



**MEDICAL TECHNOLOGY INDUSTRY
CODE OF PRACTICE**

Administered by the Medical Technology Association of Australia

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Explanatory Notes

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 it extends to all Companies in the Medical Technology Industry.

2.1 a) 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 and to interactions between Healthcare Professional and Australian Companies. 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.

The MTAA Code is aligned with the principles expressed in the Consensus Statement of Shared Values and Ethical Principles for Collaboration and Interaction Among Organisations in the Healthcare Sector, published by the Australian Ethical Health Alliance, of which MTAA is a member. The MTAA Code reflects the principles outlined in the Global Medical Technology Alliance (GMTA) Joint Statement on Global Harmonization of Ethical Business Principles in Medical Technology.

2.2 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.

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

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 Act 1989.

Code

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 Healthcare Professionals.

Company Representatives are often present in operating theatres 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 Healthcare 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 Healthcare 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 Healthcare 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:

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

The Industry supports this principle by promoting ethical collaboration between all parties in the Industry sector.

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.

2.3 The Code applies to all interactions between Companies and Healthcare Professionals practising in Australia, regardless of location, except where otherwise indicated.

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 the Industry. It aims to promote high standards of integrity across the 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 MTAA 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 the supply of Medical Technology and interactions between Companies and Healthcare Professionals. Companies are obliged, as a condition of membership of MTAA, to accept and observe all provisions of the Code and to cooperate fully with the Code Authority's Monitoring activities and Complaints handling process.

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 AND FREQUENTLY ASKED QUESTIONS

Explanatory notes and Frequently Asked Questions (FAQs) are available on the MTAA website and can be located under the Code section. These are not binding on Companies, the Code Authority or its subcommittees; Companies are strongly encouraged to review the information provided in the explanatory notes and FAQs to assist them in applying and interpreting the Code as required.

6. GLOSSARY

Where a word or phrase is capitalised, 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 a Medical Technology.

Advertising Code means the Therapeutic Goods Advertising Code (No.2) 2018 in Australia as amended or replaced from time to time.

Advisory Board means a group of Healthcare Professionals with specific expertise contracted by a Company to provide advice to the Company.

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

FAQs

Do all Australian Medical Technology companies follow the Medical Technology Industry Code of Practice (the Code)?

MTAA member companies are required to follow the Code. Non-member companies are not required, but are encouraged, to observe the Code as the recognised industry standard.

MTAA promotes the Code as a key benefit of membership and an essential component of any Medical Technology company's risk management and quality assurance programs. It also encourages government health agencies and procurement professionals in hospitals and other healthcare institutions to request their suppliers to adhere to the Code.

How does MTAA ensure its Members abide by the Code?

MTAA has a monitoring process which proactively monitors member companies' adherence to the Code.

MTAA promotes adherence to the Code through education, communication, training and providing resources to support companies.

In addition, MTAA administers a complaints process allowing the management of potential breaches of the Code.

If a company uses distributors, consultants or agents, do they have to follow the Code?

Yes. Compliance with the Code requires that companies ensure that any person or entity that represents, acts for, or advances the interests of the company conducts themselves in a manner which complies with the Code.

Does MTAA approve proposed activities as being Code compliant?

No. MTAA staff can provide general information about the Code but not approve proposed activities or locations as being Code compliant. Companies should be able to justify their activities on the spirit of the Code.

Does MTAA offer training about the Code?

Yes, and for current training resources please see the MTAA website.

When do staff need to do training on the Code?

Companies must ensure its representatives are fully aware of the provisions of the Code. All Company representatives working with Healthcare Professionals (HCPs) and every employee in a role involving promotional activities or purchasing decisions must have Code training with each new edition of the Code. New employees must be trained within six months of their employment or new role unless Code training has been completed with a former employer.

b) does not contain a Claim or Promotional statement in relation to the Medical Technology.

Breach means an act or omission in contravention of a provision of the Code.

Claim means any Claim or representation about the attributes or Therapeutic Uses of a Medical Technology and includes any statement about a disease or health condition that suggests a particular Medical Technology has a Therapeutic Use in relation to that disease or condition.

Code means this Medical Technology Industry Code of Practice as amended from time to time and administered by 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.

Code Complaint Subcommittee (CCS) means the Code Authority Subcommittee appointed under clause 14.3 a)

Code Secretary means the person appointed by MTAA to be responsible for the administration of the Code and the specific functions as set out in the Code.

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 arrangements, 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 from within or outside the Industry who lodges a Complaint with MTAA under the Code.

Complaint means a Complaint lodged with MTAA under the Code.

Complaint Appeal Subcommittee (CAS) means the Code Authority subcommittee appointed under clause 14.4 e).

Conference Organiser means the organiser of a Third-Party Educational Conference and may include a Professional Association, a Training Organisation, or a commercial entity 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 or other benefit(s).

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 Technology and does not contain any Promotional Claims.

Entertainment includes sporting, music, and other entertainment events or activities which are 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.

Fair Market Value means a value to be paid by a Company where both parties are dealing at arm's length in an open and unrestricted market, and where neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts. At the request of MTAA, a Company must be able to demonstrate the internal methodology it used to determine Fair Market Value. Fair Market Value must take into consideration qualifications, expertise, experience and services provided. Payment for services must comply with applicable tax and other legal requirements.

Hands-On Training means practical training in a procedure or in the use of Medical Technology.

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

Healthcare Professional (HCP) means any individuals or entities (including hospitals or hospital groups) involved in the provision of healthcare services and/or items to Consumers; including the purchasing, leasing, recommending, using, arranging for the purchase or lease of, or prescribing Medical Technologies in Australia. This definition includes a Person in Training or a person under the direction or control of a Healthcare Professional.

Hospitality means the provision of food and/or beverages.

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

Institution means any legal entity involved in the acquisition, supply or distribution, assessment, funding, administration, recommendation, education, training or Regulation of Medical Technologies (other than the Company's contracted distributors) and is not a Company.

Laws and Regulations means any Law or Regulation in force in Australia.

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 Medical Technology and includes discussions about product features and performance.

Third-Party Educational Conference includes short meetings of a clinical nature that occur in a hospital setting. For example, weekly case meetings and journal clubs.

Although in some circumstances 'Unique' may be used to describe some clearly defined special feature of Medical Technology, in many instances it may be taken as implying a general superiority. In such instances, this is unacceptable unless the Claim can be supported in every respect.

The Advertising of therapeutic goods to Consumers and Healthcare Professionals is governed 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 1990;
- c) Therapeutic Goods (Medical Devices) Regulations 2002;
- d) Competition and Consumer Act 2010.

Advertisements directed to Consumers must follow the Therapeutic Goods Advertising Code (No.2) 2018. 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.

Medicine has the meaning given to it in the TG Act.

Monitoring is the review by MTAA 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 means the various websites and applications that enable users to create and share content or to participate in social networking, and includes, but is not limited to Facebook, YouTube, blogs, Twitter, LinkedIn, wikis and similar communication tools.

Sponsor has the meaning given to it in the TG Act.

TGA means Therapeutic Goods Administration.

TG Act means the *Therapeutic Goods Act 1989 (Cth)* as amended or replaced from time to time.

Therapeutic Use means use in or in connection with:

- a) preventing, diagnosing, curing, or alleviating a disease, ailment, defect or injury in persons;
- b) influencing, inhibiting or modifying a physiological process in persons;
- c) testing the susceptibility of persons to a disease or ailment; or
- d) controlling or preventing conception in persons; or
- e) testing for pregnancy in persons; or
- f) the replacement or modification of parts of the anatomy in persons.

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 of a Company;
- 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 or exhibit of promotional or educational material about a Medical Technology, and/or a display of 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.

Unique means a significant attribute relevant to the use of a particular Medical Technology, that is materially different from the attributes of all other Medical Technologies that are available on the Australian market.

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.

7.2 This Edition 11 of the Code replaces and supersedes all previous editions.

8. ADVERTISING AND PROMOTION OF MEDICAL TECHNOLOGY

8.1 Application

This section of the Code applies to Advertising directed to Healthcare Professionals. It does not apply to Advertising directed to Consumers.

8.2 General

Advertising 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 Advertising;

What are the Code's requirements where claims are made in an Advertisement?

All claims made in Advertisements directed at HCPs must be substantiated. Companies 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 registered intended purpose of the technology and conform to current standards for clinical evidence.

The source of a claim should be cited (e.g. by footnote) where the claim is likely to mislead or deceive if the source is not cited. Care should be taken to ensure the correct reference for the particular claim is provided in the footnote and that it fully supports that claim.

Explanatory Notes

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 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.

MTAA members should inform themselves about any applicable laws or regulations, or any 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. Social media promotions directed to HCPs should be restricted to Healthcare Professionals. Companies must have a robust method of restricting access to social medial promotions directed to Health Care Professionals. A pop-up box is insufficient for this purpose.

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- 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 any Advertising to describe a Medical Technology after one year from the date of the Medical Technology'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.

8.3 Claims and endorsements

- a)** A Company must:
 - (i) be able to substantiate all Claims in its Advertising by reliable technical, scientific or other support;
 - (ii) cite the source of the Claim where the Claim is likely to mislead or deceive if its source is not cited;
 - (iii) if a third-party requests substantiation of a Claim, provide substantiation to that third party within ten (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 or deceive by implication or omission.
- b)** Advertising must not denigrate a competitor's Medical Technology.
- c)** A Company may report (in any Advertising) on the outcomes of comparative testing of Medical Technologies, providing that:
 - (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 Advertising and is consistent with the body of evidence.
- d)** If the comparative data that supports a Claim referred to in clause 8.4 c) arises from separate studies, then a qualifying statement must be included to the effect that substantiating data arose from separate studies.
- e)** A Company must not make a Claim in any Advertising that describes or shows a competitor's Medical Technology or other product as broken, defaced, inoperative or ineffective.
- f)** Advertising must not contain, whether expressly or by implication, exaggerated or unqualified superlative Claims.

8.5 Specific Information Required

- a)** Advertising 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 Medical Technology not required to be entered in the Register);
 - (iii) Claims consistent with the Medical Technology's registration, listing or inclusion on the Australian Register of Therapeutic Goods; and
 - (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 8.5 a), the Company must provide the information within ten (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 CCA.
- c)** Where a CCA is used solely for the purpose of supporting a Claim, including a comparative Claim, the Claim must be appropriately referenced.

8.7 Social Media in Promotions to Healthcare Professionals

- a)** All Companies must have policies and procedures in place 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 Medical Technology to Healthcare Professionals must comply with the requirements of this Code relating to Advertising and other relevant Laws and Regulations.

FAQs

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

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

Companies should 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.

Who may request to see supporting evidence of a claim?

Any third party may request substantiation (i.e. supporting evidence) of a claim which must be made available within 10 working days of the request. Such evidence may comprise published studies, reports etc. It should be accessible so that the time frame can be met. Where a claim is referenced by 'data on file' (in the case of unpublished data) or 'in press' material, the advertiser is committed to honouring the request from any third-party for production of the supporting data. A statement that the data is 'confidential' will not be accepted.

What is Comparative Advertising?

In the Code "Comparative Advertising" refers to advertising which compares one product with another product which has the same intended purpose.

The intent of any comparison should be to provide valuable and accurate information comparing products for the benefit of HCPs and their patients. Graphical or visual comparisons should be accurate and appropriate.

Can an advertisement report on the outcomes of comparative testing?

It is permissible in an Advertisement to report on outcomes of comparative testing of Medical Technologies, provided the Medical Technologies have been subject to the same and appropriate testing; the outcomes are reported in a fair and balanced manner; and each outcome is referenced and consistent with the body of evidence.

Best practice would require, for example, that inclusion and exclusion criteria were of a similar patient population, demographic or risk profile. A comparison of pivotal trials may not necessarily be a basis for similarity.

Where a comparative claim is made, there must be strong evidence to support the claim and must be referenced in the body of the advertisement. Claims should be current, accurate and balanced and must not mislead by implication or omission.

Subject to the above requirements being met, if the relevant data used arises from separate studies then there must be a qualifying statement to that effect.

Explanatory Notes

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. Companies should develop clear guidelines in relation to its interactions with Healthcare Professionals, which can be disclosed to MTAA if required.

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 choice of venue must be consistent with professional and public standards of ethics and good taste. 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.

9.2 b) The interpretation of modest lodging costs may be affected by the proximity to Company sponsored training.

The accommodation selected should not become the main attraction of the event.

Companies should avoid luxury or resort facilities without an appropriate justification (for example, availability).

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, guest or family member of the Healthcare Professional.

For clarity, by way of example, if an Australian based Healthcare Professional is attending a Third-Party Educational Conference in San Francisco and is attending a Company-sponsored training elsewhere within the United States; then a Company can fund reasonable hospitality, accommodation and flights for the component only related to the Company-sponsored training. In this example, International flights could not be paid by the Company as these constitute substantial travel for the Third-Party Educational Conference.

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.

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

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.

Code

9. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

9.1 General interactions

a) 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 Medical Technology.

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 geographic location selected must not become the main attraction of the event.

b) If the program requires "Hands-On" Training in medical procedures or Medical Technology Demonstration:

(i) it must be held at a training facility, medical Institution, laboratory, or other appropriate facility; and

(ii) the training staff must have the proper qualifications and expertise to conduct such training.

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

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

e) A Company must not pay for the Hospitality, travel, or other expenses of any partner, guest or family member 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;

(iii) where the event is modest in nature (e.g. accommodation and travel are not provided), 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;

(iv) where there is a Third-Party Educational Conference that a Healthcare Professional is attending, and there is a Company-sponsored Training and Education or Medical Technology Demonstration event adjacent to the Third-Party Educational Conference, the principles of clause 9.3 continue to apply; that is, a Company must not pay for any travel, hospitality or accommodation expenses related to the Healthcare Professional attending the Third-Party Conference. All costs related to the Third-Party Educational Conference, including travel to and from the Healthcare Professional's originating location to the Third-Party Educational Conference must be covered by the Healthcare Professional and must not be paid for by the Company. To avoid doubt, a Company may pay for the travel to and from the Third-Party Educational Conference to the Company-sponsored Training and Education or Medical Technology Demonstration event, but not to and from the Healthcare Professional's originating location.

(v) the Company may not fund or facilitate personal or private side trips before or after the Company-sponsored Training and Education or Medical Technology Demonstration event.

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 or Medical Technology 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 by Companies to healthcare conferences organised by professional organisations and Conference Organisers on behalf of or for groups of Healthcare Professionals.

A Company must not make a direct payment to an individual Healthcare Professional or provide travel or accommodation to a Healthcare Professional to attend a Third-Party Educational Conference (unless where expressly permitted by this Code) or perform any other act that might be regarded as an inducement to make a recommendation on product selection of a Medical Technology.

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.

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;

FAQs

We would like to arrange a visiting surgeon program. The program would involve surgeons visiting a surgeon who has experience with our company's technology to view the use of the technology in procedures. What are the factors a company should consider in this situation?

Companies can arrange visiting surgeon programs under clause 9.2; considerations should include but are not limited to:

- whether there is a bona fide training need, and will the need be met at this activity
- surgeon selection criteria, both trainer and trainees
- appropriateness of the location

Can a company pay the host surgeon who is being visited under such a program?

Companies can contract with a host surgeon as a consultant. Clause 9.4 allows reasonable compensation to be paid for consulting services.

A Queensland HCP will be holidaying in Singapore and has heard about a Company sponsored training workshop in Shanghai in the same week. She has asked if she can register for the workshop as there isn't an equivalent workshop in Brisbane. Can the company fund the HCP to the workshop under the Code?

The company can invite the HCP to attend a company sponsored training workshop if a legitimate need for the HCP to receive the training exists. A Company can pay reasonable travel costs. It would not be reasonable to fund the HCP's trip from Australia to China given that they will already be in Singapore for personal reasons. It is reasonable to arrange modest travel and accommodation so that the HCP can travel from Singapore to Shanghai return for the training workshop.

If we hold company training adjacent in time and location to a third-party educational conference, can we fund HCPs to attend the training or could this be considered indirectly funding the HCPs to the conference?

Companies can fund a HCP to attend genuine company sponsored training and education as long as no part of that funding can be construed as directly sponsoring an individual HCP to attend an adjacent third-party conference. HCPs who would like to attend the adjacent company sponsored training and the third-party educational conference must fund any required travel to and from the location themselves; the company should only fund any additional accommodation required to attend the company sponsored training.

Can we offer Training and Education to HCPs which may not relate to the Company's Medical Technologies (e.g. supply chain management; training in Presentation Skills/ Training Techniques)?

The Code permits companies to provide training and education, which is defined as the provision of educational material, product specification material, lectures and training sessions to HCPs in relation to medical technologies.

It should be noted that the definition of a Health Care Professional (HCP) in the Code includes "... any individuals or entities ... involved in the provision of healthcare services ... including the purchasing, leasing, recommending, using, arranging for the purchase or lease of ... Medical Technologies in Australia". If, for example, supply chain management is directly relevant to the Company's Medical Technologies – and the HCPs in question have a legitimate need for training/education on this topic (eg hospital purchasing officers) – then it would be reasonable to consider the training as being related to (the provision of) the Company's Medical Technologies and the Company would therefore be permitted by the Code to provide the training and to pay for travel etc. Similarly, training on presentation skills/ training techniques that is provided to assist an HCP in delivering training on a Company's Medical Technologies would be permitted by the Code.

However, Training and Education which does not relate to Medical Technologies may be construed as a gift or benefit in breach of the Code.

Does the Code permit a Company to pay for travel to a Company conducted general educational program not concerning a Medical Technology?

No. It may be appropriate for a Company to conduct a general educational session not concerning a Medical Technology, but it is not the type of program for which Company-supported travel would be appropriate under the Code. For example, a training session on "stress management" or "time management for professionals" would not be regarded as provision of training and education as defined by the Code.

Are ski resorts and tropical islands permitted for company training and education sessions for HCPs? Is there an approved list of venues?

The Code requires that company sponsored training and education is conducted in a clinical, educational, conference or other setting that is conducive to the effective transmission of knowledge and is not selected because of its leisure or recreational facilities. The 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. The agenda must be educationally robust.

The choice of venue must also uphold professional and public standards of ethics and good taste.

Holding company training at a well-known tourist destination may well attract negative public perception and complaints, regardless of the specific venue chosen for company training. This risk is heightened if the training will be held during a recognised tourist season at the location, such as ski season. Companies may find it useful to consider both the venue and surrounding town/region when deciding whether the training and education will meet the Code's requirement of being held in a setting that is conducive to learning and is not renowned primarily as a holiday destination.

There is no approved list of venues.

9.3 I am a conference organiser and I am organising a third-party conference for HCPs at a resort location overseas. Can Medical Technology companies sponsor this event?

The primary consideration should be the agenda and the quality of the education that will be provided. Companies should consider the image that may be projected to the public when deciding whether to support a conference. This includes whether an ordinary member of the public would consider that the conference is going to be for the genuine purpose of promoting scientific knowledge, medical advancement or the delivery of effective healthcare.

Can we offer refreshments at our trade display at a third-party educational conference?

Yes, you may offer refreshments as long as it does not draw attendees away from the planned conference and it complies with the provisions in clause 9.5



Explanatory Notes

Clause 9.3.2 b) (vi)(E) does not prohibit the Conference Organiser or Third-Party Educational Conference from acknowledging sponsorship by the Company.

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.

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.

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.

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- (C) is consistent with guidelines established by the Conference Organiser;
- (D) does not give rise to, or facilitate any Breach of the Code; and
- (E) should in no way be connected to the Third-Party Educational Conference providing an endorsement of a Company's Medical Technology.

To avoid doubt:

- (vii) the Conference Organiser and the Company must enter into a written agreement specifying the nature and conditions of the sponsorship or grant; and
- (viii) the agreement must require the Conference Organiser to account to the Company for the use of the sponsorship or grant, without being required to disclose the identity of the recipient(s), if any.

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.
- b) A Company may provide Hospitality at a Third-Party Educational Conference provided the Hospitality 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 9.3.4 a).

9.3.5 Advertisements and Trade Displays at Third-Party Educational Conferences

- a) The purchase of any Advertising 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 Advertising that does 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 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 or meeting 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 or Medical Technology collaboration, provided that a legitimate need and purpose for the services is identified in advance, and the Promotion of a Medical Technology to the Healthcare Professional is not a purpose for the engagement.
- b) 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 attend 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 consistent with Fair Market Value.
- f) Consulting Arrangements between a Company and a Consultant must comply with the following:
 - (i) the arrangement must be documented and agreed 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;

FAQs

We have engaged a healthcare professional (HCP) as a consultant to travel overseas to facilitate a two-day company training session. Can the HCP arrive the night before the training session and leave the day after the training session or would this be a prohibited side trip?

If the travel arrangement is linked to the proper performance of the consultancy services, such as allowing the consultant reasonable rest before performing the consultancy services, then it is permitted within the Code. Companies need to assess what is reasonable in the circumstances of each consulting arrangement.

Can we engage a HCP as a consultant to speak at a third party educational conference and pay their associated expenses?

Companies cannot make direct payments to HCPs to speak at third party educational conferences. They are only allowed to provide sponsorship to a conference organiser, which can then be used to provide support for a speaker as part of the expenses for the conference.

We have engaged a HCP from Sydney as a consultant to speak at a company training event in Brisbane. The HCP has asked us to facilitate a 'side trip' after the consultancy so she can have a weekend in Byron Bay before flying back to Sydney. Is this permitted?

No, the Code allows for the provision of reasonable and actual expenses incurred by a consultant in carrying out the engagement. It does not permit companies to facilitate a side trip for any other purpose, even if the side trip is at no further cost to the company.

The Code states that a Company may pay the Healthcare Professional reasonable compensation for performing services as a Consultant. Further it states that the compensation must be consistent with fair market value for the services provided. How can a Company determine fair market value?

Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts. A Member Company should use objective and verifiable criteria to determine fair market value and should ensure this is documented. Some criteria that Members make take into consideration when determining fair market value include: the consultant's qualifications, expertise, clinical experience, presentation skills and the actual services to be provided. Some state health departments publish hourly rates to use as a comparative guideline.

How can a Company establish "fair market value"?

There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

Explanatory Notes

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 9.4 f) (ix) is to prohibit funding 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.

9.6 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 educational item must have a 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.

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- (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 Medical Technology or 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 for which the Company has engaged the Consultant; 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 any person 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.

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 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) 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.
- g) 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.

FAQs

What is meant by fair market value in the context of consulting arrangements?

Fair market value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

How should Member Companies determine fair market value for a service?

A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company

The Code states that a Company may pay the Healthcare Professional reasonable compensation for performing services as a Consultant. Further it states that the compensation must be consistent with fair market value for the services provided. How can a Company determine fair market value?

Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts. A Member Company should use objective and verifiable criteria to determine fair market value and should ensure this is documented. Some criteria that Members make take into consideration when determining fair market value include: the consultant's qualifications, expertise, clinical experience, presentation skills and the actual services to be provided.

Some state health departments publish hourly rates to use as a comparative guidance. 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.

Can a Company Representative regularly bring coffee and cake to share with the surgical team when providing daily case coverage?

Hospitality must be incidental to the presentation of scientific, educational or commercial information. Provision of hospitality such as refreshments should not be made in a manner that may create an expectation that it is a routine occurrence. The primary requirement is that any hospitality is modest and subordinate in focus to the primary intent of the meeting.

Can a Company representative provide hospitality to hospital staff if they are visiting to demonstrate a new product?

Yes. If a company employee visits a hospital to conduct a product demonstration, modest hospitality could be provided if it was incidental to the educational presentation.

Is taking a HCP to dinner at a restaurant permitted by The Code?

There are several factors to take into consideration to determine whether the hospitality meets the requirements of the Code. The first consideration is the reason for the dinner, is it for the purpose of educating the HCP or explaining a Medical Technology? If so, has this objective been documented beforehand? After the dinner, have you made notes of the topics discussed and any follow up required? Finally, would a reasonable person consider the cost of the dinner was modest in the circumstances? By making sure you can answer 'Yes' to all of these questions, you can help ensure that the dinner will not be found to be an improper inducement offered to the HCP.

We have bought a table at a charity fundraiser to raise funds for medical supplies for outback communities. Can we invite HCPs to attend and sit at our table?

You can invite HCPs to sit at your company's table at a charity fundraiser, but they would need to meet the cost of themselves and their guests to attend. The Code permits companies to offer hospitality to HCPs in limited circumstances which are:

- in the context of a third-party educational conference;
- where there is an educational element or a Medical Technology demonstration; or
- as an occasional courtesy in conjunction with business interactions involving the presentation of scientific, educational or commercial information.

Does the Code allow companies to give conference delegates branded disposable coffee cups and water bottles?

A company must not give a HCP any type of non-educational branded promotional item, even if the item is of minimal value. As such, food and beverages should not feature product or company branding. The Code permits company or product branding on items that serve a genuine educational purpose only.

Under the Code, what does the terms "modest" hospitality mean? And how much is considered to be "modest" hospitality?

The Code does not place a threshold for expenditure on hospitality because this may be too restrictive to address all possible scenarios, the Code states: "A company may pay for modest Hospitality for attending Healthcare Professionals".

The term 'modest' will vary in specific circumstances. Companies are therefore encouraged to develop their own internal standards which address a range of typical scenarios for the provision of hospitality both locally and off shore. Provision of hospitality at international venues should be appropriate to the region. Actual expenditure will naturally vary by location but should continue to be modest and reasonable by Australian standards. Each company should be able to justify what they consider to be "modest" hospitality.

9.7 Can we give HCPs a branded mouse pad or wall planner if it has useful information on it, such as conference dates?

No. Companies are not permitted to give HCPs non-educational branded promotional items. In terms of a wall planner or mouse pad, the items themselves are not educational. Including conference dates may be of some interest to the HCP but doesn't make the items themselves an educational item.

Can we give HCPs a non-branded USB with educational files on it?

Yes. If the USB was preloaded with files which served a genuine educational function for the HCP then it would be consistent with clause 9.7(a) of the Code.

Can we give out branded stationery at a company organised training and education event?

Yes, stationery can be provided to attendees to meet their needs at the training and educational event.

As part of our sponsorship for third party educational conferences, can we sponsor company branded items that will be provided by the conference organiser?

Yes, company branded items of nominal value can be provided by the conference organisers to attendees of the conference to meet the legitimate needs of the event.

Does the prohibition on non-educational branded promotional items apply to company branding or just product branding?

The Code's prohibition on non-educational branded promotional items includes both company and product branding.

Explanatory Notes

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.

Any such educational grant must be intended to benefit the broader advancement of medical or public education, and not an individual Healthcare Professional or Institution. To avoid doubt, this includes the provision of grants for referral dinners or similar.

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

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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) compliant with clause 9.7;
 - (B) directly relevant to the practice of medicine or field of other specialist healthcare; and
 - (C) of minimal monetary value or be an item of an educational nature.
 - (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 grants, educational grants and charitable donations

9.9.1 General

A Company may provide research grants, 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 Medical Technology;
- 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 receiving organisation 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
A 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
A Company may make grants for the purposes of supporting genuine education of Consumers or the public about important healthcare topics.
- b)** 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).
- c)** A Company may make an educational grant to an Institution.
- d)** A Company must not make an educational grant if it is aware that the educational grant will be used to directly fund a nominated individual Healthcare Professional or Person in Training to attend 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)** A Company may grant funds to an organisation accredited by a Professional Association or with an academic affiliation to provide a fellowship for the specialty education of a Healthcare Professional or a Person in Training.
- b)** When providing funding for a Fellowship, the principles in clause 9.9.1 apply.

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 Medical Technology, including identifying appropriate coverage, coding, or billing of the Company's Medical Technology, or of procedures using that Medical Technology.
- 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 transparent and disclosed at the time of publication.

FAQs

We are exhibiting at an upcoming conference. The conference organisers want to run a competition involving exhibitors who pay an additional amount. Delegates who visit all the stands of participating exhibitors go into the draw. Is this permitted under the Code?

Yes, provided the competition complies with clause 9.8 Competitions for Healthcare Professionals of the Code.

Can we run a competition where the prize is a \$500 education grant?

No, the Code prohibits companies from giving educational grants directly to individual HCPs or practitioners in training.

We have been asked by a group of HCPs at a particular hospital to give them an educational grant which we are aware they will use to fund a specific HCP from their group to attend a third-party conference. Can we give them the educational grant?

No, clause 9.9.3 allows educational grants for genuine medical education programs with an academic affiliation. The clause should not be used to circumvent clause 9.3.2's prohibition on companies funding HCPs directly to attend third party conferences. Clause 9.9.3(c) prohibits companies from making an educational grant directly to a healthcare professional or a practitioner in training.

If a company has a reasonable concern that an educational grant is going to be used to directly fund a HCP to a conference, it must not give the grant.

In addition, clause 9.9.1(c) requires companies to ensure that the recipient of an educational grant makes an independent decision on how the funds are used. This means that companies should satisfy themselves that those involved at the recipient level in deciding where the grant will be allocated do not have a conflict of interest (such as being a potential recipient of the educational grant or closely associated with potential recipients).

Our company has received a fellowship grant request from a hospital. The hospital has indicated that the requested amount is for the salary of the fellow as well as administration costs for the time and fees spent applying for the fellow's visa. Can a company cover all these costs as part of a fellowship grant?

Yes. Clause 9.10 Fellowships allows companies to grant funds to certain bodies to provide a fellowship for the specialty education of a HCP or a Practitioner in Training. Funds can be used for the fellow's salary and reasonable administration fees associated with establishing the fellowship, such as applying for any required visa.

Do the general requirements for educational grants at clause 9.9(a) apply to fellowship grants given by companies?

Yes. Fellowship grants given by companies under clause 9.10 to support specialty education are a type of educational grant. They must comply with the general requirements for all educational grants that are outlined at clause 9.9(a).

Explanatory Notes

In order to ensure that the Code is well-understood within a Company, its 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 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 (including those who work in sales, marketing or customer service roles) must undertake training on the Code within three months of commencing employment with the Company and for each new edition of the Code.

To ensure that training on the Code is consistent, all training must be delivered by MTAA face to face or online.

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.

Code

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 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 patient care; and
 - (iv) 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.
- d) A Company must ensure that a Company Representative who attends procedures at the invitation of a Healthcare Professional complies with all of the Institution's relevant requirements, standards, codes and all relevant Laws and Regulations.

10.2 Requirements for training

- a) A Company must ensure that every Company Representative employed in a role that involves contact with Healthcare Professionals and/or undertaking Promotional activities or purchasing decisions on behalf of the Company undertakes training on the operation of the Code provided by MTAA (either face-to-face or online). This training must:
 - (i) be completed by such new Company Representatives within three (3) months of commencing in the role, and
 - (ii) be completed for each new edition of the Code (unless a direction is otherwise provided by MTAA).

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 Advertising unless it conforms with the Code; and
 - (ii) must be issued conditionally upon the publisher ensuring that the release or extracts be published in compliance with the Code and all relevant Laws and Regulations including the Advertising Code.
- c) MTAA recognises and supports relationships between Industry and Health Consumer Organisations, government bodies and other independent bodies having an interest in providing Consumer education in relation to Medical Technologies that facilitate and enhances the Consumer's safe and effective use of that Medical Technology.

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 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, the Company must require the Healthcare Professional to disclose their ownership interest to a Consumer before or at the time the Healthcare Professional recommends a Medical Technology 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. CA members are appointed by the 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 the Code administration, including Monitoring, Complaints handling, and appeals.

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

FAQs

What are the responsibilities of a company representative under the Code?

All company representatives must be fully aware of the provisions of the Code and are required to complete training on the Code within six months of joining the industry. A company must ensure that its representatives maintain a high standard of ethical conduct and professionalism, comply with the Code, do not compromise the professional behaviour or independence of a HCP, and do not compromise patient care. Company representatives must not engage in behaviour that risks bringing their company or the wider MedTech industry into disrepute.

If a Complainant fails to provide valid contact details, the information is not sufficient to trigger the formal Complaint process and the MTAA is not obliged to accept the Complaint.

13.3 Promoting Awareness of the Code

- a) MTAA will 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 by the CA; however, where a Complainant is an individual, and the Complaint is not made on behalf of a Company or other entity, the Complainant may request to have their identity withheld. If the Complainant makes a request to have their identity withheld, the CA and the Code Secretary must take all reasonable measures to keep the identity of the Complainant confidential and not reveal the Complainant's identity to the Respondent, the public or any third-party unless expressly permitted by the Complainant or otherwise required by Law.
 - c) Where a Complaint is about a matter that is the subject of court proceedings:
 - (i) a Complainant is not precluded from resorting to litigation, but the CA must either suspend or discontinue, at its discretion, a Complaint where civil or criminal proceedings in any jurisdiction with respect to the same or similar subject matter have commenced; and
 - (ii) a party to a Complaint must notify the Code Secretary immediately upon becoming aware of any civil or criminal proceedings in any jurisdiction 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 the MTAA website and shall be submitted to the Code Secretary.
 - (ii) the Complaint must set out the facts that form the basis of the allegation that the Respondent Breached the Code.
 - (iii) 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.
 - (iv) the Code Secretary must acknowledge the Complaint in writing within seven (7) working days of its receipt and deal with the Complaint expeditiously.
 - (v) the Code Secretary must forward a copy of the Complaint to the Chair of the CA as soon as practicable, and to the Chief Executive Officer of the Respondent within seven (7) working days, of receiving the Complaint.
 - (vi) the Respondent must respond in writing to the Code Secretary within fifteen (15) working days.
 - (vii) the Code Secretary must provide the Complainant with a copy of the Respondent's response within seven (7) working days of receipt.
 - e) The Code Secretary may invite both parties to engage in mediation as follows:
 - (i) 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 witnessed by the mediator. The agreement must remain confidential between the parties and the mediator, unless the parties agree that it be made available to MTAA.
 - (ii) In relation to the mediator and mediation:
 - (A) the mediator must be a person with demonstrable mediation experience;
 - (B) the selection of mediator must be approved by the parties to the mediation;
 - (C) the mediator may seek the advice or participation of an expert, as required;
 - (D) the mediator is responsible for arranging and conducting the mediation and, subject to confidentiality arrangement agreed between the parties, reporting to the CA on progress and any outcome; and
 - (E) subject to any agreement reached by the parties before the mediation to the contrary, the parties shall be equally responsible for the mediator's charges and the costs incurred in arranging a mediation session. The parties will meet their own expenses of participating in mediation.
 - (iii) 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 14.3 a) by written notice to the Code Secretary in which the Complainant 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 for the withdrawal; and
 - (ii) the Complaints handling procedure is terminated.

- b) A Company Complainant who withdraws its 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 at any time 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. The CA may then refer the Complaint to that authority.
- 14.3** Hearing of Complaints
- a) The CA will appoint a Code Complaint Subcommittee (“CCS”) and delegate to the CCS the role of hearing and considering the Complaint.
- b) The terms of reference of the CCS shall be as determined by the Board from time to time.
- c) 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.
- d) 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 14.3 b).
- e) The deliberations of the CCS are confidential and must not be disclosed by any member of the CCS.
- f) If the CCS considers a Breach of the Code to have occurred, it must determine the appropriate sanction as provided in clause 15.2.
- g) 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.
- 14.4** Appeals
- a) An appeal against the decision of the CCS may be lodged with the Code Secretary by either party within ten (10) 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 Code 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 Code Secretary must provide a copy of the response to the appellant within five (5) working days of receipt.
- e) The CA will appoint a Complaint Appeal Subcommittee (“CAS”) and delegate to it the hearing and consideration of the appeal. The terms of reference of the CAS shall be as approved by the Board from time to time. Any member(s) of the CCS who heard the Complaint being appealed cannot be a member of the CAS hearing the appeal. The CAS must consider:
- (i) the material considered by the CCS in the matter;
 - (ii) the appeal papers including the written decision of the CCS;
 - (iii) any response from the Respondent to the appeal; and
 - (iv) any additional material which the CAS reasonably believes will assist its deliberations provided a copy of such material has been provided to the parties to the appeal at least five (5) working days before the appeal hearing.
- f) Each party is entitled to be heard by the CAS in person on prior arrangement with the Code Secretary.
- g) The CAS has the right to question each party at the hearing.
- h) The deliberations of the CAS in relation to the appeal are confidential and must not be disclosed by a party or any members of the CAS.
- i) The findings of the CAS are final and binding on the parties. The Code Secretary must provide to each party the CAS’s reasons for decision no later than ten (10) working days after the hearing of the appeal.
- 14.5** Costs associated with the Complaint and Appeal process
- a) The award of costs and expenses in relation to a Complaint and/or an appeal shall be at the discretion of the CA provided that if a Complaint is upheld (and not appealed) or upheld on appeal, the Respondent must reimburse MTAA its reasonable 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 a Company 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 twelve (12) months.
- b) MTAA must not publish in any form the name of a Complainant if it has been withheld in accordance with clause 14.1 b).

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 that is 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 that is 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 that is 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 twenty-four (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 twenty-four (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:

- (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 ten (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 ten (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 ten (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 Code Secretary within thirty (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.

The time periods specified for response or action are subject to any appeal that may be lodged under clause 14.4.

- b) Subject to this clause 15.2, if the CA resolves that a Complaint from a Company is frivolous or vexatious, the CA may request the Complainant to show cause why it should not pay the Code Secretary's 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.

In relation to clause 15.3 a), 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.