



Medical Technology
ASSOCIATION OF AUSTRALIA



www.mtaa.org.au



MEDICAL TECHNOLOGY INDUSTRY CODE OF PRACTICE

Administered by the Medical Technology Association of Australia

Edition 10 – 2018



Copyright © 2018 Medical Technology Association of Australia Limited (MTAA)

To the extent permitted by law, all rights are reserved, and no part of this publication covered by copyright may be reproduced or copied in any form or by any means except with the written permission of MTAA Limited.

CONTENTS

	PAGE
1	PREAMBLE 4
2	STATEMENT OF PRINCIPLES 4
3	BACKGROUND AND PURPOSE OF THE CODE 4
4	OBJECTIVES AND SCOPE OF THE CODE 5
5	EXPLANATORY NOTES 5
6	GLOSSARY 5
7	INTERPRETATION 8
8	ADVERTISING AND PROMOTION OF PRODUCTS 9
9	INTERACTIONS WITH HEALTHCARE PROFESSIONALS 11
10	COMPANY REPRESENTATIVES 19
11	INTERACTIONS WITH CONSUMERS 20
12	INTERESTS HELD BY HEALTHCARE PROFESSIONALS IN MEDICAL TECHNOLOGY COMPANIES 21
13	ADMINISTRATION OF CODE OF PRACTICE 21
14	COMPLAINTS 22
15	SANCTIONS 25

Contact Details

Email: code@mtaa.org.au

All correspondence to:

Medical Technology Association of Australia

PO Box 2016, North Sydney NSW 2059, Australia.

1. PREAMBLE

Medical Technologies occupy a special place in the healthcare system. They often require Companies to provide 'hands-on' education, supervision and technical support to Health Care Professionals.

Company Representatives are very often present in theatre to train and advise physicians in the proper use of new tools, products and techniques.

The Industry's range and scope is vast. Medical Technologies sometimes serve as extensions of a surgeon's hands. Others are inserted into the human body to replace or strengthen a body part. In other circumstances, they can be non-invasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other treatments; or are paired with other products that deploy devices in the safest and most effective manner. Many require technical support before, during and after deployment.

The development and evolution of innovative Medical Technologies is a collaborative process between Companies and Health Care Professionals. It very often occurs outside the laboratory. Companies' support of bona fide research, education and enhancement of professional skills improves patient safety and increases affordable access to the latest Medical Technologies.

All the above speaks to the unique relationship between Companies and Health Care Professionals, one based on trust, integrity and the primacy of patient well-being. This is given expression through The Code.

2. STATEMENT OF PRINCIPLES

2.1 The Australian therapeutic products industry promotes the principle of good health through the proper use of therapeutic products based on genuine Consumer health needs and is supported by the ethical conduct of all parties in:

- a) selecting diagnostic and treatment options and products based on the best available evidence, clinical judgement and the Consumer's needs; and
- b) using therapeutic products safely and effectively.

2.2 MTAA members are committed to the improvement of patients' lives through the advancement of medical science and, in particular, the contributions that high quality, effective and innovative Medical Technologies make in achieving these goals. This commitment is given expression through The Code.

3. BACKGROUND AND PURPOSE OF THE CODE

3.1 The Medical Technology sector is a major component of the therapeutic products Industry. It includes companies that develop, produce, manufacture, and market medical products, technologies and related services, and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.

3.2 The Code was introduced in 2001 to formalise ethical business practices for member companies and promote socially responsible conduct by all companies in this

This is an important distinction from pharmaceuticals, which are administered by physicians without the direct supervision of a representative from the company that created them.

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

The Code sets out self-regulatory standards that MTAA members must follow, and all Industry participants are urged to observe. The Code is compulsory for members of MTAA but as a voluntary Industry code extends to all companies in the Medical Technology Industry.

The Code is part of a wider regulatory framework for ensuring appropriate behaviour by Industry. Several Industry codes apply to different therapeutic sectors. It is the intention that The Code is to apply to the supply of Medical Technology products. Where there is another therapeutic Industry code that is more relevant in the circumstances, then that code will generally be the more appropriate code. It is complemented and supplemented by a range of training and related programs to assist awareness of the ethical responsibilities of Industry.

Many companies in the Medical Technology Industry have their own internal guidelines. To the extent that a company's guidelines might require a higher standard of behaviour in a particular area also covered by this Code, the company should have regard to its own guidelines.

MTAA assumes responsibility for maintaining and enforcing the agreed standards of behaviour set out in The Code.

Industry sector. It aims to promote high standards of integrity across the Medical Technology Industry so that patients and Healthcare Professionals can have confidence in their dealings with the Industry and its products. The Code provides a framework and mechanisms for setting standards of behaviour, educating Companies in the agreed standards, monitoring Industry activities, and providing self-regulation and disciplinary functions.

- 3.3 The Code is regularly reviewed and updated to keep pace with changes in technology, business practice and community expectations.

4. OBJECTIVES AND SCOPE OF THE CODE

- 4.1 The primary objective of The Code is to build and maintain the trust and confidence of, and accountability to, all communities with which Members engage. The effectiveness of these efforts is assessed through the eyes of the relevant community.
- 4.2 The Code is a self-regulatory code applying to Medical Technology Companies. Companies are obliged, as a condition of membership in MTAA, to accept and observe all provisions of The Code.
- 4.3 A Company that is not a member of MTAA but which is engaged in the Industry is encouraged to accept and observe The Code as an Industry self-regulatory code.
- 4.4 The Code is not intended:
- to provide, nor shall it be construed as, legal advice; or
 - 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 prevail.
- 4.5 A Company should always have regard to its own company code which may provide a higher standard.

5. EXPLANATORY NOTES

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

6. GLOSSARY

Where a word is used with a capital letter at the beginning, it has the meaning given to it in this Glossary.

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

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

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

Board means the board of directors of MTAA.

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

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

In summary, The Code aims to help Companies:

- adhere to the ethical Promotion of therapeutic products;
- maintain trust and confidence in the Industry through transparency and accountability;
- respect ethical requirements and codes of practice which apply to Healthcare Professionals;
- uphold not just the letter but also the spirit of The Code;
- have in place a comprehensive process to monitor behaviour and deal with complaints; and
- remedy behaviour if found to be in Breach of The Code.

This definition also applies to the terms 'Advertise', 'Advertiser' and 'Advertisement'. For clarity and consistency, the definition aligns with the Therapeutic Goods Advertising Code.

Breach means a Breach of any provision of The Code.

Code means the Medical Technology Industry Code of Practice as amended from time to time, administered by the MTAA.

Code Authority (CA) means the entity established to administer The Code including any subcommittee appointed by the CA to exercise any of its functions.

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

- a) any entity within the Industry which agrees to abide by The Code, however that agreement is expressed; and
- b) any other relevant entity within the Industry that submits to the Complaints process and outcomes in accordance with the provisions of The Code.

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

Company Representative means any person or entity engaged in representing, acting for or advancing the interests of a Company pursuant to any agreement, arrangement or understanding between that person or entity and the Company, including a contract of employment or other employment arrangement, or any agency or consultancy arrangement.

Competition means any Promotional activity as a result of which a person may win a prize or receive a reward, and includes a game that involves skill, chance or both.

Complainant means a person who lodges a Complaint from within or outside the Medical Technology Industry with MTAA under The Code.

Complaint means a complaint lodged with MTAA under The Code.

Complaints Secretary means the person from the MTAA secretariat responsible for administration of a Complaint under The Code.

Conference Organiser means the organiser of a Third Party Educational Conference. The Conference Organiser can be a Professional Association, a Training Organisation (i.e. a hospital or other body that provides training to Healthcare Professionals or trainees), or a bona fide commercial Conference Organiser that is independent of the Company.

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.

Educational Material means any material or literature that provides information about a medical condition or Medical

This may include external arrangements which require a person or entity to abide by The Code, such as a condition of participating in a tender.

Technology and which does not contain specific promotional claims.

Entertainment includes sporting events, musical and any other activity not directly related to Training and Education and genuine business interactions.

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 (HCP) includes any individuals or entities involved in the provision of health care services and/or items to patients; which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Medical Technologies in Australia. This definition includes a person in training and or a person under the direction and control of a Healthcare Professional.

Hospitality means the provision of food and beverages.

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

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

Laws and Regulations means any law or regulation in force in Australia to which any act or omission the subject of The Code applies, including the Therapeutic Goods Act.

Market Research means the gathering of data on the scope or dimensions of a market and its components including the needs of customers in that market.

Medical Device has the meaning given to it in the TG Act.

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

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

Medicine as defined by the TG Act.

Monitoring is the review of compliance with The Code.

MTAA means Medical Technology Association of Australia Limited.

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

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

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

Register means the Australian Register of Therapeutic Goods

Regulator means a government agency performing a statutory regulatory function.

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

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

Social Media is an umbrella term that incorporates the various online platforms and activities that engage users to participate in, comment on and create digital content on the Internet to allow them to interact, share information and network with others, including peer-to-peer conversations. Examples of Social Media include Facebook, YouTube, blogs, Twitter, LinkedIn, wikis and similar communication tools.

Sponsor has the meaning defined in the TG Act.

TGA means Therapeutic Goods Administration.

Therapeutic Goods Act (TG Act) means the Therapeutic Goods Act as amended from time to time.

Third Party Educational Conference means a conference or meeting sponsored or conducted by or on behalf of a Professional Association or a Training Organisation with a genuine educational purpose or function that is:

- a) independent;
- b) of an educational, scientific, or policymaking nature; and
- 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 persons in Training.

7. INTERPRETATION

7.1 In The Code:

- a) the singular includes the plural and vice versa, and a gender includes other genders;
- b) another grammatical form of a defined word or expression has a corresponding meaning;
- c) a reference to a clause, paragraph, schedule or annexure is to a clause or paragraph of, or schedule or annexure to, The Code and a reference to The Code includes a reference to any schedule or annexure;

- d) a reference to A\$, \$A, dollar, or \$ is to Australian currency;
- e) the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions; and
- f) headings are for ease of reference only and do not affect interpretation.

This Edition 10 of The Code replaces and supersedes all previous editions.

8. ADVERTISING AND PROMOTION OF PRODUCTS

8.1 Application

This section of The Code applies to Advertisements directed to HCPs. It does not apply to Advertisements directed to Consumers.

8.2 General

An Advertisement must:

- a) comply with The Code and relevant Laws and Regulations;
- b) not be misleading or deceptive, or likely to mislead or deceive;
- c) reflect a high standard of social responsibility and conform to generally accepted standards of good taste;
- d) be readily recognisable by the target audience as an Advertisement;
- e) not claim that a Medical Technology is unique or has some special merit, quality or property unless the claim can be substantiated;
- f) not use the term 'safe' without appropriate qualification;
- g) not imitate the branding, names, logos, get-up or graphic design, copy, slogans, or general layout adopted by a competitor in a way that is likely to mislead, deceive or confuse;
- h) not use, the term 'new', or any other term having the same connotation in an Advertisement to describe a Medical Technology after one year from the date of the product's launch in Australia, unless appropriately qualified;
- i) comply with the Advertising Laws and Regulations for both Medical Devices and Medicines, where the Medical Technology consists of both a Medical Device and a Medicine; and
- j) conform with all requirements of The Code, except to the extent that any such requirement may be in conflict with any provision of the Advertising Code.

8.3 Claims and endorsements

- a) A Company must:
 - (i) be able to substantiate all claims in an Advertisement by reliable technical, scientific or other support;
 - (ii) cite the source of the claim where the claim is likely to mislead or deceive if its source is not cited;

The Advertising of therapeutic goods to Consumers and Healthcare Professionals is done by a co-regulatory system. All Advertisements are subject to relevant Laws and Regulations including, but not limited to:

- a) Therapeutic Goods Act
 - b) Therapeutic Goods Regulations
 - c) Competition and Consumer Act
- Advertisements directed to Consumers must follow the Therapeutic Goods Advertising Code. Advertisements directed exclusively to Healthcare Professionals must follow the relevant Industry code. In the case of Medical Technology, this is The Code.

Companies have a responsibility to ensure the content and presentation of their Advertising and Promotional material promotes the proper use of Medical Technology products through encouraging Healthcare Professionals to select appropriate management options, suitable products for their patients and then to use those products safely and effectively.

While a term such as 'unique' may be used to describe some special feature of a device, there is a risk it may be taken as implying general superiority. This is unacceptable unless the claim can be supported.

Advertisers/Sponsors are required to hold appropriate, balanced, comprehensive and credible evidence to substantiate Advertising/Promotional claims. It is fundamental that any therapeutic claim made must be consistent with the intended purpose of the technology and conform to current standards for clinical evidence.

In determining whether sufficient evidence is available to

- (iii) if a third-party requests substantiation of a claim, provide substantiation to that third party within 10 working days; and
 - (iv) identify any unpublished data as 'data on file' when cited in a claim and make the data available on request.
- b) A Company must not use the name or photograph of a Healthcare Professional without their written permission or in any way that is:
- (i) contrary to The Codes and ethical requirements of that Healthcare Professional, if so informed by the Healthcare Professional; or
 - (ii) likely to mislead, deceive or confuse.
- 8.4 Comparative Advertising
- a) When comparative claims are made there must be strong evidence to support the claim. Given the potential for competitive disputes arising from comparative claims, companies must ensure that claims are current, accurate and balanced and do not mislead by implication or omission.
- b) An Advertisement must not denigrate a competitor's Medical Technology.
- c) A Company must report (in an Advertisement) on the outcomes of comparative testing of Medical Technologies, provided:
- (i) the Medical Technologies have been subjected to the same and appropriate testing;
 - (ii) the outcomes are reported in a fair and balanced manner; and
 - (iii) each outcome is adequately referenced in the advertisement and is consistent with the body of evidence.
- d) If the comparative data that supports a claim referred to in clause 8.4c arises from separate studies, then a qualifying statement must be included to the effect that substantiating data arise from separate studies.
- e) A Company must not make a claim in an Advertisement that describes or shows a competitor's product as broken, defaced, inoperative or ineffective.
- f) An Advertisement must not contain, whether expressly or by implication, exaggerated or unqualified superlative claims.
- 8.5 Specific Information Required
- a) An Advertisement must contain the following information:
- (i) the brand name of the Medical Technology (where applicable);
 - (ii) the name and contact details of the Sponsor or the Company Representative (for devices entered in the Register) or the Company Representative (for products not required to be entered in the Register);
 - (iii) claims consistent with the manufacturer's intended purpose of the Medical Technology; and

support a claim, Companies should have regard to issues such as the study design, the number of patients, the location of the trial or study, its primary purpose and endpoints, the results, its consistency with the current body of evidence and whether or where the study has been published.

Advertising/Promotional claims should not rely solely on evidence from sources such as poster presentations or abstracts that do not provide sufficient evidence to assess the veracity of the claim.

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

In response to a reasonable request, supporting evidence must be made available to Healthcare Professionals, Industry Members and, where appropriate, Consumers within 10 working days. For example, members should be aware that by referencing 'data on file' or 'in press' material, they commit to honouring the request for supporting data. A statement that the data are 'confidential' will not be accepted.

The intent of any comparison should be to provide valuable and accurate information comparing products for the benefit of Healthcare Professionals and their patients. Care should be taken to distinguish between statistical significance and clinical significance. Graphical or visual comparisons should be accurate and appropriate.

A company should be able to justify their decision.

(iv) any other information required by law or as a condition of grant of a licence.

- b) If a third-party requests information on the intended purpose of a Medical Technology Advertised in accordance with 8.5a, the Company must provide the information within 10 working days.
- c) Despite the terms of this clause, Brand Name Reminder Advertisements do not need to contain any mandatory statements unless otherwise required by law.

8.6 Company Commissioned Articles

- a) A Company Commissioned Article (CCA) must be clearly identified as such.
- b) The Sponsor must be clearly identified at either the top or the bottom of the article.
- c) Where a CCA is used solely for the purpose of supporting a claim, including a comparative claim, the claim must be cited.

8.7 Social Media in Promotions to Healthcare Professionals

- a) All companies must have policies and procedures describing the roles and responsibilities of Company Representatives when interacting with Healthcare Professionals via Social Media, if such media are used.
- b) All use of Social Media by Companies in the Promotion of products to Healthcare Professionals must comply with the requirements of this Code relating to Advertisements.

9. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

9.1 General interactions

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

9.2 Company-sponsored Training and Education and Medical Technology Demonstrations

- a) The program must be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of knowledge and is not selected because of its Entertainment, leisure or recreational facilities. The choice of venue must be consistent with professional and public standards of ethics and good taste.
- b) If the program requires “hands on” training in medical procedures or Medical Technology Demonstration:
- (i) it must be held at a training facility, medical Institution, laboratory, or other appropriate facility; and
- (ii) the training staff must have the proper qualifications and expertise to conduct such training.

MTAA members should inform themselves about the Social Media policies of other health care Industry stakeholders. For example, the Australian Health Practitioner Regulation Agency has a Social Media policy for its members. MTAA members should have regard to this policy when dealing with AHPRA members via Social Media.

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

Companies need to determine, with each interaction with Healthcare Professionals, if the interaction may constitute an inducement or would appear to an ordinary member of the public to be an inducement or dealing that influenced the decision or product choice of the Healthcare Professional.

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

The geographic location selected should not become the main attraction of the event. It should be centrally located with regard to the place of origin of the invited participants. It should also provide ease of access (close proximity to airports, train stations and highways) and have a good ground transportation infrastructure.

Training and Education which does not relate to Medical Technologies may be construed as a gift or benefit rather than permitted Training and Education under The Code.

- c) A Company may pay for reasonable travel and modest lodging costs incurred by attending Healthcare Professionals.
- d) A Company may pay for modest Hospitality for attending Healthcare Professionals.
- e) A Company must not pay for the Hospitality, travel, or other expenses of any guest of a Healthcare Professional, or for any other person who does not have a genuine professional interest in the information being shared at the program.
- f) In the interests of transparency and accountability:
 - (i) A Company must enter into a simple written agreement with each Healthcare Professional attending the program, which sets out the nature of the program and the services to be provided by or on behalf of the Company;
 - (ii) the agreement must require the Company and the Healthcare Professional to make all necessary disclosures to any relevant Professional Association or Institutions; and
 - (iii) where the event is modest in nature, the requirement to enter into an agreement may be satisfied by the provision of a detailed program or agenda outlining the services to be provided to the Healthcare Professional.
- g) A Company must not impose any requirement on a Healthcare Professional to purchase or cause to be purchased any Medical Technologies or other goods or services associated with the training, in consideration for attending the program.
- h) A Company must not provide any free products to attending Healthcare Professionals, other than in compliance with clause 9.7.

9.3 Third Party Educational Conferences

9.3.1 General

An aspect of the relationship between Industry and Healthcare Professionals is the financial support provided to healthcare conferences conducted by the professional organisations and Conference Organisers on behalf of groups of Healthcare Professionals.

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

9.3.2 Sponsorship or grants for Third Party Educational Conferences

- a) A Company may provide sponsorship or a grant to the Conference Organiser to:
 - (i) reduce conference costs;
 - (ii) provide for attendance by a Healthcare Professional or a Person in Training; or
 - (iii) provide a reasonable honorarium, travel, lodging, and Hospitality expenses for a Faculty Member.

Hospitality may be provided but as an ancillary offering. It must not be the main focus of the training event. In assessing whether Hospitality and lodging costs are modest, companies should consider not only the financial cost but whether a member of the general public would consider the venue and Hospitality to be modest.

A company may pay for the cost of the Healthcare Professional to attend the education or training, but this does not extend to the partner of the Healthcare Professional.

Companies should consider the image that may be projected to the public when deciding whether to support a conference. This would include whether or not an ordinary member of the public would consider that a conference is going to be for the genuine purpose of promoting scientific knowledge, medical advancement or the delivery of effective healthcare.

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

Reducing costs of the event does not include recreational/ Entertainment activities.

CODE

- 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 dedicated to promoting objective medical, scientific and educational activities and discourse;
 - (iii) the Conference Organiser selects the recipient of the sponsorship or grant, who may be a Faculty Member;
 - (iv) the Conference Organiser makes the arrangements and pays for the travel and accommodation of the recipient;
 - (v) the Conference Organiser is responsible for and controls the selection of program content, Faculty Members, educational methods and materials. A company must not direct the organiser on content but may suggest possible content if requested by the organiser.
 - (vi) the sponsorship or grant:
 - (A) is not conditional on any obligation to or by the recipient;
 - (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 Person in Training;
 - (C) is consistent with guidelines established by the Conference Organiser; and
 - (D) does not give rise to, or facilitate any Breach of The Code;
 - (vii) the Conference Organiser and the Company enter into a written agreement specifying the nature and conditions of the sponsorship or grant; and
 - (viii) the agreement requires the Conference Organiser to account to the Company for the use of the sponsorship or grant, without being required to disclose the identity of recipient(s).

9.3.3 Hospitality at Third Party Educational Conferences

- a) A Company may provide funding to the Conference Organiser to support Hospitality at a Third Party Educational Conference provided the Conference Organiser and the Company enter into a written agreement:
- (i) specifying the nature and conditions of the Hospitality; and
 - (ii) which requires the Conference Organiser to account to the Company for the use of the funding.

EXPLANATORY NOTES

It is recognised that some conferences are very large events with many attendees. Others may be quite small events directed to a smaller group of Healthcare Professionals (e.g. a regional meeting). For this reason, The Code does not cap the amount that may be paid by a company by way of sponsorship but requires that it be proportionate to the overall cost of the conference.

If requested by the organiser, a company may suggest names of possible speakers for consideration. Where the sponsorship is used to pay for travel, accommodation or attendance costs, a company must not pay the participating Healthcare Professional directly. The payment may only be made to the Conference Organiser. This is to avoid the perception, or reality, of payments as inducements to Healthcare Professionals.

The purpose of a written agreement is to improve transparency reporting and facilitate Code monitoring.

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.

- 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 clause 9.5.

9.3.4 Company-sponsored symposia with Faculty Members

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

- a) the symposium uses a Faculty Member, a Consultant or an employee of the Company to speak at or facilitate the symposium;
- b) any Hospitality complies with the provisions of clause 9.5; and
- c) a Company does not pay the costs of attendees to attend the symposium, other than those referred to in 9.3.4a).

9.3.5 Advertisements and Trade Displays at Third Party Educational Conferences

- a) The purchase of an Advertisement or lease of booth space for a Trade Display by a Company at a Third Party Educational Conference must be done transparently and at commercially sensible rates.
- b) A Trade Display must:
 - (i) not display Advertisements that do not comply with clause 8 of The Code;
 - (ii) prominently identify the Sponsor of the Medical Technology that is the subject of the Trade Display, unless;
 - (A) samples of the Medical Technology are provided for examination, demonstration or display and are not registered with the Regulator, in which case a notice must be included to the effect that the device is not available for general supply;
 - (iii) comply with requirements of the Conference Organiser, provided that such requirements are lawful and do not conflict with any provision of The Code; and
 - (iv) only include activities that can withstand public scrutiny and conform to professional and community standards of good taste.

9.4 Arrangements with Healthcare Professionals acting as Consultants

- a) A Company may engage a Healthcare Professional to provide genuine consulting services, including research, participation on advisory boards, presentations at Company-sponsored training, and product collaboration, provided that a legitimate need and purpose for the services is identified in advance,

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.

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

Where a product has not yet been registered with the relevant Regulator, the company must make it clear by use of a display notice that the product has not yet been registered and that it is on display for the purposes of a demonstration only. Any claimed use must be consistent with the intended purpose assigned by the manufacturer.

and the Promotion of a Medical Technology to the Healthcare Professional is not a purpose for the engagement.

- b) Arrangements with Consultants who are clinical trial investigators may include attendance at Third Party Educational Conferences to present clinical trial results. Clinical research services should be addressed in a clinical research protocol.
- c) A Company must not engage a Healthcare Professional to provide services at a company-sponsored symposium at a Third Party Educational Conference in order to circumvent the prohibition on directly funding the Healthcare Professional to the Third Party Educational Conference. Where a Company engages a Healthcare Professional to provide such services at a company-sponsored symposium at a Third Party Educational Conference, there must be a legitimate need for the services and the engagement should generally be part of a broader range of services that the Company is engaging the Consultant to provide, rather than a single engagement.
- d) A Company must not engage a Healthcare Professional to provide services at Company- Sponsored Training and Education in order to circumvent the prohibition on directly funding the Healthcare Professional to a Third Party Educational Conference. Where a Company engages a Healthcare Professional to provide services at Company-sponsored Training and Education which will take place in close proximity in date and location to a Third Party Educational Conference, there must be a legitimate need for the services on the part of the company and the engagement should generally be part of a broader range of services that the Company is engaging the Consultant to provide, rather than a single engagement.
- e) A Company may pay the Healthcare Professional reasonable compensation for performing services as a Consultant.
- f) Consulting Arrangements between a Company and a Consultant must comply with the following:
 - (i) the arrangement must be documented in writing between the Company and the Consultant, specifying all services to be provided and compensation to be paid;
 - (ii) the compensation paid to a Consultant must be consistent with fair market value for the services provided;
 - (iii) selection of the Consultant must be on the basis of the Consultant's qualifications and expertise in dealing with the subject matter of the engagement, and must not be on the basis of volume or value of business generated or potentially generated by the Consultant;
 - (iv) when a Company contracts with a Consultant to conduct clinical research services there should be a written research protocol;
 - (v) Consulting Arrangements should only be entered into where a legitimate need for the services relevant to the Company's products is identified in advance and documented;

- (vi) the calculation of royalties payable to a Healthcare Professional in exchange for intellectual property arising from the Consulting Arrangements should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence;
- (vii) the location and circumstances for any meetings between the Company and the Consultant must be appropriate to the subject matter of the engagement and the meeting must be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of information;
- (viii) Company-sponsored Hospitality that occurs in conjunction with a Consultant meeting or a meeting with a prospective Consultant must be modest in value and subordinate in time and focus to the primary purpose of the meeting;
- (ix) the Company may pay for reasonable and actual expenses incurred by a Consultant in carrying out the engagement, including reasonable and actual travel, modest Hospitality and lodging costs in attending meetings with, or on behalf of, the Company. The Company may not fund or facilitate personal or private side trips from a consulting engagement which the Company has engaged the Consultant for; and
- (x) the written agreement documenting the Consulting Arrangement must require the Company and the Consultant to make all necessary disclosures to any relevant Professional Association or Institutions concerning any existing or potential conflict of interest.

9.5 Hospitality

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

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

The amount of any royalties to be paid for the intellectual property input of the Healthcare Professional should be based on objective factors such as the amount of effort of the Healthcare Professional reflected in the product development.

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

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

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

Provision of Hospitality such as refreshments should not be done in such a way as to create an expectation on the part of Healthcare Professionals that such Hospitality is a normal and regular occurrence.

Companies need to exercise their own judgment on a case-by-case basis, in assessing whether Hospitality is modest, companies should consider not only the financial cost but whether an ordinary member of the public would consider the venue and Hospitality arrangements to be modest.

9.6 Market Research

A Company may conduct Market Research with a Healthcare Professional provided that:

- a) the sole purpose is to collect data and the Market Research is not calculated to Promote to and/or reward the Healthcare Professional;
- b) the Market Research study is clearly identified as such to the Healthcare Professional;
- c) any compensation is kept to a minimum and does not exceed a level commensurate with the work performed by or on behalf of the Healthcare Professional; and
- d) where the Market Research includes a Competition or allows for the provision of any prize, it complies with clause 9.8.

9.7 Educational Items and Prohibition on Gifts between Companies and Healthcare Professionals

- a) A Company may not provide a gift to a Healthcare Professional.
- b) A Company occasionally may provide a Healthcare Professional with an item that benefits patients or serves a genuine educational function for the Healthcare Professional provided that the item has a fair market value of less than \$100, except in the case of medical textbooks or anatomical models.
- c) A Company may not give a Healthcare Professional any type of non-educational branded Promotional item, even if the item is of minimal value and related to the Healthcare Professional's work or for the benefit of patients.
- d) A Company may not accept a gift from a Healthcare Professional.
- e) A Company must ensure that sales of Medical Technology are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a Healthcare Professional receiving payments, gifts or Hospitality.
- f) For the avoidance of doubt, this clause does not preclude the legitimate practice of providing to Healthcare Professionals appropriate sample Medical Technologies for genuine Training and Education or Medical Technology evaluation purposes.

9.8 Competitions for Healthcare Professionals

- a) A Company may conduct a Competition for Healthcare Professionals that complies with the following provisions:
 - (i) the Competition must be based entirely on medical or other specialist healthcare knowledge or the acquisition of that knowledge;
 - (ii) all Competition prizes must be:
 - (A) directly relevant to the practice of medicine or field of other specialist healthcare; and

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.

Any provision of a 'gift' to a Healthcare Professional runs the risk of being perceived by the general public as an inducement; however, provision of an item that benefits patients or serves a genuine educational purpose may be appropriate.

Any such item must have a fair market value of no more than AUD\$100 and be of an educative nature. The limit of AUD\$100 does not apply if the item is a medical textbook or anatomical model given that these invariably cost more than \$100. Nonetheless, they should not be extravagant. While branded Promotional items are not permitted, it is permissible to have company or product branding on items that serve a genuine educational purpose.

Sample Medical Technologies can only be provided for a reasonable time period, which will depend on the type of Medical Technology and whether it is being used for training, education or evaluation.

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. This should comply with clause 9.7.

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

(B) of minimal monetary value or be an item of an educational nature; and

(iii) entry into a Competition must not be dependent on the ordering, recommending, using or prescribing of a Medical Technology;

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

9.9 Research, educational grants and charitable donations

9.9.1 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;
- (c) does not participate in any decision on the part of the receiving organisation as to which individuals may benefit from the grant or donation;
- (d) ensures that the recipient of the funds has an appropriate process in place for impartially allocating the funds or selecting any beneficiary of the funds; and
- (e) ensures that all such grants and donations are appropriately documented.

9.9.2 Research grants

- a) A Company may provide research grants to support medical research with scientific merit provided that such activities have well-defined objectives and milestones.
- b) A Company must not make a research grant directly to an individual Healthcare Professional or a Person in Training. A Company may make a research grant to an Institution.

9.9.3 Educational grants

- a) A Company may make an educational grant for the following purposes:
 - (i) Advancement of medical education Company may make a grant to support the genuine medical education of Healthcare Professionals and Persons in Training participating in programs which are charitable or have an academic purpose;
 - (ii) Advancement of public education
- b) A Company may make grants for the purposes of supporting genuine education of Consumers or the public about important healthcare topics.
- c) A Company must not make an educational grant directly to an individual Healthcare Professional or a Person in Training (whether to attend a Third Party Educational

Conference or not).

- d) A Company may make an educational grant to an Institution.
- e) A Company must not make an educational grant if it has a reasonable concern that the educational grant will be used to directly fund a nominated individual Healthcare Professional or Person in Training to a Third Party Educational Conference.

9.9.4 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 organisations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission.
- b) A Company must not make any charitable donation or philanthropic gift for the purpose of inducing a Healthcare Professional to purchase, lease, recommend, use or arrange for the purchase, lease or use of the Company's Medical Technology.
- c) A Company must document every donation it makes.

9.10 Fellowships

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

9.11 Provision of reimbursement and other information

- a) A Company may support accurate and responsible billing to Medicare and other payers by providing reimbursement information to a Healthcare Professional, regarding the Company's products, including identifying appropriate coverage, coding, or billing of the Company's products, or of procedures using those products.
- b) A Company may provide to a Healthcare Professional who has acquired or uses a Medical Technology of the Company, information for the purposes of aiding in the appropriate and efficient use or installation of the Medical Technology.

9.12 Disclosure

A Company should ensure that its involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of publication.

10. COMPANY REPRESENTATIVES

10.1 General

A Company must:

- a) ensure that its Company Representatives are fully aware of the provisions of The Code
- b) provide ongoing training to Company Representatives on compliance with the provisions of The Code as

Disclosure should be made in a prominent place such as the 'preface' or 'introduction' to the publication or presentation.

In order to ensure that The Code is well-understood within a company, the employees and agents who have primary contact with Healthcare Professionals and others with product-purchasing authority must be fully trained in The Code and its provisions. All employees within the Medical Technology Industry should receive, as a minimum, broad training on The Code and the

CODE

detailed in clause 10.2.

- c) ensure that its Company Representatives at all times:
 - (i) maintain a high standard of ethical conduct and professionalism;
 - (ii) conduct themselves in a manner that complies with The Code;
 - (iii) act in a manner that does not compromise, appear to compromise or appear likely to compromise the professional behaviour or independence of a Healthcare Professional
 - (iv) act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.
- d) A Company must ensure that a Company Representative who attends procedures at the invitation of a Healthcare Professional complies with all relevant Institution's requirements, standards, codes and all relevant Laws and Regulations.

10.2 Requirements for training

- a) A Company must ensure that every Company Representative working with Healthcare Professionals undertakes training on The Code which is approved by MTAA. This is a requirement of each new edition of The Code. For new employees, this training must be completed within six months of commencing in the role.
- b) A Company must ensure that every employee employed in a role that involves Promotional activities or purchasing decisions on behalf of the Company undertakes training on The Code approved by MTAA. This is a requirement of each new edition of The Code.

10.3 Company Representatives - compliance program

- a) Companies must take all measures reasonably required to ensure compliance with The Code by Company Representatives. Companies must adopt effective compliance programs by issuing written policies and procedures, conducting training programs and implementing clear procedures, controls and enforcement mechanisms.
- b) Companies are encouraged to inform all customers, Institutions and Healthcare Professionals of the requirements of The Code

11. INTERACTIONS WITH CONSUMERS

11.1 General

- a) If a Company receives a request from a Consumer for advice of a medical or diagnostic nature, the Company must recommend that the Consumer consult an appropriate Healthcare Professional.
- b) A media release to one or more organisations or through one or more channels intended or likely to result in publication to Consumers:
 - (i) must not be an Advertisement unless it conforms with The Code; and

EXPLANATORY NOTES

need for ethical and professional dealings.

Company Representatives should be aware of all relevant Institutional requirements, standards, codes and all relevant Laws and Regulations

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.

In support of the requirement to ensure adequate knowledge of The Code, employees who work directly with Healthcare Professionals, those that make purchasing decisions, or work in marketing or customer service roles must undertake training in The Code within six months of commencing employment with the company and for each new edition of The Code. To ensure that training in The Code is consistent, all training must either be delivered by MTAA or be reviewed and approved by MTAA.

(ii) must be issued conditionally upon the publisher ensuring that the release or extracts be published in compliance with The Code and all relevant Laws and Regulations.

c) MTAA recognises and supports relationships between Industry and Health Consumer Organisations, government bodies and other independent bodies having an interest in Consumer education in relation to Medical Technologies, which are used by Consumers for the sole purpose of facilitating education of Consumers and enhancing their quality use of those products.

11.2 Competitions for Consumers

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

11.3 Funding of Health Consumer Organisations

a) MTAA recognises and supports positive and beneficial relationships between the Industry and Health Consumer Organisations. Companies may enter into relationships with Health Consumer Organisations with the objective of enhancing the quality use of Medical Technology and supporting better outcomes for the Australian community.

b) In supporting Health Consumer Organisations, Companies should have regard to the guidelines developed in collaboration between Medicines Australia and the Consumers Health Forum.

12. INTERESTS HELD BY HEALTHCARE PROFESSIONALS IN MEDICAL TECHNOLOGY COMPANIES

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

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

13. ADMINISTRATION OF THE CODE

A Company is entitled to fair and equitable treatment under The Code.

13.1 General

The Code is administered by The Code Authority (CA) which is a strategic committee of the Board of MTAA. CA members are appointed by the MTAA Board to represent Medical Technology companies, Consumers and Healthcare Professionals.

13.2 Code Authority (CA)

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

Each Company is encouraged to make publicly available on its website, a list of Health Consumer Organisations to which it provides financial support and/or significant direct/indirect non-financial support.

In practice, this can be done by having in place contractual arrangements with Healthcare Professionals that require them to disclose their ownership interest in the company. Note: most professional colleges require their members to disclose such interests.

The terms of reference of the CA shall be as determined by Board of MTAA from time to time and shall be made available on the MTAA website. Refer to <https://www.mtaa.org.au/>.

13.3 Promoting Awareness of The Code

- a) MTAA must undertake an awareness campaign every time changes are made to The Code.
- b) MTAA must ensure The Code is available on the MTAA website at all times and encourage Companies to reference and provide links to The Code on their own websites.
- c) MTAA must encourage Companies to promote awareness of The Code by their staff, suppliers and clients on a regular basis.

13.4 Training on The Code

- a) MTAA must ensure that ongoing training is provided to the Industry on the interpretation and application of The Code.
- b) MTAA must ensure education programs are updated every time changes are made to The Code.

14. COMPLAINTS

14.1. Code Complaint Process

- a) Before lodging a complaint, the Complainant is encouraged to resolve the matter directly with the Company, and
 - i) If the parties resolve the matter, no further action is taken;
 - ii) If the parties are unable to resolve the matter, a formal Complaint may be lodged.
- b) Anonymous Complaints will not be received; however, a Complainant may request to have their name withheld from the Respondent and from public release.
- c) Where a Complaint is about a matter the subject of court proceedings:
 - i) A Complainant is not precluded from resorting to litigation, but the CA must not consider a Complaint while its substance is the subject of pending court proceedings; and
 - ii) A party to a Complaint must notify the Complaints Secretary immediately upon becoming aware of any court proceedings concerning the substance of the Complaint.
- d) When a Complainant lodges a formal Complaint:
 - i) The Complaint must be in writing using the form approved by the CA and available on MTAA's website and shall be submitted to The Code Secretary.
 - ii) Notwithstanding MTAA's obligation 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 all parties until all avenues of appeal are exhausted and the outcomes of appeals known.

- iii) The Code Secretary must acknowledge the Complaint in writing within seven working days of its receipt and deal with the Complaint expeditiously.
- iv) The Complaints Secretary must forward a copy of the Complaint to the Chief Executive Officer of the Respondent within seven (7) working days of receiving the Complaint.
- v) The Respondent must respond in writing to the Complaints Secretary within fifteen (15) working days.
- vi) The Code Secretary must provide the Complainant with a copy of the Respondent's response within seven (7) working days of receipt.
- vii) The Code Secretary may invite both parties to engage in mediation as follows:
 - (a) if both parties consent, the mediation process, including assignment of costs, will be agreed between both parties and the mediator and in consultation with The Code Secretary. Any agreement reached shall be confidential, binding, in writing and signed by the parties and the mediator. The agreement must remain confidential between the parties and the mediator, unless the parties agree that it be made available to MTAA.
 - (b) if either party does not consent to mediation, the Complaint process will be continued.

14.2 Withdrawal and Dismissal of Complaints

- a) The Complainant may withdraw the Complaint at any stage prior to the formation of a Code Complaints Subcommittee in accordance with clause 14.3a) by written notice to the Complaints Secretary which shall provide reasons for the withdrawal, after which:
 - (i) The Code Secretary must inform the Respondent in writing within seven (7) days detailing the reasons of the withdrawal; and
 - (ii) The Complaints handling procedure is terminated.
- b) An Industry Complainant who withdraws their Complaint must reimburse MTAA its secretariat costs and out-of-pocket expenses associated with the Complaint, unless the CA determines otherwise.
- c) The CA may dismiss a Complaint if it is satisfied that:
 - (i) the Complaint is trivial, vexatious, misconceived or lacking in substance; or
 - (ii) the subject matter of the Complaint has been dealt with previously by the CA or another authority; or
 - (iii) the subject matter of the Complaint can be more effectively or conveniently dealt with by another authority and refers the Complaint to that authority.

14.3. Hearing of Complaints

- a) The CA will appoint a Code Complaint Subcommittee ("CCS") and delegate to it the hearing and consideration of the Complaint.
- b) The CCS may inform itself of any matter relating to the Complaint 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 CCS 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 this clause and are afforded a period of ten (10) working days within which to respond in writing.
- c) Neither the Complainant nor the Respondent, nor a representative of either of them, may be present during the hearing of a Complaint. The CCS must determine the outcome of the Complaint based on the material submitted by the parties and any information obtained under clause 14.3b).
- d) The deliberations of the CCS are confidential and must not be disclosed by any member of the CCS.
- e) If the CCS considers a breach of The Code to have occurred, it must determine the appropriate sanction as provided in clause 15.2 of The Code.
- f) The CCS must provide written notice of and reasons for its decision to the Complainant and Respondent within ten (10) working days of the hearing, including details of appeal procedures.
- g) Both parties need to confirm in writing within five (5) working days of notification of the decision of the CCS that they will either accept the decision of the CCS or intend to lodge notice of its intention to appeal in writing with the Complaints Secretary.

14.4. Appeals

- a) An appeal against the decision of the CCS may be lodged with the Complaints Secretary by either party within fifteen (15) working days of receipt of notification of the decision.
- b) The appeal must be in writing outlining the reasons for the appeal and include all material relevant to the appeal.
- c) Within five (5) working days of lodgement of the appeal the Complaints Secretary must provide a copy of the written appeal to the respondent to the appeal who has ten (10) working days in which to respond and lodge material in support of its response.
- d) The Complaints Secretary must provide a copy of the response to the appellant within five (5) working days of receipt.
- e) All appeals will be heard by the CA. Any members of the

CCS who heard the Complaint being appealed cannot be a member of the CA hearing the appeal. The CA may consider:

- i. the material considered by the CCS in the matter;
 - ii. the appeal papers; and
 - iii. any response from the respondent to the appeal; and
 - iv. any additional material which the CA reasonably believes will assist its deliberations provided a copy of such material has been provided to the parties to the appeal no later than five (5) working days before the appeal hearing.
- f) A party is entitled to be heard by the CA in person on prior arrangement with The Code Secretary.
 - g) The CA has the right to question each party at the hearing.
 - h) The deliberations of the CA in relation to the appeal are confidential and must not be disclosed by a party or any members of the CA.
 - i) The findings of the CA are final and binding on the parties. The Code Secretary must provide to each party the CA's reasons for decision no later than ten (10) working days after the hearing of the appeal.

14.5. Costs associated with complaint and appeal process

- a) If a Complaint is upheld (and not appealed) or upheld on appeal, the Respondent must reimburse MTAA its secretariat costs and out-of-pocket expenses associated with the determination of the Complaint and conduct of any appeal, unless the CA determines otherwise. This payment is separate from and in addition to any fine payable under clause 15.2. In the case of a Complaint by an Industry Complainant, the CA may require such costs to be shared by the parties in proportions determined by the CA.

14.6. Publication of outcomes

- a) To ensure transparency of procedures, MTAA must publish on its website the outcome of every upheld Complaint and appeal finalised during the year. When a Complaint or appeal is partially upheld, only that portion of the complaint that is upheld must be published. The website publication must be removed after 12 months.
- b) MTAA must not publish in any form the name of a Complainant if it has been withheld in accordance with clause 14.1b).

15. SANCTIONS

15.1 Classification of Breaches

Where a Breach of The Code has been established, before determining any sanction under clause 15.2, the CA must first classify the severity of the Breach, in accordance with the classification set out below.

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

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

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

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

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

Serial Breach: when a Company Breaches The Code, and that Company has been found to have Breached The Code on not less than two previous occasions in the preceding 24 months.

15.2 Available Sanctions

- a) Where the CA finds that a Company breached The Code, the CA must apply one or more of the following sanctions. The time periods specified for response or action are subject to any appeal that may be lodged under clause 14.4 of The Code.
- (i) A requirement that the Company take immediate action to discontinue or modify any practice which is determined to constitute a Breach of The Code, in which event the Company must confirm in writing to the CA that it has taken the required action within 10 working days of receipt of the decision.
 - (ii) A requirement that the Company recall and destroy any offending material in which event the Company must confirm in writing to the CA, within 10 working days of receipt of the decision, that it has taken the required action.
 - (iii) A requirement that the Company issue a retraction, including corrective letters and advertising. The retraction must comply with all directions of the CA, including directions in relation to recipient, number, format, size, wording, mode of publication, prominence, timing and method of distribution. The Company must confirm in writing to the CA, within 10 working days of receipt of the decision, that it has taken the required action and provide a copy of the retraction once published.
 - (iv) The imposition by the CA of a fine in accordance with the following schedule. The Respondent must pay the fine to the Complaints Secretary within 30 days of being advised of the decision of the CA.

Minor Breach: Nil

Moderate Breach: Maximum AUD \$50,000

Severe Breach: Maximum AUD \$75,000

Repeat Breach: Maximum AUD \$100,000

Serial Breach: An amount not less than AUD \$25,000 and not more than AUD \$200,000.

- a) Subject to clause 16.2, if the CA resolves that a Complaint from a member of the Industry is frivolous or vexatious, the CA may request the Complainant to show cause why it should not pay the Complaints Secretary costs and any out of pocket expenses associated with the Complaint as well as a fine not exceeding AUD\$10,000 for abuse of The Code.
- b) Subject to clause 16.2, if the CA resolves that a Complaint from a member of the Industry is frivolous or vexatious, the CA may request the Complainant to show cause why it should not pay the Complaints Secretary costs and any out of pocket expenses associated with the Complaint as well as a fine not exceeding AUD\$10,000 for abuse of The Code.
- c) If the CA resolves that a Breach of The Code by a Company warrants the suspension or the expulsion of the Company from MTAA, it must make such a recommendation to the relevant Board. The Board may deal with the recommendation under the provisions of its constitution.
- d) In the event that the CA requires a Respondent to cease a conduct or withdraw an Advertisement and the Respondent wishes to appeal the decision, the CA's decision will stand and must be complied with, pending the outcome of the appeal.

15.3 Failure to comply with sanctions

- a) If a Company, having been found by the CA to have Breached The Code, fails to comply with any sanctions imposed on it by the CA, such failure:
 - (i) is a further Breach of The Code;
 - (ii) is deemed to increase the classification of the previously imposed sanction by one level; and
 - (iii) in addition to any further sanctions imposed pursuant to clause 15.2, entitles the CA to direct MTAA to publish in the next edition of its newsletter and/ or on its website details of the Breach of The Code and the subsequent failure to undertake remedial action.
- b) The continued refusal by the Company to undertake the required remedial action/s entitles the CA to direct MTAA to publish in the trade media details of the Breach of The Code and the subsequent failure to undertake remedial action.
- c) In addition to the sanction set out in clause 15.2 above, the CA may direct MTAA to notify the Regulator of the continued Breach of The Code.

In relation to clause 15.3a, failure to comply with any sanction imposed by the CA amounts to a further Breach of The Code. It also increases the classification of the previously imposed sanction by one level as follows:

- If the previously imposed sanction was a minor Breach, it becomes a moderate Breach;
- If the previous imposed sanction was a moderate Breach, it becomes a severe Breach.

Street Address

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

Postal Address

PO Box 2016 North Sydney
NSW 2059 Australia

Phone: (+612) 9900 0650

Facsimile: (+612) 9900 0655

Email: code@mtaa.org.au

www.mtaa.org.au



Medical Technology
ASSOCIATION OF AUSTRALIA