Medical Technology Industry Code of Practice

Administered by the Medical Technology Association of Australia

Edition 14

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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.[1]

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.[2]

[1] **Explanatory Note**: This an important distinction from pharmaceuticals, which are administered by physicians without the direct supervision of a representative from the Company that created them.

[2] **Explanatory Note**: This is based on the principle of evidence-based medicine where clinicians, Consumers and evidence are used to make decisions.

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:

- 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.[3, 4]

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.[5]

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 Health-care Professionals must be based on a legitimate need.[6]

BACKGROUND

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.[7]

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

[3] **Explanatory Note**: 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.

[4] **Explanatory Note**: 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.

[5] **Explanatory Note**: 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.

[6] **FAQ**: What is legitimate need? Legitimate need is a justifiable clinical, business, charitable or education reason for an interaction or activity. Anything provided directly or indirectly to reward past purchases or to influence an HCP to purchase or use Medical Technologies in the future is not a "Legitimate Need" and is prohibited.

[7] **Explanatory Note**: MTAA assumes responsibility for maintaining and enforcing the agreed standards of behaviour set out in the Code.

Companies in the agreed standards, monitoring Industry activities, and providing self-regulation and disciplinary functions.[8, 9]

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 Australian Standard 5182:2018 – Vendor Credentialling for Healthcare Facilities, and to cooperate fully with the Code Authority's Monitoring activities and Complaints handling process.[10, 11]

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.[12]

Compliance with the Code requires that Member Companies take reasonable steps to ensure that an entity that represents, or acts on behalf of the Company, conducts themselves in a manner consistent with the requirements of the Code.[13]

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[8] **FAQ**: 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.

[9] **Explanatory Note**: 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.

[10] **FAQ**: If a Company uses distributors, resellers, intermediaries, consultants or agents, do they have to follow the Code? Yes. Compliance with the Code requires that MTAA Member Companies take reasonable steps to ensure that an entity that represents or acts on behalf of the Company conducts themselves in a manner consistent with the requirements of the Code.

[11] **FAQ**: 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.

[12] **FAQ**: 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.

[13] **Explanatory Note**: For example, if an MTAA Member Company engages a non-member distributor to sett and/or market its products, the Member Company should take reasonable steps to ensure that any actions taken on its behalf are consistent with the Code. Similarly, if (for example) a related corporate entity of the MTAA Member Company undertakes activities in Australia (for instance, pays for an educational event directly), reasonable steps should be taken to ensure that this activity is consistent with the requirements of the Code, whether or not there has been direct involvement of the local MTAA Member Company entity.

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:

- to provide, nor shall it be construed as providing, legal advice, or
- 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.[14]

EXPLANATORY NOTES AND FREQUENTLY ASKED QUESTIONS

The accompanying Explanatory Notes and Frequently Asked Questions (FAQs) – provided as footnotes – 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.

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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,[15]

b) not be misleading or deceptive, or likely to mislead or deceive,

[14] **FAQ**: In the event the Code and the Company's code contradict, which code should prevail? It this were to occur, the code with the stricter requirement or higher standard should prevail.

[15] **Explanatory Note**: 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 1989
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 (Therapeutic Goods Advertising Code) Instrument 2021. 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.

c) reflect a high standard of social responsibility and conform to generally accepted standards of good taste,[16]

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[17, 18]

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[19], 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.

[16] **FAQ**: What are generally accepted standards of good taste? Advertising/Promotional claims should not contain anything that would or would be likely to cause offence, or be insulting, demeaning or indecent, taking into consideration prevailing community standards.

[17] **Explanatory Note**: 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.

[18] **Explanatory Note**: 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. Selectively inserting abstracts into an Advertisement which do not accurately reflect the results of the study has the potential to mislead by omission or implication.

[19] **Explanatory Note**: Supporting evidence must be made available to Healthcare Professionals, Industry Members and, where appropriate, Consumers within 10 working days of their request. 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.

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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.[20, 21, 22, 23]

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.[24]

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[20] **Explanatory Note**: 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.

[21] **Explanatory Note**: Legal obligations when engaging in comparative advertising: There is no specific prohibition against comparative advertising under Australian law. But comparative advertising will be subject to the general prohibition on misleading and deceptive conduct and false and misleading representations contained in the Australian Consumer Law*, AANA Code of Ethics^, the TGA Advertising Code**, and the MTAA Code^^.

*Schedule 2 to the Competition and Consumer Act 2010 (Cth)
^Section 1 of the Australian Association of National Advertisers Code of Ethics.
**Section 9(b) of the Therapeutic Goods Advertising Code (No.2) 2018.
^^Clause 1.2(b) of the Medical Technology Industry Code of Practice by the Medical Technology Association of Australia.

This means that comparative advertising must not be misleading or deceptive (or likely to mislead or deceive) or contain a misrepresentation, which is likely to cause damage to the business or goodwill of a competitor. The consequences of getting a comparative advertising campaign wrong can be severe. There are substantial penalties as well as other orders which can be made including expensive corrective advertising, and of course, bad publicity***.

***Breaches of the Australian Consumer Law of up to $1.1 million, breaches of the MTAA Code up to $50,000.

[22] **Explanatory Note**: A company must not mislead Healthcare Professionals about the results of a comparison. The nature and scope of the comparative claim must be clear to an audience when viewing a comparative claim. A Company must ensure its representations are truthful, accurate and provide references to further information that is relevant to the content.

[23] **FAQ**: 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 factual, balanced, valuable and accurate information comparing products for the benefit of HCPs and their patients. Graphical or visual comparisons should be accurate and appropriate. Comparisons may be:

- direct or express ("product A has more features than product B" or "product A is cheaper than product B"); or
- indirect or implied (product A is "number 1", or "the best" or "the cheapest" or "the fastest" or the "most efficient" or "longer", "better" or "faster"), provided that strong evidence is supplied to support the claim(s) as specified in this clause.

[24] **FAQ**: 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.

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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.[25, 26, 27]

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.[28]

1.5 Specific Information Required

a) Advertising of any Medical Technology 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 Medical Technology entered in the Register) or the Company Representative (for Medical Technology that is not entered in the Register or is not required to be entered in the Register), and

(iii) any other information required by law or as a condition of grant of a licence.[29]

b) Advertising of Medical Technology that is entered in the Register must only include Claims consistent with the Medical Technology's registration, listing or inclusion in the Register.

c) Advertising of Medical Technology that is not entered in the Register must:

(i) include a clear statement that the Medical Technology is not entered in the Register,

(ii) not make any definitive statement as to the date that the Medical Technology will be entered in the Register, and

(iii) only make Claims consistent with the Medical Technology's intended purpose.

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[25] **FAQ**: Can product features be compared? Yes, product features can be compared but a Company must ensure that all material features of the products are included so that the comparisons are fair, balanced and accurate. Any graphics or diagrams must also be fairly and accurately presented.

[26] **FAQ**: How can bench testing be used to compare products? Bench testing data can be used if the data is strong enough to support the claim being made and the products are subject to the same and appropriate testing. For example, a Company can't rely on bench testing to make patient outcome claims as these require clinical studies. When using bench test data, the claims should only be based on parameters of the Medical Technology itself.

[27] **FAQ**: Can different studies be used to support a comparative claim? Yes, but the data must always be comparable to be able to compare the results side by side. This means a Company must use similar testing parameters for bench testing or a statistically adjusted indirect comparison for clinical trials. If the trials are not the same or the differences have not been appropriately accounted for then using a graph with the results of two separate studies side by side would be misleading. It must be immediately clear for all graphs and in the main body of any claims if the results are from separate studies (footnotes will not be acceptable). A qualifying statement must also be made to indicate that substantiating data arose from separate studies.

[28] **Explanatory Note**: 'Hanging' comparative claims should not be used. Examples of 'hanging' comparatives include those that merely claim a product is better, stronger, or more widely prescribed; as it doesn't answer the question "better, stronger etc. than what?".

[29] **Explanatory Note**: The TGA does not currently prohibit the advertising of unregistered Medical Technology directed exclusively to Healthcare Professionals (see s 422AA). While MTAA would like to ensure members are not unreasonably restricted from discussing emerging technologies in advertising directed exclusively to Healthcare Professionals, we would urge members to take care when advertising such products. Wherever possible, members should have robust internal processes in place to ensure that such advertising is reviewed internally prior to any release, publication and dissemination.

d) 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.

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

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 Use of Social Media by Companies[30]

a) All Social Medial activity undertaken by Companies that is Advertising must comply with the provisions of the Code as it relates to Advertising.

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.[31]

c) Companies must ensure that Social Media content created by the Company that is not directed exclusively to Healthcare Professionals:

(i) does not relate to Medical Technology that is not entered in the Register, and

[30] **Explanatory Note**: When creating, initiating or hosting content for publication on Social Media or on Company-controlled websites, Companies need to remain aware that Advertising and other Promotional activities on Social Media and their websites must company the TGA Act and Rules, and the Therapeutic Goods Advertising Code (TGAC). Where Advertising or other Promotional content, by virtue of the TGA Act and/or TGAC, is not permitted to be published to the general public, Companies must ensure that such content is directed exclusively to Healthcare Professionals and all the provisions of Part 1 of the MTAA Code of Practice shall apply. For further guidance on Advertising on Social Media, Companies may refer to the TGA's *Social Media Advertising Guide*. For further information on how to direct Advertising exclusively to Healthcare Professionals, whether on Social Media or Company-controlled websites, Companies may refer to the TGA's guidance at *Advertising to Healthcare Professionals*. Companies should contact the TGA directly if they have questions on whether specific content can be published to the general public or whether it must be directed exclusively to Healthcare Professionals, on Social Media or on Company-controlled websites, or otherwise.

[31] **FAQ**: What should companies include in their social media policies and procedures required under the Code? Companies should consider including (at least) the following in their social media policies:

- Mechanisms for ensuring social media advertising relating to Restricted Medical Technologies is exclusively directed to HCPs
- Written policies and procedures for ensuring social media advertising is not misleading, does not include unregistered or off-label products or uses and complies with the requirements of the Code and other applicable Laws and Regulations
- Processes for monitoring comments sections and removing and/or correcting inaccurate information.

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 media promotions directed to Health Care Professionals. A pop-up box is insufficient for this purpose.

(ii) only contains information in line with approved indications for use of a Medical Technology.[32]

d) Any content or activities on Social Media sites that the Company controls or creates is the responsibility of the Company.

e) Any content on Social Media provided by a Company to a third-party (such as distributors, agents or consultants) to use online should comply with all relevant provisions of the Code, including the provisions of 1.7.

1.8 Content Hosted Online

This section refers to Company-controlled websites intended for use within Australia and hosted online in Australia.[33]

a) Any content on a Company-controlled website that is Advertising must comply with the provisions of the Code as it relates to Advertising.

b) Any mention of and/or links to other sources or websites on a Company-controlled website are the responsibility of the Company.

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[32] **FAQ**: How do companies ensure that social media or digital/online promotions exclusively directed to HCPs cannot be accessed by the general public? With public social media networks such as Facebook, Twitter or LinkedIn, there is not existing way to restrict access to verified HCPs for posts. For this reason, these forms of social media are usually not appropriate for advertising Restricted Medical Technology. Disclaimers on posts are not adequate for restricted medical devices. A private verified group within Social Media platforms may be able to be restricted to HCP audience, there must be an authenticated HCP process for this to occur. For other digital advertising, such as website promotions or company-owned social media platforms directed at HCPs, these should have a login in mechanism that can only be accessed by verified HCPs – for example by requiring HCPs to log in with their AHPRA number. Health workers without an AHPRA registration number (e.g. professionals not regulated by AHPRA or procurement officers in hospitals) may present challenges in establishing health professional status, especially if they are operating outside of a hospital or clinic setting. In these cases, a declaration from the worker themselves and/or their employer may be necessary. A pop-up is not sufficient. Click here to access the TGAs guidance document on Advertising to health professionals.

[33] **Explanatory Note**: How to identify the allowed information for different digital channels: risk considerations - It is important to understand what content is appropriate for different digital channels and the respective audience. All laws and regulations in this regard must be compliant in the same way as for other media. Member companies should ensure that information on their digital channels is up-to-date and should clearly display, for each page and/or item, as applicable, the date when the information was posted or updated. The following questions can be useful to assess risks associated with digital communication and appropriateness of digital channel content, access, set-up, and maintenance:

- What is the objective of the communication (promote, inform, exchange)?
- What content will be made available on the digital channel?
    - Is the content related to products?
    - Is the content promotional or non-promotional?
    - Is the content related to disease awareness?
    - Is the content related to healthcare information, e.g. in connection with diagnosis, treatment education, dietary support?
    - Is the role of the company providing/developing the content clear?
- Who is the intended audience? e.g. employees, the general public, HCPs or a combination?
    - Is verification of the audience required?
    - If yes, how is it done?
    - Are there other access controls in place?
    - Has the company added a statement about the intended audience (e.g., "This site is intended for Australian Audience only")?
- What is the digital channel standard set-up?
    - Is the digital channel open to audience reaction such as sharing, commenting, exchanging?
    - How is the information cascaded across the digital channels (company sourced, medical journals, news, blogs)?
    - Is the digital channel an open platform or the platform has the feature to create closed audiences?
    - Are there limitations in content size (e.g. Twitter)?
    - Are there any community guidelines applicable (e.g. Facebook, YouTube)?
    - How is the information about the channel audience processed?
- How is the content reviewed, approved, maintained, and monitored including by the company?
- Who controls, owns, or operates the digital channel?
- What are the potential limitations of each channel and the caveats to add for the users (for example, geo-targeting, addressing online influencer interactions)?
- What is the company's role and responsibility in cases where the content on digital channels is accessible in countries where such content is not permitted (for instance, differences in approval status, etc.)?

c) A Company must ensure these sources and/or websites are appropriate and will enhance appropriate prescribing, disease awareness and the provision and use Medical Technologies in Australia.

d) When a Healthcare Professional 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 or legal requirements in Australia.[34]

e) 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.

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2. INTERACTION WITH HEALTHCARE PROFESSIONALS

2.1 Geneal 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 Australian Standard 5182:2018 – Vendor Credentialling for Healthcare Facilities is a requirement of the Code.[35]

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:

[34] **FAQ**: Should multinational companies be concerned that global online or social media advertising that can be seen in Australia? Companies should be conscious of the global nature of social media networks and online advertising. Material that complies within one jurisdiction's regulatory requirements may not be appropriate in other jurisdictions and could potentially breach overseas laws. Companies should ensure they are not locally directing Australian HCPs to global content that is not appropriate. Companies should be aware that employees posting/ reposting global content that does not meet Australian regulatory requirements could possibly breach local laws and restrictions.

[35] **Explanatory Note**: MTAA Member Companies can apply to be 'certified' as complying with AS 5182:2018. The certification process requires companies to complete a detailed questionnaire, which is then reviewed by the MTAA Code Monitoring Committee for completeness and accuracy; companies may be asked to provide additional information to verify their claims in certain cases. Once the Code Monitoring Committee approves an application, the company will receive a certificate of compliance, which will be valid for a period of up to two years. Please note, while certification is not a requirement of the Code, Member Companies that choose not to be certified are not exempt from the requirement to comply with AS 5182:2018.

(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.[36]

[36] **Explanatory Note**: During presentation to Healthcare Professionals at Company-initiated or Company-led sessions at Third-Party Sponsored events or conferences, representatives acting on behalf of or engaged by Companies may share information with Healthcare Professionals that is not directly related to a Medical Technology or to the treatment of a medical condition, provided:

- the person presenting the information holds all relevant qualifications and is suitably qualified to present on the relevant topic,
- the information is materially relevant to the subject of the presentation or to the aims of the event or conference,
- the information is not of a type that a Healthcare Professional would otherwise be required to pay for such that the provision of such information amounts to a prohibited gift and/or provision of entertainment (e.g. financial advice), and
- the presentation of such information is incidental to the main purpose of the event and doing so would not take up an inordinate or inappropriate amount of time.

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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.

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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.[37]

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 reasonable rates.

(b) A Trade Display must[38]:

(i) not display Advertising that does not comply with Clause 1 of the Code,

(ii) prominently identify the Sponsor or Company Representative of any Medical Technology that is the subject of the Trade Display,

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[37] **FAQ**: 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.

[38] **Explanatory Note**: The notice required by 2.3.5(b)(ii) and 2.3.5(b)(iii) should be in sufficient proximity to the Medical Technology or any promotional or educational material provided about the Medical Technology. As an example, it is not considered sufficient to have:

- the Medical Technology on the far-left side of a conference booth, and the notice on the far-right side of the conference booth, or
- the notice is shown quickly for 3 seconds at the end of a rolling electronic display after the image of the Medical Technology is shown.

For further information, companies should refer to the TGA's guidance on "Prominently Displayed or Communicated Information, which is available here: Applying the Advertising Code rules: prominently displayed or communicated information | Therapeutic Goods Administration (TGA). Companies should always be cognisant that Third-party conferences may include attendees who are not Healthcare Professionals and that the TGA prohibits the promotion to consumers of Medical Technology that is not entered in the Register. Companies should consider the mix of conference attendees when assessing how to display a Medical Technology that is not entered in the Register.

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(iii) If the Medical Technology is presented for examination, demonstration or display and is not entered in the Register, include a prominent notice stating that the Medical Technology is not entered in the Register, and is not available for general supply,

(iv) 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

(v) 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[39, 40]

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.

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[39] **FAQ**: Our company has engaged an HCP as a consultant as a presenter for educational videos about our products, however, our legal department has reviewed the videos and advised that the videos appear to be promotional. Does the Code allow an industry member to engage an HCP under a consultancy agreement to promote products to other HCPs whether they are on videos for circulation or for other face to face promotional meetings? The Code prohibits engaging an HCP as a consultant as a means of promoting a product to that HCP. The Objectives and Scope of the Code aim to "help Companies maintain trust and confidence in the industry through transparency and accountability". Therefore, in the interest of maintaining transparency, if an HCP is engaged as a Consultant to promote the company's products (however the promotion is delivered), then the nature of the relationship must be disclosed, and the promotion must be compliant with the relevant Laws and Regulations.

[40] **Explanatory Note**: There must be a legitimate need for HCPs to act as consultants for Companies. A legitimate need arises when a Company requires the services of a Health Care Professional to achieve a specific objective, such as:

- the need to train Health Care Professionals on the technical components of safely and effectively using Medical Technologies
- the need for clinical expertise in conducting product research and development, or
- the need for a physician's expert judgment on clinical issues associated with Medical Technologies.

Designing or creating an arrangement to generate business or to reward referrals from the contracted Health Care Professional (or anyone affiliated with the Health Care Professional) are not legitimate needs for a consulting arrangement. Developing a relationship with an HCP or generating potential business is not a legitimate reason for obtaining consulting services. Companies should not pay an HCP for services with the intention of influencing the HCP. Companies should be aware of the aggregate amount paid to an HCP and how it might be perceived when engaging the HCP for additional activities.

e) A Company may pay the Healthcare Professional reasonable compensation for performing services as a Consultant consistent with Fair Market Value.[41, 42]

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

[41] **FAQ**: When determining whether a Health Care Professional is qualified to serve as a consultant, is it appropriate to consider the Health Care Professional's subjective abilities, for example his or her recognition as an expert or thought leader on the specific topic? Yes. There is no single method of evaluating a Healthcare Professional's qualifications to serve as a consultant. A Company may take into account objective factors, such as number of years of practice, familiarity with the Company's products, educational and training background, or geographic location, among others. A Company may also take into account subjective factors, such as recognition as a thought leader or the ability to effectively deliver training content. A Company may weigh these factors differently in making consultant selections, depending upon the type of consultant the Company needs and the type of services to be delivered. For example, a Company may consider educational background and clinical experience to be important factors when engaging an HCP to perform clinical research or a Company may consider recognition as a thought leader as a critical factor for some types of HCP consulting services.

[42] **FAQ**: How can a Company establish "fair market value" for goods or services? There are different valuation methods that may be used to establish fair market value. For example, many third-party vendors or other experts can assist a Company in developing an approach to assessing fair market value compensation. In all instances, a Company should use a method that incorporates objective criteria – for example, a Health Care Professional's specialty, years and type of experience, geographic location, practice setting, the type of services performed, etc. A Company is encouraged to document its method(s) for evaluating whether compensation reflects the fair market value of the services provided. Please refer to the Fair Market Value table provided in the Appendices of the Code.

(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, [43, 44, 45, 46]

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,[47]

d) is modest in value,[48]

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

[43] **Explanatory Note**: 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.

[44] **FAQ**: 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.

[45] **FAQ**: 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.

[46] **FAQ**: 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.

[47] **FAQ**: 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.

[48] **FAQ**: 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 offshore. 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.

g) does not involve delivery of food or beverages to a Healthcare Professional's home location.[49]

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[50]

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.[51, 52, 53]

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.[54, 55]

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.

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[49] **Explanatory Note**: Delivery of food or beverages to a Healthcare Professional's home location is prohibited because in this circumstance the recipient of the hospitality cannot be verified.

[50] **Explanatory Note**: 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.

[51] **FAQ**: 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.

[52] **Explanatory Note**: Any such educational item must have a market value of no more than $100 and be of an educative nature. The limit of $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.

[53] **FAQ**: 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.

[54] **FAQ**: 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 maybe of some interest to the HCP but doesn't make the items themselves an educational item.

[55] **FAQ**: 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.

f) Medical Technology Samples 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, and must be provided in accordance with a written agreement.

(i) For single-use products, including consumables, the quantity supplied should not exceed what is reasonably necessary to conduct an adequate evaluation.

(ii) For multi-use products, the evaluation should be limited to the time reasonably required for proper assessment and sufficiently documented to outline the evaluation period and terms agreed for the return or retention of any Medical Technology Samples.

g) For the avoidance of doubt, this clause does not preclude the legitimate practice of providing to Healthcare Professionals appropriate Medical Technology Samples for genuine Training and Education or Medical Technology evaluation purposes.

2.8 Competition for Healthcare Professionals[56, 57, 58]

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
(D) 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[59]

A Company may provide research grants, educational grants, and Charitable Donations provided that the Company:

[56] **FAQ**: 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 2.8 of the Code: Competitions for Healthcare Professionals.

[57] **Explanatory Note**: 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. The prize must comply with clause 2.7 and the entry must not be dependent on ordering or using a particular product.

[58] **FAQ**: 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.

[59] **FAQ**: 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 2.9.3 allows educational grants for genuine medical education programs with an academic affiliation. The clause should not be used to circumvent clause 2.3.2's prohibition on companies funding HCPs directly to attend third party conferences. Clause 2.9.3(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 2.9.1(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).

a) adopts objective criteria for providing such grants and Charitable 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 Charitable 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 Charitable 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 Charitable 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. [60]

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 Charitable Donations.

[60] **Explanatory Note**: 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.

b) Charitable 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 or philanthropic cause.

c) A Company must not make a Charitable Donation 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.

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.[61, 62]

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.

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3. COMPANY REPRESENTATIVES

3.1 General

A Company must:

a) ensure that its Company Representatives are fully aware of the provisions of the Code.[63]

[61] **FAQ**: 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 2.10 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.

[62] **FAQ**: Do the general requirements for educational grants at clause 2.9.1 (a) apply to fellowship grants given by companies? Yes. Fellowship grants given by companies under clause 2.10 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 2.9.1 (a).

[63] **Explanatory Note**: 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.

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 Australian Standard 5182:2018 – Vendor Credentialling for Healthcare Facilities.

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).[64, 65]

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.

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[64] **FAQ**: 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.

[65] **Explanatory Note**: 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.

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.[66, 67]

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.[68]

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.[69]

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

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[66] **FAQ**: How can a company establish that consent has been provided by the patient for the company to discuss a request for assistance with a prescribed Medical Technology? An appropriately qualified Company Representative should establish the relationship between the enquirer and the patient, on a case-by-cases basis.

[67] **Explanatory Note**: There are circumstances where a patient or their representative (e.g., parent, carer, or guardian) may seek advice on the usage of a Medical Technology that has already been prescribed. In these circumstances, it is appropriate for the company to provide such information according to the requirements of this clause.

[68] **Explanatory Note**: In this context, Promotion means encouraging the patient or their representative (e.g., parent, carer, or guardian) to use the Medical Technology in a manner that has not been prescribed.

[69] **Explanatory Note**: 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.

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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.[70]

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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,[71]

(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.

[70] **Explanatory Note**: 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.

[71] **Explanatory Note**: It is important for both parties to maintain confidentiality at this early stage during inter-company dialogue because of the potential for reputational risk.

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.[72]

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

[72] **Explanatory Note**: 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.

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 Appeals 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).

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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.

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.

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.

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.[73]

[73] **Explanatory Note**: 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, and
- if the previous imposed sanction was a Moderate Breach, it becomes a Severe Breach.

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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.

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8. 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.

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9. 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.

g) This Edition 14 of the Code replaces and supersedes all previous editions.

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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.
Charitable Donation	A Charitable Donation is the provision of cash, equipment, Member Company products including Medical Technologies, or relevant third-party products, intended solely for charitable or philanthropic purposes and/or to support a charitable or philanthropic cause.
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 the MTAA Code Monitoring Committee of compliance with the Code.
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 in Training	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.
Sample	A Medical Technology Sample is a single or multi-use Medical Technology provided at no cost by or on behalf of a Member Company to healthcare organisations or Healthcare Professionals (HCPs) who are appropriately qualified and equipped to use them. These Samples are intended solely to enable HCPs to become familiar with the Medical Technology and/or related services in a clinical setting. Medical Technology Samples do not include: - Demonstration products: This includes Medical Technology not intended for clinical use, resale, or transfer, and used solely for training or education purposes for HCPs or patients. - Products provided under other arrangements: This includes items supplied as part of a Charitable Donation, research or educational grant, clinical trial, or as part of a commercial supply agreement (e.g. bundled at no additional cost, provided under a discount, or as warranty replacements.)
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.
Australian Standard 5182:2018 – Vendor Credentialling for Healthcare Facilities	AS 5182:2018 is an independently developed, comprehensive, and fully separate set of standards for appropriate conduct by Company Representatives entering Healthcare Facilities in Australia that MTAA members are obliged to comply with as a condition of membership; that is to say, in addition to other requirements of the Code.
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.

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