comply in all respects with all relevant Laws and Regulations.</p>	<p>practice of medicine or area of healthcare. This means that eg. a prize of cinema tickets or wine would not be appropriate.</p> <p>Entry must not be dependent on ordering or using a particular product.</p>
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<p><b>6.9 Donations and philanthropic gifts</b></p> <p>a. A Member may make a donation provided that the donation is made only to a charitable or philanthropic organisation or for educational or research purposes or, in very rare cases, to an individual engaged in a charitable mission, for the support of that mission, including but not limited to organisations established for the following purposes:</p> <p>(i) <b>Advancement of Medical Education</b>, by supporting the genuine medical education of Practitioners in Training through programs which are charitable, philanthropic or have an academic affiliation (subject to clause 6.2h if the donation is to enable attendance at a Third Party Educational Conference);</p> <p>(ii) <b>Advancement of Research with Scientific Merit</b>, by supporting genuine medical research (subject to clause 6.4 if a Member engages a Healthcare Practitioner to conduct research on its behalf); and</p> <p>(iii) <b>Advancement of Public Education</b>, by supporting genuine education of Consumers or the public about important healthcare topics.</p> <p>b. A Member must not make any charitable donation or philanthropic grant for the purpose of inducing a Healthcare Practitioner or Other Professional to purchase, lease, recommend, use, or arrange for the purchase, lease or use of the Member's Product.</p> <p>c. The Member must fully document every donation made by the Member.</p>	<p>A company may make a donation for limited purposes:</p> <ul style="list-style-type: none"> <li>• To a charitable or philanthropic organisation</li> <li>• To an organisation for educational or research purposes</li> <li>• In rare cases, to an individual to support a charitable mission.</li> </ul> <p>The types of organisations that are appropriate to receive donations are those established:</p> <ul style="list-style-type: none"> <li>• To advance medical education</li> <li>• To advance research with scientific merit</li> <li>• To advance public education.</li> </ul> <p>The amount and purpose of the donation must be documented.</p>
<p><b>6.10 Provision of reimbursement and other information</b></p> <p>a. In Australia, a Member may support accurate and responsible billing to Medicare and other payers by providing reimbursement information to a Healthcare Practitioner regarding the Member's Products, including identifying appropriate coverage, coding, or billing of the Member's</p>	

<p>Products, or of procedures using those Products.</p> <p>b. A Member may provide to a Healthcare Practitioner or Other Professional who has acquired or uses a Product of the Member, information for the purposes of aiding in the appropriate and efficient use or installation of the Product.</p>	
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<p><b>7 COMPANY REPRESENTATIVES</b></p> <p><b>7.1 General</b></p> <p>a. A Member must:</p> <ul style="list-style-type: none"> <li>(i) ensure that its Company Representatives are fully aware of the provisions of the Code; and</li> <li>(ii) provide ongoing training to Company Representatives on compliance with the provisions of the Code.</li> </ul> <p>b. A Member must ensure that its Company Representatives at all times:</p> <ul style="list-style-type: none"> <li>(i) maintain a high standard of ethical conduct and professionalism;</li> <li>(ii) conduct themselves in a manner that complies with the Code;</li> <li>(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 Practitioner or Other Professional; and</li> <li>(iv) act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.</li> </ul> <p>c. A Member must ensure that a Company Representative who attends procedures at the invitation of a Healthcare Practitioner complies with all relevant institutional requirements, standards, codes and all relevant Laws and Regulations.</p>	<p><b>Explanatory Notes</b></p> <p>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.</p> <p>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.</p> <p>A company has the responsibility of ensuring adequate awareness of the Code and its provisions. A company must also ensure that employees understand the nature of the professional relationship with healthcare professionals to ensure that there is no inappropriate behaviour that might compromise the professional independence of the healthcare professional.</p>
<p><b>7.2 Requirement for training</b></p> <p>a. A Member must ensure that every Company Representative undertakes an education program on the Code approved by the Association:</p> <ul style="list-style-type: none"> <li>(i) within the first six months of employment in the role of Company</li> </ul>	<p>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</p>

<p style="text-align: center;">Representative; and</p> <p>(ii) as a refresher program at no less frequency than once every three years.</p> <p>b. A Member must ensure that every employee employed in a role which involves Promotional activities on behalf of the Member undertakes an education program on the Code approved by the Association:</p> <p>(i) within the first six months of employment in the role; and</p> <p>(ii) as a refresher program at no less frequency that once every three years.</p>	<p>these employees will have a refresher on the changes.</p> <p>To ensure that training in the Code is consistent all training must either be delivered by MTAA or reviewed by MTAA.</p>
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<p><b>8 INTERACTIONS WITH CONSUMERS</b></p> <p><b>8.1 General</b></p> <p>a. If a Member receives a request from a Consumer for advice of a medical or diagnostic nature, the Member must recommend that the Consumer consult an appropriate Healthcare Practitioner.</p> <p>b. A media release to one or more organisations or through one or more channels intended or likely to result in publication to Consumers:</p> <p>(i) must not be an Advertisement unless it conforms with the Code; and</p> <p>(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.</p> <p>c. The Associations recognise and support relationships between Industry and Health Consumer Organisations in relation to Products which are used by Consumers, for the sole purpose of facilitating education of Consumers and enhancing their quality use of those Products.</p>	<p><b>Explanatory Notes</b></p>
<p><b>8.2 Competitions for Consumers</b></p> <p>a. A Competition must not be directed to Consumers in relation to any Restricted Medical Device.</p> <p>b. To the extent a Competition comprises an Advertisement, it must comply with clause 5 of the Code.</p> <p>c. Entry into a Competition must not, as a condition of entry, require a Consumer to use or purchase a Product.</p> <p>d. The conduct of a Competition must comply in all respects with all relevant Laws and Regulations.</p>	

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<p><b>9 ADMINISTRATION OF CODE OF PRACTICE</b></p> <p><b>9.1 Code of Practice Strategic Advisory Committee - general</b></p> <p>The Code of Practice Strategic Advisory Committee (<b>COPSAC</b>) is established to supervise the administration of the Code and is responsible to the Boards.</p> <p><b>9.2 Composition of COPSAC</b></p> <p>COPSAC shall be made up of:</p> <p><b>Full Members:</b></p> <ol style="list-style-type: none"> <li>a. an independent Chair;</li> <li>b. six representatives from MTAA elected from among the Authorised Representatives or a senior delegate of Authorised Representatives;</li> <li>c. one representative from MIANZ; and</li> <li>d. a Consumer Representative.</li> </ol> <p><b>Observers:</b></p> <ol style="list-style-type: none"> <li>a. a representative of the secretariat of each of MTAA and MIANZ; and</li> <li>b. the secretary to COPSAC, provided by MTAA.</li> </ol>	<p><b>Explanatory Notes</b></p> <p>The structure of the administrative provisions of the Code is to provide for a series of committees established for complementary purposes:</p> <ul style="list-style-type: none"> <li>• Code of Practice Strategic Advisory Committee - member-based committee which reviews Code implementation and education and reports annually on Code complaints and outcomes. Each Association has its own COPSAC but with cross-representation</li> <li>• 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</li> <li>• Code Complaints Committee - initial complaints review body which is drawn from a cross-section of representatives of healthcare professionals, healthcare institutions, consumers and industry</li> <li>• Code Appeal Committee - similar cross-section of representatives, established to hear an appeal from findings of the Code Complaint Committee.</li> </ul>
<p><b>9.3 Role of COPSAC</b></p> <p>COPSAC is responsible for the review and evaluation of the Code and its administration. To achieve this, COPSAC must:</p> <ol style="list-style-type: none"> <li>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;</li> <li>b. consult with key stakeholders if it is considered that more than minor</li> </ol>	

<p>amendments are required;</p> <ul style="list-style-type: none"><li>c. submit all proposed amendments to the Boards for approval;</li><li>d. publicise all amendments in accordance with clause 9.5;</li><li>e. oversee the effective operation and administration of the complaints handling procedures;</li><li>f. collate statistical data of complaints received and their outcomes; and</li><li>g. conduct a regular review and analysis of complaints and Industry issues they may raise and make recommendations to the Boards.</li></ul>	
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<p><b>9.4 COPSAC procedures</b></p> <p>COPSAC must operate in accordance with the following procedures:</p> <ul style="list-style-type: none"> <li>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.</li> <li>b. In its first year, all COPSAC members elected by each of MTAA and MIANZ 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 COPSAC has a term of two years and may stand for re-election for one further term of two years.</li> <li>c. COPSAC may from time to time second one or more experts to assist it in its deliberations. Experts and observers do not have voting rights.</li> <li>d. A quorum consists of the Chair, and three other members.</li> <li>e. COPSAC must meet at a minimum twice per year. The Chair may request more frequent meetings on an as needs basis.</li> <li>f. Decisions of COPSAC must be made unanimously or by a majority vote of its members.</li> </ul>	
<p><b>9.5 Reviews</b></p> <ul style="list-style-type: none"> <li>a. External reviews of the Code must be carried out once every three years or more frequently if so determined by COPSAC.</li> <li>b. External reviews may be conducted by: <ul style="list-style-type: none"> <li>(i) an independent, appropriately qualified and experienced, consultant; or</li> <li>(ii) a panel of independent, appropriate qualified and experienced</li> </ul> </li> </ul>	

persons.

- c. For the purposes of conducting an internal review, COPSAC may seek comment or submissions from Members and other relevant stakeholders.

<p><b>9.6 Publicising the Code</b></p> <ul style="list-style-type: none"> <li>a. COPSAC must identify and recommend to the Associations the optimal means for the Associations to promote the Code to Members, the Industry, Healthcare Practitioners, Other Professionals, Regulators and other relevant stakeholders and participants in the healthcare industry.</li> <li>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.</li> <li>c. The Associations must ensure that the Code is available on the MTAA and MIANZ websites at all times and encourage Members to reference and provide links to the Code on their own websites.</li> <li>d. The Associations must encourage Members to promote the Code on a regular basis.</li> </ul>	
<p><b>9.7 Education on the Code</b></p> <ul style="list-style-type: none"> <li>a. COPSAC must ensure the regular provision of education on the interpretation and application of the Code to Members, the Industry, Healthcare Practitioners, Other Professionals, Regulators and other relevant stakeholders and participants in the healthcare industry.</li> <li>b. COPSAC 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.</li> </ul>	
<p><b>9.8 Reporting</b></p> <p>Each year, COPSAC must provide a written report on the administration of the Code, for inclusion in the Annual Reports of each Association.</p>	

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10 COMPLIANCE MECHANISMS	Explanatory Notes
<p><b>10.1 General</b></p> <ul style="list-style-type: none"> <li>a. Members must take all measures reasonably required to ensure compliance with the Code by Company Representatives. Members must adopt effective compliance programs by issuing written policies and procedures, conducting training programs and implementing clear procedures, controls and enforcement mechanisms.</li> <li>b. Members are encouraged to inform all customers, Institutions and Healthcare Practitioners and Other Professionals of the requirements of the Code.</li> <li>c. A Complaint regarding: <ul style="list-style-type: none"> <li>(i) an Advertisement, or Promotional activities by a Member; or</li> <li>(ii) an interaction with a Healthcare Practitioner or Other Professional,</li> </ul> must be dealt with by the Code Complaints Committee (CCC), contact details for which are listed in Appendix 2.</li> <li>d. Subject to clause 10.1e, a Complaint regarding an Advertisement directed to Consumers must be forwarded to the bodies listed in Appendix 1.</li> <li>e. Notwithstanding the provisions of clause 10.1d of the Code, if a Complaint: <ul style="list-style-type: none"> <li>(i) is made in relation to an Advertisement directed to Consumers; and</li> <li>(ii) in addition asserts other conduct that may be in breach of the Code,</li> </ul> then the CCC may deal with any assertion in the Complaint insofar as it relates to the other conduct.</li> <li>f. All Complaints and responses must be in writing.</li> <li>g. In support of a fair and transparent complaints system, anonymous Complaints are not accepted.</li> </ul>	

<p>h. The CCC must deal with all Complaints it receives in accordance with the provisions of the Code.</p> <p>i. Notwithstanding the obligations on MTAA and MIANZ to report on the outcome of Complaints as provided in the Code, all information about a Member, a complainant, and the subject matter of a Complaint, must be kept confidential by MTAA and MIANZ until all avenues of appeal are exhausted and outcomes of appeals known.</p>	
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## 10.2 Code Monitoring Committee - composition and procedures

- a. To support compliance with the Code the Code Monitoring Committee will proactively monitor selected Promotions and activities of Members on a regular and ongoing basis.
- b. The Code Monitoring Committee may request a Member to submit a copy of the selected Promotion over the past three months for the Product under review. The Authorised Representative must provide a signed written statement that the material provided to the Code Monitoring Committee constitutes all the relevant material.
- c. The membership of the Code Monitoring Committee will comprise six 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;
  - (ii) Two representatives of Professional Associations;
  - (iii) Two representatives of Industry, one with experience in marketing and the other with experience in technical issues;
  - (iv) One Consumer Representative.
- d. 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.
- e. 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.
- f. If, following the review of submitted material or activities, the Code Monitoring Committee determines that a breach of the Code may have occurred, the Code Monitoring Committee must contact the Member to verify if that determination is correct and to receive any further material that the Member deems relevant to the process.

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

The Code Monitoring Committee has the authority to review any material or actions that appear to disclose a breach of the Code, to the Code Complaints Committee for further investigation.

<p>g. The Code Monitoring Committee must consider the response and, if appropriate, refer the matter to the Code Complaint Committee as a Complaint.</p>	
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### 10.3 Code Complaint Committee - composition and procedures

- a. No later than the end of January in each year the secretariats of MTAA and MIANZ 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 areas to ensure appropriate expertise across relevant disciplines and activities:
  - (i) Healthcare Practitioners;
  - (ii) Institutions;
  - (iii) Consumer Representatives;
  - (iv) Industry; and
  - (v) lawyers.
- e. Australian panelists must be:
  - (i) resident or available to sit on the CCC in Australia, and
  - (ii) approved by the Board of MTAA.

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| <ul style="list-style-type: none"> <li>f. New Zealand panelists must be: <ul style="list-style-type: none"> <li>(i) resident or available to sit on the CCC in New Zealand, and</li> <li>(ii) approved by the Board of MIANZ.</li> </ul> </li> <li>g. Each Board may add or remove panelists during the year.</li> <li>h. The selection of particular panelists to form the CCC to hear a Complaint will be determined by the secretariat of MTAA or MIANZ as applicable, having regard to the nature of the Product and potential conflicts of interest.</li> <li>i. Each CCC must comprise: <ul style="list-style-type: none"> <li>(i) an independent Chair; and</li> <li>(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.</li> </ul> </li> <li>j. The Chair of the CCC: <ul style="list-style-type: none"> <li>(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;</li> <li>(ii) will be determined by the secretariat of MTAA or MIANZ as applicable; and</li> <li>(iii) may be a person not included on a CCC panel.</li> </ul> </li> <li>k. The MTAA or MIANZ 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.</li> <li>l. The quorum for the CCC is the Chair and two other members.</li> </ul> |  |
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<ul style="list-style-type: none"><li>m. Decisions of the CCC must be made unanimously or by a majority vote of its members.</li><li>n. The MTAA or MIANZ 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.</li><li>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.</li><li>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.</li></ul>	
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<p><b>11 COMPLAINT HANDLING PROCEDURES</b></p> <p><b>11.1 General</b></p> <p>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.</p> <p>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.</p> <p>c. The Complaints Secretary must acknowledge a Complaint, whether concerning a Member or a non-member, in writing within seven working days of its receipt and deal with the Complaint expeditiously.</p>	<p><b>Explanatory Notes</b></p> <p>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 MIANZ, depending on the location of the behaviour.</p> <p>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.</p> <p>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.</p>
<p><b>11.2 Complaints by Consumer or Non-Industry Complainant</b></p> <p>The following applies to a Complaint to be made by a Consumer or Non-Industry Complainant.</p> <p>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 Member whose behaviour has given rise to the Complaint.</p> <p>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</p>	

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### **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 Member 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**

- a. A Complaint must be in writing with six copies of the Complaint and supporting material (one for each member of the CCC, one for the Complaints Secretary and one for the Respondent) and:
  - (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(iii) by an Industry Complainant on the basis that the Member 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 MIANZ,

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 the CCC identifies a possible breach of the Code it may refer the matter to the Code Monitoring Committee for further investigation.

<p><b>11.5 Withdrawal</b></p> <p>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.</p> <p>b. The CCC may treat a Complaint as withdrawn if it is satisfied that:</p> <ul style="list-style-type: none"> <li>(i) the Complaint is trivial, vexatious, misconceived or lacking in substance; or</li> <li>(ii) the subject matter of the Complaint has been dealt with previously by the CCC or another authority; or</li> <li>(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.</li> </ul> <p>c. If the Complaint is treated as withdrawn under clause 11.5b, the Complaints Secretary must inform the complainant and the Respondent in writing, detailing the reasons.</p> <p>d. Termination of the Complaints handling procedure under clause 11.5a will not prevent the CCC from referring to the relevant Board for its consideration any action or conduct on the part of a Member which in its opinion may constitute a criminal offence or be likely to bring the Industry into grave disrepute.</p>	
<p><b>12 SANCTIONS</b></p> <p><b>12.1 Classification of Breaches</b></p> <p>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.</p> <p><b>Minor Breach:</b> a breach of the Code that has no safety implications and will have no adverse effect on</p>	<p><b>Explanatory Notes</b></p> <p>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.</p>

	<p>how Healthcare Practitioners, Other Professionals or the general public view the Product the subject of the Complaint, similar Products or the Industry.</p>	
<b>Moderate Breach:</b>	<p>a breach of the Code with no safety implications but which will adversely impact on the perceptions of Healthcare Practitioners, Other Professionals or the general public regarding the Product the subject of the Complaint, similar Products or the Industry.</p>	
<b>Severe Breach:</b>	<p>a breach of the Code that has safety implications or will have a major adverse impact on how Healthcare Practitioners, Other Professionals or the general public view the Product the subject of the Complaint, similar Products or the Industry.</p>	
<b>Repeat Breach:</b>	<p>when a Member commits the same or similar breach of the Code to a breach found against the Member within the preceding 24 months.</p>	
<b>Serial Breach:</b>	<p>when a Member breaches the Code, and that Member has been found to have breached the Code on not less than two previous occasions in the preceding 24 months.</p>	

## 12.2 Available Sanctions

- a. Where the CCC finds that a Member 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 Member take immediate action to discontinue or modify any practice which is determined to constitute a breach of the Code, in which event the Member 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 Member recall and destroy any offending material in which event the Member 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 Member 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 Member 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

<p><b>Serial Breach:</b> An amount not less than \$5,000 and not more than \$75,000.</p> <p>b. 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.</p> <p>c. If the CCC resolves that a breach of the Code by a Member warrants the suspension or the expulsion of the Member from MTAA or MIANZ, it must make such a recommendation to the relevant Board. The Board may deal with the recommendation under the provisions of its constitution.</p> <p>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.</p>	
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<p><b>12.3 Failure to comply with sanctions</b></p> <p>a. If a Member, 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:</p> <ul style="list-style-type: none"> <li>(i) is a further breach of the Code; and</li> <li>(ii) in addition to any further sanctions imposed pursuant to clause 12.2, entitles the CCC to direct MTAA and/or MIANZ 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.</li> </ul> <p>b. The continued refusal by the Member to undertake the required remedial action/s entitles the CCC to direct MTAA and/or MIANZ to publish in the trade media details of the breach of the Code and the subsequent failure to undertake remedial action.</p> <p>c. In addition to the sanction set out in clause 12.2 above, the CCC may direct MTAA and/or MIANZ to notify the Regulator of the continued breach of the Code.</p>	
<p><b>13 APPEAL PROCEDURES</b></p> <p><b>13.1 Appeals - general</b></p> <p>a. A Member who has been found under clause 12 to be in breach of the Code may lodge an appeal against the findings and any imposed sanctions.</p> <p>b. A Member 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 Member 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).</p>	

<p>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.</p> <p>d. The unsuccessful party to an appeal from an Industry complainant must reimburse MTAA or MIANZ, 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.</p>	
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<p><b>13.2 Abuse of Code</b></p> <p>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.</p>	
<p><b>13.3 Appeals Committee - composition and procedures</b></p> <p>a. The Code Complaint Appeals Committee (Appeals Committee) must comprise the following:</p> <ul style="list-style-type: none"> <li>(i) an independent Chair who must be a qualified lawyer; and</li> <li>(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.</li> </ul> <p>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.</p> <p>c. The quorum for the Appeals Committee is the Chair and two other members.</p> <p>d. The Appeals Committee must make decisions by consensus and/or a majority of its members.</p> <p>e. The Appeals Committee must consider only:</p> <ul style="list-style-type: none"> <li>(i) the material that was considered by the CCC in the matter;</li> <li>(ii) the appeal papers and any response from the complainant; and</li> <li>(iii) any additional material which the Appeals Committee reasonably</li> </ul>	

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.

<p><b>14 REPORTING BY CCC</b></p> <ul style="list-style-type: none"> <li>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 Member.</li> <li>b. To ensure transparency of procedures, MTAA and MIANZ 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.</li> <li>c. MTAA and MIANZ must not publish in any form the name of a complainant if it has been withheld in accordance with clause 11.2b.</li> </ul>	
<p><b>15 MEDIATION</b></p> <p><b>15.1 General</b></p> <ul style="list-style-type: none"> <li>a. Either Association may invite a Member, a Consumer, a Non-Industry Complainant or an Industry Complainant to participate in mediation as an alternative to participating in the Complaints process established under the Code.</li> <li>b. The Complaints Secretary may appoint an independent mediator to assist the parties to discuss, negotiate and achieve a resolution.</li> <li>c. Where the parties consent to a mediation, the Complaints Secretary must arrange the mediation session in consultation with the parties and mediator.</li> <li>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.</li> </ul>	

<p>e. The parties may be present in person at the mediation. It is not expected that the parties will be legally represented at mediation.</p> <p>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 MIANZ, as applicable.</p>	
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<p><b>15.2 Mediator</b></p> <ul style="list-style-type: none"> <li>a. The mediator must be a person with demonstrable mediation experience.</li> <li>b. The mediator may seek the advice or participation of an expert, as required.</li> <li>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.</li> <li>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.</li> </ul>	
<p><b>16 INTERPRETATION</b></p> <p><b>16.1</b> In the Code:</p> <ul style="list-style-type: none"> <li>a. the singular includes the plural and vice versa, and a gender includes other genders;</li> <li>b. another grammatical form of a defined word or expression has a corresponding meaning;</li> <li>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;</li> <li>d. a reference to A\$, \$A, dollar, or \$ is to Australian or New Zealand currency as applicable in the circumstances;</li> <li>e. the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions; and</li> </ul>	

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](mailto: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](mailto: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 Practitioners and Other Professionals

Complaints regarding Advertisements directed to, and interactions with, Healthcare Practitioners and Other 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](mailto: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](mailto:asa@asa.co.nz)

#### OR

MIANZ  
PO Box 8378  
Symonds Street  
Auckland  
New Zealand  
Ph: +64- (0)9 - 917 3645  
Fax: +64- (0) 9 -917 3651  
Email: [admin@mianz.co.nz](mailto:admin@mianz.co.nz)