

MEDICAL TECHNOLOGY ASSOCIATION OF NEW ZEALAND
CODE OF PRACTICE 2016



6th EDITION



medical technology
ASSOCIATION OF NEW ZEALAND

CONTENTS

- 1 Goal and Scope of MTANZ Code — **p3**
 - 2 Definitions — **p4**
 - 3 General Principles — **p6**
 - 4 Advertising and Promotion of Products — **p6**
 - 5 Interactions with Healthcare Practitioners and other Professionals — **p7**
 - 6 Company Representatives — **p15**
 - 7 Administration of Code of Practice — **p16**
 - 8 Compliance Mechanisms — **p18**
 - 9 Complaint Handling Procedures — **p19**
 - 10 Sanctions — **p20**
- Appendix 1 — **p22**
Complaints on Advertisements Directed to Consumers
- Appendix 2 — **p22**
Complaints on Advertisements to and Interactions with Healthcare Professionals



Code of Practice is a self-regulatory industry code that facilitates ethical interactions between healthcare professionals and the medical technology industry.



GOAL AND SCOPE OF MTANZ CODE

► EXPLANATORY NOTES

- 1 Medical Technology Association of New Zealand (MTANZ) represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in order to enable patients to live longer and healthier lives (collectively “Companies,” and individual “Company”).

MTANZ is dedicated to the advancement of medical science, the improvement of patient care, and, in particular the contributions that high quality, innovative Medical Technologies make toward achieving these goals.

MTANZ recognises the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in New Zealand (“Health Care Professionals”). ■

The Explanatory Notes (right side of page) 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 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.

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

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

Republication Code of Practice 2013 version 6 edition with additional explanations.

DEFINITIONS

- 2 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 MTANZ Code of Practice can be found at the following web address: <http://mtanz.org.nz/>

DEFINITIONS IN THE CODE

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

Advertising Code means the Advertising Standards Authority in New Zealand, as amended or replaced from time to time.

Association means the Medical Technology Association of New Zealand (MTANZ).

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

Board means the board of directors of MTANZ.

Breach means a breach of any provision of the Code.

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

Code of Practice Committee (CPC) means the committee established in accordance with clause 7 to review and evaluate the Code and its administration.

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

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

Company Representative means any person or entity engaged in representing, acting for or advancing the interests of a Company in the New Zealand market pursuant to any agreement, arrangement or understanding between that person or entity and the Company, including a contract of

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 MTANZ under the Code.

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

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

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

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

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

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

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

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

Entertainment includes sporting events, musical and other entertainment.

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

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

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

DEFINITIONS

employment or other employment arrangement, or any agency or consultancy arrangement.

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

Inducement means inappropriate influence.

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

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

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

Laws and Regulations means any law or regulation in force in New Zealand (as applicable to the relevant Association) to which any act or omission the subject of the Code applies.

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 New Zealand Medicines Act 1981, as amended from time to time.

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

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

MTANZ means Medical Technology Association of New Zealand Inc.

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

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

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

Hospitality means the provision of food and beverages.

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

Regulator means a government agency performing a statutory regulatory function.

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

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

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

Scheduled Medicine has the meaning given in the New Zealand Medicines Act 1981.

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

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

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

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

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

Training Organisation means a hospital or other institution that provides training to healthcare professionals and/or practitioners in training. ■

3 GENERAL PRINCIPLES

MTANZ recognizes that ethical interactions between the medical device and diagnostics industry and healthcare professionals to advance Medical Technologies and ensure public confidence in the Medical Device and Diagnostics industry. The purpose of this Code is to facilitate ethical interactions between companies that develop, manufacture, sell, market or distribute Medical Technologies in New Zealand and those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in New Zealand.

3.1 Companies at all times should comply with provisions of all relevant legislative requirements.

3.2 Companies should not engage, directly or indirectly, or be knowingly concerned in any unethical behaviour, misleading or deceptive conduct, or unfair or unconscionable practice.

3.3 Companies should place the highest priority on the safety and welfare of users of their Medical Technologies.

3.4 Companies should always respect ethical requirements and Codes of Practice which apply to Healthcare Professionals and their business associates within the Industry.

3.5 MTANZ will provide a framework and mechanisms for setting minimum standards of behaviour, educating Companies, monitoring industry development, providing self-regulation and interacting with governmental, professional and other industry bodies, associations and consumers.

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

3.7 The Code is not intended:

- a. to provide, nor shall it be construed as, legal advice; or
- b. to take precedence over any relevant law or regulation. To the extent that any provision of the Code conflicts with a law or regulation, that law or regulation will take precedence.

4 ADVERTISING AND PROMOTION OF PRODUCTS

An Advertisement must:

- a. comply with the New Zealand Advertising Standards Authority Therapeutic Products Code of Practice;
- b. comply with the Therapeutic Advertising Pre-

The Code reflects the commitment of industry to adherence to legal principles and ethical and transparent behaviour. Companies must have regard to applicable legislative obligations including those found in the Fair Trading Act, the New Zealand Medicines Act 1981 and others.

Companies should have regard to the requirements of the various codes of ethics and codes of practice that apply to the members of the many professional bodies with which companies have dealings.

The Code provides guidance to industry best practice standards which shall apply to business practices of Companies. Companies are obliged, as a condition of membership of MTANZ, to accept and observe all provisions of the Code. In accepting and observing the Code, Companies should comply with both the letter and the spirit of the Code. As the Code provides guidance to a minimum standard, a Company should also have regard to its own company code which might provide for a higher standard. ■

Advertisements for medical device products must comply with the current New Zealand Advertising Standards Authority Therapeutic Products Code of Practice. The New Zealand Advertising Standards 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, and not bring the industry into disrepute.

- vetting System (TAPS) when advertising direct to consumers;
- c. comply with New Zealand relevant Laws and Regulations; and
 - d. reflect a high standard of social responsibility and conform to generally accepted standards of good taste.

5 INTERACTIONS WITH HEALTHCARE PRACTITIONERS AND OTHER PROFESSIONALS

Ethical interactions between Companies and Healthcare Professionals enhance patient access to the safe and effective use of Medical Technologies by ensuring appropriate training of Healthcare Professionals by Companies. Ethical interactions also promote innovation and the ongoing development of advanced Medical Technologies through legitimate and transparent collaboration between Healthcare Professionals and Companies. Further, ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies to participate in global markets. In all dealings with Healthcare Professionals a Company should undertake and encourage ethical business practices and socially responsible Industry conduct and should not use any inappropriate inducement or offer any personal benefit or advantage in order to promote or encourage the use of its products.

5.1 Company-sponsored Training and Education and Medical Technology Demonstrations

Companies may provide training of Healthcare Professionals on product specific device deployment, use and application to facilitate the safe and effective use of medical technologies by Healthcare Professionals. Companies may also provide education to Healthcare Professionals on topics concerning or associated with the use of their Medical Technologies. Training and Education programs include “hands-on” training sessions, cadaver workshops, lectures and presentations. Training and Education should be conducted by qualified personnel, which may include sales personnel with appropriate technical expertise.

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

- a. The program should be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of knowledge.
- b. If the program requires “hands on” training in medical procedures or Medical Technology

A Company should undertake and encourage ethical business practices and socially responsible industry conduct and should not use any inappropriate inducement or offer any personal benefit or advantage in order to promote or encourage the use of its products. ■

The overarching purpose of the Code is to encourage, educate 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.

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

To this end there is extensive training and education conducted by companies for the benefit of healthcare professionals and ultimately for enhanced patient outcomes. However in conducting the education and training companies need to ensure that the focus of the relationship is educative and not an opportunity to provide inappropriate hospitality. Training and education includes both formal, structured sessions and the in-service instruction that occurs in a healthcare setting. ■

The training should not be held at a Resort Location. It should be at an appropriate location for education purposes and in a clinical setting where there is ‘hands on’ or instructional training. The primary consideration in choice of a venue for any training should be whether it provides an environment that is conducive to the effective transmission of knowledge. The physical attractiveness of the venue or available sporting or leisure facilities should not determine the venue. A venue of an exclusively resort nature would not be appropriate.

Hospitality (i.e. the provision of food and beverages – excluding entertainment) may be provided but as an ancillary offering. It should not be the main focus of the training event.

A Company may pay for the cost of the healthcare professional to attend the education or training but this does not extend to the partner, or guest of the healthcare professional.

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

Gifts and other inducements are not permitted. ■

Demonstration:

- (i) it should be held at a training facility, medical institution, laboratory, or other appropriate facility; and
 - (ii) the training staff should have the proper qualifications and expertise to conduct such training.
- c. A Company may pay for reasonable travel and modest lodging costs incurred by attending Healthcare Professionals.
- d. A Company should not pay for the Hospitality, travel, or other expenses of any person who does not have a genuine professional interest in the information being shared at the program.
- e. In the interests of transparency and accountability:
- (i) Subject to paragraph (ii), the Company should enter into a simple written agreement with each Healthcare Professional attending the program which sets out the nature of the program and the services to be provided by or on behalf of the Company;
 - (ii) Where the event is modest in nature, the requirement to enter into an agreement may be satisfied by the provision of a detailed program or agenda outlining the services to be provided to the Healthcare Professional.
- f. The Company should not impose any requirement on any Healthcare Professional to purchase or cause to be purchased any Medical Technologies or other goods or services associated with the training, in consideration for attending the program.
- g. The Company should not provide to attending Healthcare Professionals any gifts, rewards or free products.

5.2 Third Party Educational Conferences

General

Bona fide independent, educational, scientific or policy-making conferences promote scientific knowledge, medical advancement and assist in the delivery of effective health care. Companies may participate in and support a Third Party Conference in accordance with Clauses 5.2 to 5.4 inclusive,

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.

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

provided that the support is consistent with relevant guidelines established by the conference organizer and any accrediting body. Company support of third-party educational conferences should preserve the independence of medical education and should not be used as a means of inappropriate inducement.

5.3 Sponsorship or grants for Third Party Educational Conferences

- a. A Company may provide sponsorship or a grant to the Conference Sponsor to:
 - (i) reduce conference costs;
 - (ii) provide for attendance by a Healthcare Professional or a Practitioner in Training; or
 - (iii) provide a reasonable honorarium, travel, lodging, and Hospitality expenses for a Faculty Member.
- b. A Company may provide sponsorship or a grant provided:
 - (i) it is proportionate to the overall cost of the conference;
 - (ii) the conference is primarily dedicated to promoting objective medical, scientific and educational activities and discourse;
 - (iii) the Conference Sponsor selects the recipient of the sponsorship or grant, who may be a Faculty Member;
 - (iv) the Conference Sponsor makes the arrangements, and pays for, the travel and accommodation of the recipient;
 - (v) the Conference Sponsor is responsible for and controls the selection of program content, Faculty Members, educational methods and materials;
 - (vi) the sponsorship or grant:
 - (A) is not conditional on any obligation to or by the recipient;
 - (B) is not offered or provided in a manner or on conditions that would interfere with the independence or professional obligations of a Healthcare Professional or Practitioner in Training;
 - (C) is consistent with guidelines established by the Conference Sponsor; and;

on behalf of groups of healthcare professionals. This section sets out the parameters within which a company should operate to provide financial support to a conference aimed at healthcare professionals and others in the healthcare sector with responsibility for purchasing decisions.

The relationship promoted under the Code is between the company and the Conference Sponsor. The Conference Sponsor can be a professional association, a Training Organisation (ie. a hospital or other body that provides training to healthcare professionals or trainees), or a bona fide commercial conference organiser that is independent of the company. ■

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

A company may provide sponsorship for a broad range of purposes - to contribute generally to reduce the cost of the conference to participants, to provide grants or direct support by the conference organiser to a healthcare professional or trainee, or provide support for a participating speaker. Companies may choose a level of sponsorship i.e Gold, Silver, Bronze. It is recognised that some conferences are very large events with many attendees. Others may be quite small events directed to a smaller group of healthcare professionals (eg. a regional meeting). For this reason the Code does not cap the amount that may be paid by a company by way of sponsorship but requires that it be proportionate to the overall cost of the conference.

A company should ensure its sponsorship funds are not applied to the costs of social activities that take place during the conference e.g sponsored dinners, bands or cocktail functions.

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 conference organiser.

Where the sponsorship is used to pay for travel, accommodation or attendance costs, a company should not pay the participating healthcare professional directly. The payment may only be made to the organiser.

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

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

- (vii) Companies should assess the conference educational programme and delivery of it ensuring that the education is the main focus of the conference.
- (viii) the Conference Sponsor and the Company enter into a written agreement specifying the nature and conditions of the sponsorship or grant; and
- (IX) the agreement requires the Conference Sponsor to account to the Company for the use of the sponsorship or grant, without being required to disclose the identity of recipients.

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

If the conference educational programme shows that there are ½ days and ample time for other activities that out-weigh the time spent in the conference room then this would be deemed an inappropriate educational programme. ■

5.4 Hospitality at Third Party Educational Conferences

- a. A Company may provide funding to the Conference Organiser to support Hospitality at a Third Party Educational Conference provided the Conference Organiser and the Company enter into a written agreement:
 - (i) specifying the nature and conditions of the Hospitality; and
 - (ii) which requires the Conference Organiser to account to the Company for the use of the funding.
- b. A company may provide Hospitality at a Third Party Educational Conferences provided the Hospitality is provided in a manner that does not interfere with attendance at conference functions.
- c. All Hospitality at Third Party Educational Conferences funded by or supplied by a Company must comply with the provisions of Hospitality clause 5.7.

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

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

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

5.5 Company-sponsored symposia with Faculty Members

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

- a. the symposium uses a Faculty Member, a Consultant or an employee of the Company to speak at or facilitate the symposium;
- b. any Hospitality complies with the provisions of Hospitality clause 5.7; and

A company may conduct a symposium which it sponsors under the wider umbrella of a third party conference provided that the symposium complies with the Hospitality restrictions referred to above for general conference Hospitality and uses either a conference speaker or a Consultant who is subject to a contractual arrangement with the company. This is to ensure that a company is not inviting Healthcare Professionals directly to a conference in contravention of the restrictions on direct individual sponsorship. A company may invite its employees to participate as speakers. ■

- c. a Company does not pay the costs of attendees to attend the symposium, other than those referred to in 5.5a.

5.6 Arrangements with Healthcare Professionals acting as Consultants

- f. A Company may engage a Healthcare Professional to serve as a Consultant to provide valuable genuine consulting services, including research, participation on advisory boards, presentations at Company-sponsored training, and product collaboration, provided that such an engagement may take place only where a legitimate need and purpose for the services is identified in advance, and the Promotion of a Medical Technology to the Healthcare Professional is not a purpose for the engagement.
- g. A Company may pay the Healthcare Professional reasonable compensation for performing services as a Consultant.
- h. Consulting arrangements between a Company and a Consultant must comply with the following:
- (i) the arrangement should be documented in writing;
 - (ii) between the Company and the Consultant, specifying all services to be provided and compensation to be paid;
 - (iii) the compensation paid to a Consultant should be consistent with fair market value for the services provided;
 - (iv) selection of the Consultant should 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;
 - (v) when a Company contracts with a Consultant to conduct clinical research services there should be a written research protocol;
 - (vi) Consulting Arrangements should only be entered into where a legitimate need for the services is identified in advance and documented;
 - (vii) the calculation of royalties payable to a Healthcare Professional in exchange for intellectual property arising from the Consulting Arrangements should

Where a company has a consulting arrangement with a healthcare professional it should set out the terms and conditions of that arrangement in an agreement. Any compensation should reflect 'fair market value' which will vary depending on the medical speciality and the seniority of the professional. Fees should not be based on or influenced by the value or volume of the consultant's business. However regardless of these criteria the arrangements should reflect fair payment for fair input and be proportionate to the effort involved.

The consultant should be selected by reference to objective criteria such as the skills and appropriateness of experience, not on the basis of recommendation of volume of product or value of business.

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

be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence;

- (viii) the location and circumstances for any meetings between the Company and the Consultant should 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;
- (ix) Company-sponsored Hospitality that occurs in conjunction with a Consultant meeting or a meeting with a prospective consultant should be modest in value and subordinate in time and focus to the primary purpose of the meeting;
- (x) the Company may pay for reasonable and actual expenses incurred by a Consultant in carrying out the engagement, including reasonable and actual travel, modest Hospitality and lodging costs in attending meetings with, or on behalf of, the Company.

5.7 Hospitality

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

- a. is incidental to the bona fide presentation of scientific, educational, or commercial information and provided in a manner that is conducive to the presentation of such information;
- b. does not include Entertainment;
- c. takes place in a setting that is conducive to bona fide scientific, educational, or business discussions and is not selected because of its leisure or recreational facilities;
- d. is modest in value;
- e. is limited to those who actually participate in the meeting; and
- f. is not provided to any other person who does not have a bona fide professional interest in the information shared in the meeting.

The provision of hospitality to healthcare professionals or other product buyers or influencers is restricted. It can only be provided in the context of a third party educational conference referred to above, or outside of a conference, where there is an educative element to the event or where there is a Medical Technology Demonstration which is essential to the understanding by the healthcare professional of the use and operation of a Medical Technology. There will be many day-to-day interactions between industry and healthcare professionals, including assistance in procedures in the hospital setting. A company should ensure that the interaction is one that supports the healthcare professional to develop product knowledge and does not act to persuade or influence product choice on the basis of the hospitality provided.

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

5.8 Gifts to Healthcare Professionals

Companies should not provide Healthcare Professionals with gifts, including gifts of cash, food, wine or spirits, gift baskets, gift cards/certificates or flowers. Companies may not provide Healthcare Professionals any type of branded or non-branded promotional items, even if the item is of minimal value and related to the Healthcare Professional's work or for the benefit of the patients. Companies should not provide, organise or pay for any recreational or entertainment activities for Healthcare Professionals, including (without limitation) sporting events, cultural or artistic activities, or leisure activities.

It is inappropriate to provide gifts or entertainment in the context of any type of interactions with Healthcare Professionals, including in connection with sales and promotional meetings, consulting services, third party educational conferences or product training and education.

- a. A Company occasionally may provide a Healthcare Professional with an item that benefits patients or serves a genuine educational function for the Healthcare Professional provided that the item has a fair market value of less than \$100, except in the case of medical textbooks or anatomical models.
- b. A Company may not give a Healthcare Professional any type of non-educational branded promotional item, even if the item is of minimal value and related to the Healthcare Professional's work or for the benefit of patients. This restriction does not apply to Medical Devices marketed only to Consumers.
- c. A Company may not accept a gift from a Healthcare Professional which is beyond the level of what is reasonable and customary in the circumstances of the relationship.
- d. A Company should ensure that sales of Medical Technology are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a Healthcare Professional receiving payments, gifts or Hospitality.
- e. For the avoidance of doubt, this clause does not preclude the legitimate practice of providing to Healthcare Professionals appropriate samples of Medical Technologies for genuine training, educational or Medical Technology evaluation purposes.

A company may occasionally 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.

Any gift must have a fair market value of no more than NZD100 and be of an educative nature and of benefit to the patient. The limit of NZD100 does not apply if the gift is a medical textbook or anatomical model. Nonetheless they should not be extravagant. Branded promotional items are not permitted. ■

5.9 Competitions for Healthcare Professionals

A Company may conduct a Competition for Healthcare Professionals that applies with the following limited provisions:

- a. The competition must be based entirely on medical or other specialist healthcare knowledge or the acquisition of that knowledge;
- b. Entry into the competition must not be dependent on ordering, recommending, using or prescribing of a medical device;
- c. The conduct of the Competition must comply in all respects with all relevant NZ Laws and Regulations;
- d. Any prize awarded to the successful winner of the Competition must comply with Clause 5.8.

5.10 Research, Educational Grants and Charitable Donations

5.10.1 GENERAL

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

- a. adopts objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient;
- b. implements appropriate procedures to ensure that such grants and donations are not used as a condition of purchase of the Company's products; and
- c. ensures that all such grants and donations are appropriately documented.

5.10.2 RESEARCH GRANTS

A Company may provide research grants to support independent medical research with scientific merit provided that such activities have well-defined objectives and milestones (and subject to clause 5.6 where a Healthcare Professional is engaged by a Company to undertake research on its behalf).

5.10.3 EDUCATIONAL GRANTS

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

- a. Advancement of medical education – a Company may make a grant to support the genuine medical education of Healthcare Professionals and Practitioners in Training participating in programs which are charitable or have an academic affiliation;

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 an award. It includes games that involve skill or chance, or both. The competition must be based on the participant's medical or other specialist knowledge. The prize must be modest (i.e. no more than NZD100) and directly relevant to the practice of medicine or area of healthcare and of benefit to the patient (clause 5.6). This means for example a prize of cinema tickets or wine would not be appropriate. Entry to competitions must not be dependent on ordering or using a particular product. ■

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

All grants must be documented. Research grants to support independent medical research with scientific merit must have well-defined objectives and milestones. A company may make an educational grant for the advancement of medical education where the program is delivered by an organisation with an academic affiliation, or advancement of public education. For the avoidance of doubt, this excludes Third Party Educational Conferences.

A company may not provide research or educational grants as an inducement.

A company may make a charitable donation provided that the donation is directed to the charitable or philanthropic purpose. It would not be appropriate, for example, to direct the donation to funding a dinner or similar social event unless the cost of a dinner ticket was a subsidiary part of the donation. The amount and purpose of the donation must be documented. ■

- b. Advancement of Public Education – a Company may make grants for the purposes of supporting genuine education of Consumers or the public about important healthcare topics.

A Company should not make an educational grant directly to a Healthcare Professional or a Practitioner in Training.

5.10.4 CHARITABLE DONATIONS

- a. A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should only be made to genuine charitable organisations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission.
- b. A Company should not make any charitable donation or philanthropic gift for the purpose of inducing a Healthcare Professional to purchase, lease, recommend, use, or arrange for the purchase, lease or use of the Company's Medical Technology.
- c. The Company should fully document every donation made by the Company.

5.10.5 FELLOWSHIPS

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

6 COMPANY REPRESENTATIVES

6.1 General

- a. A Company must:
- (i) ensure that its Company Representatives are fully aware of the provisions of the Code; and
 - (ii) provide ongoing training to Company Representatives on compliance with the provisions of the Code.
- b. A Company should ensure that its Company Representatives at all times:
- (i) maintain a high standard of ethical conduct and professionalism;
 - (ii) conduct themselves in a manner that

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

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

A company may not provide research or educational grants as an inducement.

A company may make a charitable donation provided that the donation is directed to the charitable or philanthropic purpose. It would not be appropriate, for example, to direct the donation to funding a dinner or similar social event unless the cost of a dinner ticket was a subsidiary part of the donation. The amount and purpose of the donation must be documented. ■

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

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

A company has the responsibility of ensuring adequate awareness of the Code and its provisions. A company should 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.

MTANZ conduct regular Code of Practice workshops to assist educating new company representatives and updating existing company representatives on Code of Practice developments. ■

complies with the Code;

- (iii) act in a manner that does not compromise, appear to compromise or appear likely to compromise the professional behaviour or independence of a Healthcare Professional; and
 - (iv) act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.
- c. A Company should ensure that a Company Representative who attends procedures at the invitation of a Healthcare Professional complies with all relevant institutional requirements, standards, codes and all relevant Laws and Regulations.

6.2 Code Training

A Company should ensure that every Company Representative undertakes an education program that complies with MTANZ guidelines.

A Company should ensure that every Company Representative employed in a role which involves promotional activities on behalf of the Company undertakes an education program on the Code of Practice approved by MTANZ:

- (i) within the first six months of employment in the role; and
- (ii) as a refresher program at no less frequency than once every three years.

If there are significant changes to the Code of Practice, it is expected that Company Representatives will receive training on the changes. ■

7 ADMINISTRATION OF CODE OF PRACTICE

7.1 Code of Practice Committee – General

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

7.2 Composition of CPC

CPC shall be made up of:

- a. A minimum of six members from MTANZ membership; and
- b. A representative of MTANZ.

7.3 Role of CPC

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

- a. conduct regular internal and external reviews of the Code in accordance with clause 7.5

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

Code of Practice Committee - member-based committee which reviews Code implementation and education and reports annually on Code complaints and outcomes. ■

- to ensure it continues to reflect community, industry and regulatory standards and values;
- b. consult with key stakeholders if it is considered that more than minor amendments are required;
 - c. submit all proposed amendments to the MTANZ Board for approval;
 - d. publicise all amendments in accordance with clause 7.5;
 - e. oversee the effective operation and administration of the complaints handling procedures;
 - f. collate statistical data of complaints received and their outcomes; and
 - g. conduct a regular review and analysis of complaints and Industry issues they may raise and make recommendations to the Board.

7.4 CPC procedures

CPC must operate in accordance with the following procedures:

- a. Elect a Chair from within the group;
- b. CPC must meet at a minimum once per year. The Chair may request more frequent meetings on an as needs basis;
- c. Decisions of CPC must be made by a majority vote of its members;
- d. A quorum of four MTANZ members must participate in each CPC meeting.

7.5 Reviews

- a. External reviews of the Code must be carried out once every five years or more frequently if so determined by CPC.
- b. External reviews may be conducted by:
 - (i) an independent, appropriately qualified and experienced, consultant; or;
 - (ii) a panel of independent, appropriate qualified and experienced persons.

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

7.6 Publicising the Code

- a. CPC should identify and recommend to the MTANZ Board the optimal means for the Association to promote the Code

to Companies, the Industry, Healthcare Professionals, Regulators and other relevant stakeholders and participants in the healthcare industry.

- b. The Association must ensure that the Code is available on the MTANZ website at all times and encourage Companies to reference and provide links to the Code on their own websites.
- c. The Association must encourage Companies to promote the Code on a regular basis.

7.7 Reporting

Each year CPC should provide a written report on the administration of the Code for inclusion in the MTANZ Annual Report;

MTANZ to include any Code complaints in the regular Board meeting papers.

8 COMPLIANCE MECHANISMS

8.1 General

- a. Companies should take all measures reasonably required to ensure compliance with the Code by Company Representatives. Companies should adopt effective compliance programs by issuing written policies and procedures, conducting training programs and implementing clear procedures, controls and enforcement mechanisms.
- b. Companies are encouraged to inform all customers, Institutions and Healthcare Professionals of the requirements of the Code.
- c. A Complaint regarding promotional activities by a Company or an interaction with a Healthcare Professional, should be dealt with company to company contact, in the first instance.;
- d. If, following intercompany dialogue, the complaint remains unresolved, a complainant may lodge a complaint with the MTANZ Code of Practice committee;
- e. The COP committee should evaluate the complaint and make recommendations or action to the MTANZ Board;
- f. In support of a fair and transparent

complaints system, anonymous Complaints are not accepted;

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

9 COMPLAINT HANDLING PROCEDURES

9.1 Complaints by Consumer or Non-Industry Complainant

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

- a. Before lodging a Complaint, the party wishing to complain is encouraged (but not required) to seek to resolve the issue the subject of the Complaint with the Company whose behaviour has given rise to the Complaint.
- b. For privacy purposes, and to avoid any disincentive for making a Complaint, the Complainant may apply to the MTANZ to have the Complainant's name withheld from the Respondent and from public release.

9.2 Complaints by an Industry Complainant

Before lodging a Complaint, an Industry Complainant should seek to resolve the issue the subject of the Complaint, directly with the Company whose behaviour has given rise to the Complaint. The Industry Complainant may not make a Complaint unless the parties have been unable to satisfactorily resolve the issue.

9.3 Complaints General

- a. The following applies to all Complaints. A Complaint should be in writing with supporting material and:
- (i) state the nature of the conduct, state the provision of the Code alleged to have been breached and the reasons for asserting a breach has occurred;
 - (ii) where relevant, provide supporting scientific or other technical data;
- b. If the Complaint is brought by an Industry Complainant on the basis that the Company has not provided substantiation of a claim, the Complainant must provide evidence to support its allegations.
- c. MTANZ will acknowledge a complaint, whether concerning a Company or a non-

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 MTANZ.

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

The Code provides for a mediation process which is more appropriate than a formal complaint process. It is open to the parties to a complaint to request mediation as the means to resolve the issue. ■

- member, in writing within seven working days of its receipt and deal with the complaint expeditiously.
- d. MTANZ should forward a copy of the Complaint to the Chief Executive Officer of the Respondent within seven working days of receiving the Complaint. The Respondent should respond in writing to MTANZ within 10 working days.
 - e. MTANZ should provide the Complainant with a copy of the Respondent's response and invite the Complainant to reply in writing within 10 working days. MTANZ should provide the Respondent with a copy of the Complainant's reply within 5 working days.
 - f. If a Complaint is upheld, the Respondent must reimburse MTANZ, as applicable, its secretariat costs and out-of-pocket expenses associated with the determination of the Complaint, unless the MTANZ Board determines otherwise.

10 SANCTIONS (NON-MONETARY) CLASSIFICATION OF BREACHES

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

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

Moderate Breach: a breach of the Code with no safety implications but which will adversely impact on the perceptions of Healthcare Professionals or the general public regarding the Medical Technology the subject of the Complaint, similar products or the Industry.

Severe Breach: a breach of the Code that has safety implications or will have a major adverse impact on how Healthcare Professionals or the general public view the Medical Technology the subject of the Complaint, similar products or the Industry.

Repeat Breach: when a Company commits the same or similar breach of the Code to a breach found against the Company within the preceding 24 months.

Serial breach: when a company breaches the code, and that company has been found to have breached the code on not less than two previous occasions in the preceding 24 months.

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 sanction for the breach that has been determined. ■

10.1 Available Sanctions and Reporting

Where the MTANZ CPC committee has judged that the company has breached the Code it shall refer to the complaint to the MTANZ Board with any recommended sanctions or actions. The MTANZ Board may choose to apply one of the following sanctions:

- a. A requirement that the Company take immediate action to discontinue or modify any practice which is determined to constitute a breach of the Code, in which event the Company should confirm in writing to MTANZ that it has taken the required action within 10 working days of receipt of the decision;
- b. A requirement that the Company recall and destroy any offending material in which event the Company must confirm in writing to the MTANZ, within 10 working days of receipt of the decision, that it has taken the required action;
- c. Suspension or expulsion of the Company from MTANZ in a manner consistent with the MTANZ Constitution;
- d. Publication of the name of the company and the breach of the Code on the MTANZ website;
- e. Publication of the name of the company and the breach of the Code in the MTANZ Annual Report;
- f. Notification of any unethical business behaviour to any private or public procurement agency.

APPENDIX

APPENDIX 1

Complaints on Advertisements directed to Consumers

Complaints about Advertising directed to Consumers must be directed to:

NEW ZEALAND:

Advertising Standards Authority

PO Box 10 675, Wellington New Zealand

P: +64 4 472 7852 or
0800 ADHELP (0800 234357)
from New Zealand.

E: asa@asa.co.nz

Information on the procedure to make a complaint can be found at

<http://www.asa.co.nz/Procedure.htm>

APPENDIX 2

Complaints on Advertisements to and interactions with Healthcare Professionals

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

NEW ZEALAND:

The Secretary

Advertising Standards Complaints Board

PO Box 10-675, Wellington New Zealand

P: +64 4 472 7852

F: +64 4 471 1785

E: asa@asa.co.nz

Medical Technology Association of New Zealand

Level 1, 303 Manukau Road, Epsom, Auckland 1023
PO Box 74116, Greenlane Central, Auckland 1546

☎ : +64 9 917 3645

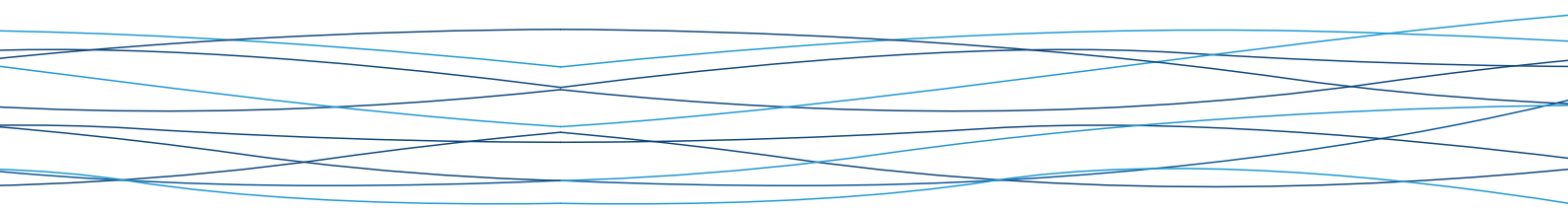
✉ : admin@mtanz.org.nz

🌐 : www.mtanz.org.nz



medical technology

ASSOCIATION OF NEW ZEALAND



medical technology
ASSOCIATION OF NEW ZEALAND

www.mtanz.org.nz

