Medical Technology
ASSOCIATION OF AUSTRALIA

www.mtaa.org.au

MEDICAL TECHNOLOGY INDUSTRY

CODE OF PRACTICE

Administered by the Medical Technology Association of Australia

Edition 13 – 2023

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CONTENTS

CODE

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 theatre to train and advise physicians in the proper use of new tools, products, and techniques.

The Industry's range and scope is vast. Medical Technologies sometimes serve as extensions of a surgeon's hands. Others are inserted into the human body to replace or strengthen a body part. In other circumstances, they can be non-invasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by 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.

STATEMENT OF PRINCIPLES
MTAA is a signatory to the Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector and endorses and embodies the Consensus Principles within the Code. The Consensus Principles are included as an Addendum to the Code.

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

a) selecting diagnostic and treatment options and products based on the best available evidence, clinical judgement, and the Consumer's needs, and

b) using therapeutic products safely and effectively.

The Industry supports this principle by promoting ethical collaboration between all parties in the Industry sector, as defined by the Consensus Principles.

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.

The Code applies to all interactions between Companies and Healthcare Professionals practising in Australia, regardless of location, except where otherwise indicated. All such interactions between Companies and Healthcare Professionals must be based on a legitimate need.

BACKGROUND AND PURPOSE OF THE CODE
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.

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.

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

OBJECTIVES AND SCOPE OF THE CODE
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.

The Code is a self-regulatory code. Companies are obliged, as a condition of membership of MTAA, to accept and observe all provisions of the Code and the Vendor Credentialing Standard and to cooperate fully with the Code Authority's Monitoring activities and Complaints handling process.

To promote compliance with the Code, the Code Authority proactively monitors the conduct of Companies on a regular and ongoing basis. All Companies are required to submit evidence of such of their activities as are covered by a section of the Code nominated by the Code Authority, during a specified period. Companies are obliged to cooperate fully with the Code Monitoring activities as a condition of membership of MTAA.

CODE

The Code provides a mechanism for addressing Complaints made by a Company against the Code-related activities of another Company, as well as Complaints made by a Consumer or non-Industry Complainant. Companies are obliged to cooperate fully with the Complaints handling process as a condition of membership of MTAA.

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.

The Code is not intended:

a) to provide, nor shall it be construed as, legal advice, or

b) to take precedence over any relevant Laws or Regulation. To the extent that any provision of the Code conflicts with a Law or Regulation, that Law or Regulation will prevail.

A Company should always have regard to its own Company code which may provide a higher standard.

EXPLANATORY NOTES AND FREQUENTLY ASKED QUESTIONS
Explanatory notes and Frequently Asked Questions (FAQs) are available on the MTAA website (under the 'Code' tab). These are not binding on Companies, the Code Authority, or its subcommittees; however, 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.

1. ADVERTISING AND PROMOTION OF MEDICAL TECHNOLOGY

1.1 Application

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

1.2 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,

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 12 months from the date of launch of the product,

i) comply with the relevant Laws and Regulations for Advertising both Medical Devices and Medicines, where the Medical Technology consists of both a Medical Device and a Medicine.

1.3 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 a Healthcare Professional's name or photograph or a direct quotation from their presentation or unpublished communication 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.

1.4 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 1.4 c) arises from separate studies, then a qualifying statement must be included to the effect that substantiating data arise from separate studies.

e) A Company must not make a Claim in 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.

1.5 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) Where an Advertisement about a Medical Technology refers to scientific or clinical research, expressly or by implication, it must:

(i) sufficiently identify the research by proper citation to enable third parties to access that research, and

(ii) identify the financial sponsor of the research if it is the manufacturer or an associated company or individual.

c) If a third-party requests information on the intended purpose of a Medical Technology Advertised in accordance with 1.5 a), the Company must provide the information within ten (10) working days.

d) Despite the terms of this clause, Brand Name Reminder Advertisements do not need to contain any mandatory statements unless otherwise required by law.

1.6 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.

1.7 Social Media in Promotions to Healthcare Professionals

a) Companies may appropriately engage in Company Social Media campaigns, which includes creating content for such purposes.

b) 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.

c) The access to any content that contains Promotional Claims relating to Restricted Medical Technology must be restricted exclusively to verified Healthcare Professionals.

d) Any content or activities on Social Media sites that the Company controls or initiates is the responsibility of the Company including:

(i) ensuring that content on their Social Media site does not relate to unapproved Medical Technology and/or indications for use or contain content that does not reflect a high standard of social responsibility and conform to generally accepted standards of good taste,

(ii) taking reasonable steps to correct or remove any misleading or inaccurate information posted by third parties on a Company's Social Media site.

e) Any content that is accessible to the public must not Advertise or include Promotional Claims relating to Restricted Medical Technology.

1.8 Content Hosted Online

a) Where content hosted online contains Promotional Claims relating to Restricted Medical Technology on a Company or third-party website, it must be restricted exclusively to verified Healthcare Professionals.

b) Any mention of and/or links to other sources or websites on a Company-controlled website, are the responsibility of the Company. The Company must ensure the sources and/or websites are appropriate and will enhance appropriate prescribing, disease awareness and the provision and use of Medical Technologies in Australia.

c) When a Healthcare Professional leaves the Company-controlled website or is redirected to a site that the Company does not control, the Company must display a statement advising the user that the website is not hosted by the Company and may not comply with the regulatory requirements in Australia.

d) Companies may link their website to the Code on the MTAA website to provide information to Healthcare Professionals; however, the link must not be used to infer endorsement by the MTAA.

2 INTERACTIONS WITH HEALTHCARE PROFESSIONALS

2.1 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.

b) Compliance with the Vendor Credentialing Standard is a requirement of the Code.

2.2 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 2.3 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 2.7.

2.3 Third-Party Educational Conferences

2.3.1 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 or perform any other act that might be regarded as an inducement to make a recommendation on product selection of a Medical Technology.

2.3.2 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,

(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,

(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; and

(ix) a Company must not seek to influence the selection of the recipient of the sponsorship or grant.

2.3.3 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 2.5.

2.3.4 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 2.5, and

c) a Company does not pay the costs of attendees to attend the symposium, other than those referred to in 2.3.4 a).

2.3.5 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 1 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.

2.4 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,

(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 Institution concerning any existing or potential conflict of interest.

2.5 Hospitality

A Company's business interactions with a Healthcare Professional may involve the presentation of scientific, educational, or commercial information at a face-to-face event or Virtual Event. 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,

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, and

g) does not involve delivery of food or beverages to a Healthcare Professional's home location.

2.6 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 2.8.

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

a) A Company may not provide a gift to a Healthcare Professional directly or indirectly, including gifts of cash, cash equivalents such as gift cards/certificates, tobacco, or alcohol.

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 may 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.

2.8 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 2.7,

(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, and

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

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

2.9 Research, educational grants, and charitable donations

2.9.1 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.

2.9.2 Research grants

a) A Company may provide research grants to support 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.

2.9.3 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.

2.9.4 Charitable donations

a) A Company may make monetary or Medical Technology donations intended solely for bona fide charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes.

b) 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.

c) 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.

d) A Company must document every donation it makes.

2.10 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 2.9.1 apply.

2.11 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.

2.12 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.

3 COMPANY REPRESENTATIVES

3.1 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 3.2.

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 complies with all of the Institution's relevant requirements, standards, codes and all relevant Laws and Regulations, including the Vendor Credentialing Standard.

3.2 **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 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).

3.3 **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.

4 INTERACTIONS WITH CONSUMERS

4.1 **General**

a) Subject to clause 4.1b) below, requests from individual members of the public for medical advice on the diagnosis of disease or choice of therapy must always be refused and the inquirer recommended to consult their Healthcare Professional.

b) Where a specific request is made by a Patient, a carer of a Patient, or a member of a Patient's family about a Medical Technology which has been prescribed, and in the case of the carer or the family member the Company has established consent has been provided by the Patient for the Company to discuss the request, an appropriately qualified Company Representative may clarify matters in a non-Promotional manner such as by using Patient aid materials and should otherwise recommend inquirers to consult their Healthcare Professional. The onus is on the Company to verify that the request is being made by or on behalf of a Patient.

c) Product-specific programs, product information, and patient aids should be provided only to Patients already prescribed the Medical Technology and must not be Promotional.

d) An appropriately qualified Company Representative may provide educational information to the general public on diseases or conditions and treatment options available in Australia.

e) 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 are published in compliance with the Code and all relevant Laws and Regulations including the Advertising Code.

f) 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.

4.2 **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.

5 INTERESTS HELD BY HEALTHCARE PROFESSIONALS IN MEDICAL TECHNOLOGY COMPANIES

5.1 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.

5.2 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.

6 COMPLAINTS

6.1 **Code Complaint Process**

a) Before lodging a Complaint, the Complainant is encouraged to resolve the matter directly with the Company. In this regard:

(i) both parties must treat all discussions as confidential unless agreed otherwise, both throughout the period of a direct resolution attempt, as well as beyond this resolution period, and the parties must enter into a confidentiality agreement,

(ii) if the parties resolve the matter, no further action is taken,

(iii) if the parties are unable to resolve the matter, a formal Complaint may be lodged.

b) 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.

(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.

c) if either party does not consent to mediation, the Complaint process will be continued.

d) 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.

e) 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.

f) 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's 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.

g) Complaints concerning the conduct of non-members will be forwarded to the non-member with an invitation to have the Complaint adjudicated by the Code Authority in accordance with clause 6 and its agreement to abide by the Code Authority's decision and any sanctions imposed. If the non-member accepts the invitation to have the complaint adjudicated by the Code Authority, the Complaint will proceed in accordance with the provisions of the Code.

h) If the non-member declines the invitation to have the Complaint adjudicated by the Code Authority, MTAA shall have the right, but not the obligation, to forward the Complaint, together with the non- member response to the invitation, to the TGA or the Australian Competition and Consumer Commission (ACCC).

6.2 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 6.3 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.

6.3 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 of MTAA 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 6.1 f).

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 7.2.

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.

6.4 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 of MTAA 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, in accordance with such terms as set out by the CAS.

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.

6.5 Costs associated with 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 7.2. 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.

6.6 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 6.1 d).

7 SANCTIONS

7.1 Classification of Breaches

Where a Breach of the Code has been established, before determining any sanction under clause 7.2, 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.

7.2 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 time periods specified for response or action are subject to any appeal that may be lodged under clause 6.4.

(v) The imposition by the CA of a fine in accordance with the following schedule:

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.

b) The Respondent must pay the fine to the Code Secretary within thirty (30) days of being advised of the decision of the CA.

c) Subject to this clause 7.2, 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.

d) 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 Board. The Board may deal with the recommendation under the provisions of its constitution.

e) 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.

7.3 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 7.2, entitles the CA to direct MTAA to publish in the next edition of its newsletter and/ or on its website details of the Breach of the Code and the subsequent failure to undertake remedial action.

b) The continued refusal by the Company to undertake the required remedial action/s entitles the CA to direct MTAA to publish in the trade media details of the Breach of the Code and the subsequent failure to undertake remedial action.

c) In addition to the sanction set out in clause 7.2 above, the CA may direct MTAA to notify the Regulator of the continued Breach of the Code.

GLOSSARY

Where a word or phrase is capitalised, it has the meaning given to it in this Glossary.

Advertising	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	Advertising Code means the Therapeutic Goods Advertising Code 2021 in Australia as amended or replaced from time to time.
Advisory Board	Advisory Board means a group of Healthcare Professionals with specific expertise contracted by a Company to provide advice to the Company.
Board	Board means the Board of Directors of MTAA.
Brand Name Reminder Advertisement	Brand Name Reminder Advertisement means an Advertisement for a Medical Technology that: a) contains at most a brand name or branding device, and purchasing details or information, and b) does not contain a Claim or Promotional statement in relation to the Medical Technology.
Breach	Breach means an act or omission in contravention of a provision of the Code.
Claim	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	Code means this Medical Technology Industry Code of Practice as amended from time to time, administered by MTAA.
Code Authority (CA)	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)	Code Complaint Subcommittee (CCS) means the Code Authority Subcommittee appointed under clause 14.3 a).
Code Secretary	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	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)	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	Company Representative means any person or entity engaged in representing, acting for or advancing the interests of a Company pursuant to any agreement, arrangement or understanding between that person or entity and the Company, including a contract of employment or other employment arrangement, or any agency or consultancy arrangement.
Competition	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	Complainant means a person from within or outside the Industry who lodges a Complaint with MTAA under the Code.
Complaint	Complaint means a Complaint lodged with MTAA under the Code.
Complaint Appeal Subcommittee (CAS)	Complaint Appeal Subcommittee (CAS) means the Code Authority Subcommittee appointed under clause 14.4 e).
Conference Organiser	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.

Consensus Principles	Consensus Principles means the Statement of Principles for Collaboration and Interaction adopted by the Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector.
Consultant	Consultant means a Healthcare Professional who is engaged by a Company under a Consulting Arrangement.
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.
Consumers	Consumers are persons other than Healthcare Professionals.
Consumer Representative	Consumer Representative is a representative from a Health Consumer Organisation.
Educational Material	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	Entertainment includes sporting, music, recreation, and other entertainment events or activities which are not directly related to Training and Education and genuine business interactions.
Faculty Member	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	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	Hands on Training means practical training in a procedure or in the use of Medical Technology.
Health Consumer Organisation	Health Consumer Organisation means any organisation that represents the health interests of Consumers.
Healthcare Professional (HCP)	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 but excludes veterinarians.
Hospitality	Hospitality means the provision of food and/or beverages.
Industry	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	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	Laws and Regulations means any law or regulation in force in Australia.
Market Research	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	Medical Device has the meaning given to it in the TG Act.
Medical Technology	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	Medical Technology Demonstration means demonstration of the operational use of Medical Technology and includes discussions about product features and performance.
Medicine	Medicine has the meaning given to it in the TG Act.
Member	Member means a member company of Medical Technology Association of Australia.
Monitoring	Monitoring is the review by MTAA of compliance with the Code, including the Vendor Credentialing Standard.
MTAA	MTAA means Medical Technology Association of Australia Limited.
Non-member	Non-member means a medical technology company that is not a member of Medical Technology Association of Australia.
Patient	Patient means a person receiving or registered to receive a Medical Technology.
Person	Person in Training means a person training to become a Healthcare Professional.

Professional Association	Professional Association means a clinical or other professional body representing Healthcare Professionals.
Promotion	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	Register means the Australian Register of Therapeutic Goods.
Regulator	Regulator means a government agency performing a statutory regulatory function.
Respondent	Respondent means, in relation to a Complaint, the Company whose conduct is the subject of the Complaint.
Restricted Medical Technology	Restricted Medical Technology means Medical Technology which is not permitted to be advertised to the public in accordance with the TG Act.
Social Media	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	Sponsor has the meaning given to it in the TG Act.
TGA	TGA means Therapeutic Goods Administration.
TG Act	TG Act means the Therapeutic Goods Act 1989 (Cth) as amended or replaced from time to time.
Therapeutic Use	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	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	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	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	Training Organisation means a hospital or other Institution that provides training to Healthcare Professionals and/or persons in Training.
Unique	Unique means a significant attribute relevant to the use of a particular Medical Technology, which is materially different from the attributes of all other Medical Technologies that are available on the Australian market.
Vendor Credentialing Standard	Vendor Credentialing Standard means AS 5182:2018 Vendor Credentialing for Healthcare Facilities (as it may be amended from time to time).
Virtual Events	Virtual Events are Third-Party Educational Conferences or Training and Education events that may consist of filming of presentations, panel discussions or live clinical procedures and their broadcasting (whether immediate or deferred) to an audience which is not physically in attendance but is still in a conference, business, or clinical setting.

ADMINISTRATION OF THE CODE

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

General

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

Code Authority (CA)

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

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.

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.

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.

INTERPRETATION

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$, $A, dollar, AUD$, or $ is to Australian currency,

e) the meaning of general words is not limited by specific examples introduced by “including,” “for example” or similar expressions, and

f) headings are for ease of reference only and do not affect interpretation.

This Edition 13 of the Code replaces and supersedes all previous editions.

Medical Technology
ASSOCIATION OF AUSTRALIA

Medical Technology Industry Code of Practice
Edition 13 - 2023
Published on 1 January 2023

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