# Pathology Technology Industry Code of Practice

Edition 4

December 2021

Administered by Pathology Technology Australia

PATHOLOGY TECHNOLOGY AUSTRALIA

# VERSION HISTORY

| Version | Description of Change | Contributors | Effective Date |
|---|---|---|---|
| **Edition 4** | **Inclusion of Code Commissioner and removal of Code Committees.**<br>**Inclusion of Vendor Credentialing and accreditation as per AS5182 2018** | **CEO and Code Commissioner** | |
| **Edition 3** | Formal Review | Code Administration Committee<br>Pathology Technology Australia Board of Directors<br>Pathology Technology Australia Members | September 2018 |
| **Edition 2.2** | Cosmetic formatting | CEO | April 2017 |
| **Edition 2.1** | Cosmetic formatting | CEO | September 2015 |
| **Edition 2** | Formal Review | Code Administration Committee<br>Code Complaints Committee<br>Pathology Technology Australia Board of Directors<br>Pathology Technology Australia Members<br>External Stakeholder Consultation | October 2013 – September 2015 |
| **Edition 1** | | | 2009 – September 2013 |

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# Part A

# Introduction to the Code

# 1. STATEMENT OF HIGH-LEVEL PRINCIPLES

The Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products which is based on genuine consumer health needs and supported by the ethical conduct of all parties. The quality use of therapeutic products means:

a. selecting diagnostic and treatment options wisely based on the best available evidence and the consumer's needs;

b. choosing suitable therapeutic products if this is considered necessary;

c. using therapeutic products safely and effectively; and

d. safe disposal of expired or otherwise unneeded therapeutic products.

The Pathology Technology Australia Code has as its primary objective the maintenance of the trust and confidence of, and accountability to all communities with which its members engage; the effectiveness of which is assessed through the eyes of the relevant community.

Pathology Technology Australia will collaborate with relevant stakeholders in code creation, updating, education, monitoring and compliance.

Pathology Technology Australia recognises the need for health professional codes to reflect the obligation both of industry and of Healthcare Professionals to mutually ensure the ethical promotion of therapeutic products. Pathology Technology Australia is committed to working with the relevant professional associations in its industry sector to achieve this objective.

# 2. BACKGROUND AND PURPOSE OF THE CODE

Pathology Technology Australia was formed in July 2009 with the purpose of providing a vehicle for the promotion of the use of *in vitro* diagnostic medical devices (IVDs) in Australia, to:

- work with the TGA and other relevant government organisations such as Biosecurity Australia (Department of Agriculture, Water and Environment), MSAC, and the Department of Health on matters relating to the regulation and reimbursement of IVDs,
- meet the needs of the Australian IVD Community through representation and professional services.

The purpose of the Code is to ensure high ethical standards and socially acceptable behaviour within the member-base in the *in vitro* diagnostics industry to ensure that Healthcare Professionals, the Regulator and the Australian community have confidence in their dealings with members and their products.

Direct to Consumer advertisements are regulated through the Therapeutic Goods Advertising Code and Pathology Technology Australia Members must adhere to this code in respect of these products.

The Pathology Technology Industry Code of Practice (the Code) sets out the standards appropriate to the various forms of relationships entered into by Pathology Technology Australia Members in their dealings with other parties in the Australian healthcare environment. The Code is not intended to supplant or supersede Australian Federal or State law, regulations or professional codes, including those that may be applied by individual companies. These may impose particular additional requirements upon Members or Healthcare

Professionals who engage in interactions of a professional nature. Generally, the strictest requirement applies in such situations.

All Pathology Technology Australia Members should independently ascertain that their interactions and communications with Healthcare Professionals and the wider community comply with all current Federal and State law, regulations and professional codes.

The Code represents an act of self-regulation in the first instance. Pathology Technology Australia Members should also acknowledge that the Code is to be applied in the spirit, as well as in the letter of the Code.

Members should ensure that employees are familiar with the Code and their obligations to comply with it.

Member Companies may have internal Codes of Conduct prescribed by their parent organisations. While the Code in no way overrides these internal codes, the Code is aimed at providing a "best practice" model that adopters can use to check compliance. The Code is not intended however to override the provisions of any internal code, should that mandate a higher level of performance or a stricter code of behaviour.

In this Edition of the Code, requirements of the Australian Standard AS5182:2018 - Vendor credentialing for healthcare facilities – is added, in line with those of like bodies such as MTAA. The intention is to provide guidance to members and their employees as to the requirements for credentialing of healthcare industry representatives and service providers (HCIRs) entering healthcare facilities (HCFs). In addition, the intention is to monitor compliance of members to this standard and issue certificates of compliance to members who accept and observe all provisions of the Code and the Vendor Credentialing Standard.

Training in AS 5182:2018 will be made available for all members wishing to participate. Certification and compliance cards will be made available to members and their employees upon completion of training and demonstration of ongoing compliance with the Standard.

A copy of the standard can be found in the resources listed in Part E of this Code.

## 3. OBJECTIVES

The Code has been developed with a number of objectives in mind:

a. To provide a framework for minimum standards of behaviour, educating Members, providing self-regulation of the industry and ensuring integrity in the interactions of Members with Healthcare Professionals;

b. To provide guidance on the requirements of AS 5182:2018, Vendor credentialing for healthcare facilities, and certify members and their employees who comply;

c. To provide a mechanism for Code breaches complaint handling;

d. To provide a means for the education of Members as to best practice in respect of interaction with Healthcare Professionals and Members' business associates;

e. To improve compliance by the Australian community in their use of IVD products by providing effective patient protection;

f. To ensure transparency for the Pathology Technology Industry in its dealings with Healthcare Professionals; and

g. To ensure that the reputation of Pathology Technology Australia and its Members is always upheld.

## 4. SCOPE

This Code sets out self-regulatory standards that Pathology Technology Australia members must follow, and all Industry participants are urged to observe. The Code is compulsory for members of Pathology Technology Australia but as a voluntary Industry code it extends to all companies in the Pathology Technology Industry. Self-regulatory standards help to safeguard industry against further imposition of regulation. Industry Codes have a vital function in the broader regulatory framework for ensuring appropriate behaviour by Industry.

There are several Industry codes that apply to different sectors of the therapeutic goods industry. It is the intention that the Pathology Technology Australia Industry Code to apply only to the supply of products. Where there is another therapeutic Industry code that is more relevant in the circumstances, then that code will generally be the more appropriate to follow.

This Code operates under the high-level principles that regulate the interaction of Industry when in the business environment.

These principles are:

a. Members must, and Industry should, at all times comply with the provisions of all relevant legislation;

b. Members must, and Industry should, not engage in unethical behaviour, misleading or deceptive conduct, or unfair or unconscionable practices; and

c. Members must, and Industry should, always respect the ethical requirements and codes of practice which apply to Healthcare Professionals and the Members' business associates.

Therefore, it is intended that the scope of the Code will cover the following:

a. All Pathology Technology Australia Members; and

b. All interactions with Healthcare Professionals and business associates.

Any non-Member involved within the Pathology Technology Industry is also expected and invited to accept and observe the Code because it is considered that the high ethical standards to be followed should apply to the industry, if it is to maintain the confidence of all the stakeholders that it serves.

**Note to the In-Vitro Diagnostics Industry Code of Practice Edition 4, *Clause 4. Scope***

Pathology Technology Australia wishes to advise Members that it has elected not to implement the *direct payment (sponsorship) to HCPs* clauses in the APAC and EU Codes for the third edition of the Code.

International companies should confirm their parent company's compliance with the APAC Code. In situations where the parent company requires adherence to the EU/APAC Code, the company is required to comply.

Please note that the APAC and EU Codes only limit the direct payment (sponsorship) to HCPs to attend 3rd Party scientific meetings. There is no restriction of HCPs being invited and paid for to attend meetings (scientific or commercial) organised and branded by the companies themselves. Sponsorship of 3rd party events such as for conferences dinners or speakers, is not an issue as the fees usually are paid to the conference organiser not to the HCP directly and decisions are made by the conference faculty. Sponsorship of 3rd party conferences is outside the scope of all Codes as companies sponsor the conference, not individuals.

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*Member Companies may have internal Codes of Conduct prescribed by their parent organisations. While the Code in no way overrides these internal codes, the Code is aimed at providing a "best practice" model that adopters can use to check compliance. The Code is not intended however to override the provisions of any internal code, should that mandate a higher level of performance or a stricter code of behaviour.* *Background and Purpose of the Code, p. 6*

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## 5. PRINCIPLES OF INTERACTIONS WITH HEALTHCARE PROFESSIONALS

The requirements are based on the following key high-level principles:

**The Principle of Separation:**

Interaction between industry and Healthcare Professionals should not be misused to influence through undue or improper advantages any purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Members' products.

**The Principle of Transparency:**

Interaction between industry and Healthcare Professionals should be transparent and comply with national and local laws, regulations or professional codes of conduct. Where specific provision is not made, Members shall nevertheless maintain appropriate transparency by requesting prior written notification be made to the hospital administration, the Healthcare Professional's superior or other locally designated competent authority, fully disclosing the purpose and scope of the interaction.

**The Principle of Equivalence:**

Where Healthcare Professionals are engaged by a member to perform a service for or on behalf of a Member, the remuneration paid by the Member should be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional.

**The Principle of Documentation:**

For interactions between a Member and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a member, there should be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member. The activities envisaged by the agreement should be substantiated and evidenced by activity reports and documentation. Adequate documentation such as the agreement, related reports, invoices etc. should be retained by the Member to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

# Part B

# Provisions of the Code

# 6. INTERACTIONS WITH CONSUMERS

Currently, the Pathology Technology Industry has limited interactions with Consumers. However, for certain conditions such as diabetes, pregnancy and for an increasing number of conditions, consumers are able to directly purchase IVD products for their own use in a self-testing mode. Such IVD products may be purchased or obtained directly from Members or via a third party such as a pharmacist, diabetes nurse educator, health practitioner or other retail outlets as permitted by the TGA.

The following principles should be observed in respect of interactions with Consumers:

a. If a member receives a request from a Consumer for advice of a medical or diagnostic nature, the Member must recommend that the Consumer consult an appropriate Health Professional;

b. Advertisements direct to Consumers must comply with the Therapeutic Goods Advertising Code and any other relevant laws and Regulations;

c. A media release to one or more organisations or through one or more channels intended to or likely to result in publication to Consumers that directly or indirectly promotes the use of the product shall be considered to be an advertisement and must therefore conform to this Code and the Therapeutic Goods Advertising Code. Media releases must be issued conditionally upon the publisher ensuring that the release or extracts from the release be published in compliance with the Code and all relevant laws or regulations, including the Therapeutic Goods Advertising Code;

d. Competitions directed at Consumers can only be conducted in relation to products that are the subject of an ARTG entry permitting sale to Australian Consumers;

   (i) To the extent that a competition directed at Consumers comprises an advertisement, it must comply with the Therapeutic Goods Advertising Code and with Clause 6 of this Code;

   (ii) Entry into a competition must not, as a condition of entry, require a consumer to use or purchase a product;

   (iii) The conduct of a competition directed at Consumers must comply in all respects with all relevant laws and regulations.

e. Disease education activities for Consumers relating to IVDs may provide information, promote awareness and educate the public about health, disease and their management.

   i. A disease education activity, prepared and delivered based on sound medical principles, may make reference to the availability of different options for diagnosis or treatment but may not direct the Consumer to purchase a specific *in vitro* diagnostic product where to do so would be in breach of the Therapeutic Goods Act.

   ii. The emphasis of the disease education activity should be on the condition and its recognition rather than on the specific IVD, unless discussion of treatment options directly with the public is permissible under the Therapeutic Goods Act. The appropriate treatment for an individual Consumer following the use of an over the counter IVD is for the Health Professional to decide, in consultation with the Consumer.

f. Funding of Health Consumer Organisations - Pathology Technology Australia recognises and supports positive and beneficial relationships between the *in vitro* diagnostics industry and Health Consumer Organisations. Members may enter into relationships with Health Consumer Organisations with the

objective of enhancing the quality use of IVD technology and pathology testing, that support better outcomes for the Australian community.

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

https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Working-Together-Brochure-2015.pdf

# 7. INTERACTION WITH HEALTHCARE PROFESSIONALS

The Pathology Technology Industry interacts with a variety of customers, including pathologists and other medical practitioners, laboratory scientific and administrative staff, practice nurses and other Healthcare Professionals. The Code is intended to provide guidance on the interactions that Members and Member Representatives have with Healthcare Professionals in the promotion and supply of IVD Products. These interactions can take a variety of forms, including but not limited to:

## 7.1 Product Education, Demonstration and Training

a. Where appropriate, Members may make education and training available to Healthcare Professionals to facilitate the safe and effective use of *in vitro* diagnostics products. Such education and training should take place at an appropriate location bearing in mind the nature of the training and the convenience and availability of the trainers and attendees.

b. Programs and events should be conducted in clinical, laboratory, conference or other settings, such as Members own premises (local or international, if necessary), which are conducive to the educational nature of the training and to the effective transmission of the knowledge, as well as allowing for any "hands on" component.

c. The training staff should have the appropriate qualifications and expertise to deliver the training.

d. Members may provide attendees with modest hospitality in connection with the training. For training programmes necessitating overnight stays, additional hospitality may be appropriate. For such training, the hospitality must be incidental to the main purpose of the training, modest in cost and extent, and provided only to the Healthcare Professionals involved in the training.

e. Members may pay for reasonable travel and accommodation expenses incurred by a Healthcare Professional attending training organised by a Member where such training necessitates overnight accommodation.

f. Members must not, however, pay for travel or accommodation for a spouse, partner or guest of such Healthcare Professional, or for any other person who does not have a *bona fide* professional interest in the information being provided during the training.

## 7.2 Hospitality

Members may only provide hospitality to Healthcare Professionals in conjunction with the provision of training or education or in support of a third-party scientific/medical educational conference (see Clause 7.3). The hospitality should be limited to those who actually participated in the meeting, be modest in nature and not include entertainment. Entertainment includes, but is not limited to, for example, theatre, sporting events, golf, skiing, hunting, and leisure or vacation trips.

## 7.3 Third Party Conferences

Participation in third-party scientific/medical educational conferences is an integral part of the legitimate commercial efforts of IVD companies. These provide an opportunity to launch new products, educate customers about existing products and seek feedback on product performance. They provide a valuable forum for the development of product ideas and for the training of Members and Healthcare Professionals.

They would typically include conferences organised by national, international, regional or local specialised medical or scientific associations or accredited continuing education providers.

Members may choose to support such conferences and meetings in a variety of ways. All such support must be clearly documented outlining the nature and conditions of the support. These would include:

a. Conference Organiser Support – Members may provide financial support to the Conference organisers to cover costs such as reasonable travel and accommodation expenses of Healthcare Professionals and other medical or scientific professionals in training, where the conference is primarily dedicated to objective medical and scientific educational activities. The Conference organisers should be responsible for and control the educational grants to Healthcare Professionals, program content, educational methods and materials used. Support from a Member for such activities should be clearly stated in advance of and at the meeting, and should be acknowledged in the proceedings of the meeting, if published;

b. Hospitality – Members may provide financial support to the conference organisers in the form of payment for meals and hospitality for attendees as decided and selected by the organisers. Such hospitality should be modest and in-line with that normally provided at the venue or at similarly organised and attended meetings. Hospitality provided as part of a satellite or ancillary meeting to the Conference should bear a direct educational relationship to the conference;

c. Faculty Expense – Members may make grants to Conference organisers for reasonable honoraria, and modest travel, accommodation, hospitality and meals for Healthcare Professionals or other individuals who are *bona fide* conference speakers. Selection of such Healthcare Professionals will be the responsibility of the Conference Organiser;

d. Advertisements, Demonstrations and Trade Displays – Members may prepare and display advertisements and lease space from Conference organisers for the purpose of Company displays at such meetings or Conferences. For exhibition booths and symposium panels, there is no need to have the name and address of the Sponsor on display.

e. Documentation – the Conference Organiser and the Member must enter into a written agreement specifying the nature and conditions of the sponsorship or grant.

### 7.4 Sales and Promotional Meetings

a. Where it is deemed necessary for Member employees to meet with Healthcare Professionals to discuss product features, conduct negotiations and arrange sales and deliveries, such meetings as a general rule should be held at a training facility, medical institution, laboratory, or other appropriate facility.

b. In connection with such meetings Members may with the agreement of the Healthcare Professional, provide or pay for modest hospitality for attendees.

c. Members may also provide or pay for reasonable travel costs of attendees to such meetings. For example, demonstrations of non-portable equipment may necessitate travel to the location of the instrument or equipment.

d. However, the Code does not permit the provision or payment of meals, travel or other hospitality for a Healthcare Professional's partner or guest, or any other person who does not have a *bona fide* professional interest in the information being presented at the demonstration or meeting.

### 7.5 Consulting Agreements

a. Healthcare Professionals may serve as consultants to Member companies, providing valuable services including research, participation on advisory boards, presentations at Member-sponsored training and in product development. It is permissible to provide reasonable compensation for such services.

b. Consulting arrangements must be in written form, signed by all parties to the consulting agreement and specify all services, compensation and expenses to be provided under the arrangement. Research-based consultancy should have a written research protocol and all appropriate consents and institutional and ethical approvals should be obtained before commencement of the research.

c. Consulting agreements should only be entered into where a legitimate purpose for the service is identified in advance. Selection of the consultant must be on the basis of their qualification and expertise to provide the service. Meetings with consultants should be held at venues and in such circumstances as are appropriate to the subject matter of the consultation.

d. Compensation must be based on the nature of, and commensurate to, the services provided, and in line with accepted practice. Compensation must not be based on the value of IVD products or services which consultants may use for, or in, their own business or place of employment. Compensation should be paid based on services actually provided and must be in accordance with applicable legislation, including tax legislation.

e. Members may pay for reasonable expenses incurred by Consultants including travel, accommodation, meals and incidentals as part of the performance of their consulting agreement. Such hospitality, however, should be subordinate in time and focus to the primary purpose of the consultation.

### 7.6 Gifts

Members may occasionally provide:

a. Modest gifts to Healthcare Professionals but these must be of an educational nature only

b. Company or Branded promotional items of minimal value (eg notepads and pens) at Trade Displays or Educational and Training Events).

c. Provision of items that may be used for both educational and non-educational purposes must not be provided directly to Healthcare Professionals, but must be provided to the healthcare professional's department or institute clearly stating their educational use. This type of gifting must be fully documented.

d. Gifts must not be in the form of cash or monetary equivalents.

e. The provision of product samples is not considered to be a gift and the provision of reasonable sample product or demonstration product for evaluation purposes is deemed to be an appropriate activity.

### 7.7 Donations & Grants

a. Members may make unrestricted donations for charitable or philanthropic purposes such as supporting independent medical or scientific research, patient or community education or for the sponsorship of

events where the proceeds are intended for charitable purposes. Donations must only be made to Institutions or entities which are able to receive them under applicable laws or regulations and must not be made in order to induce the use of a product or service.

b. Donations may also include unrestricted grants to support medical or scientific education of genuine students, residents, fellows and participants in fellowship programs, which are charitable in nature or have an academic affiliation.

c. Members may make unrestricted research grants to support genuine medical or scientific research where the purpose of the grant is clearly documented, and the research program is administered by an Institution independent of the Member. Members may also make grants to support public education of patients or the wider community in respect of important healthcare topics.

d. All donations and grants should be appropriately documented and acknowledged where appropriate.

e. A donation or grant that is linked to a direct commercial benefit to the Member is a sponsorship (not a donation or grant).

### 7.8 Advertising and Promotion

In promoting or advertising their products and services to Healthcare Professionals, Members must ensure that the following principles are adhered to:

a. Advertisements to Healthcare Professionals (excluding Brand Name Reminders) must contain the following information:

   (i) The brand name of the IVD (where appropriate);

   (ii) The name and address of the Sponsor; and

   (iii) Any other information as may be required by law or as a condition of a licence.

b. Where Claims are made, these must be consistent with the intended purpose of the IVD;

c. The term “safe” should not be used unless clearly qualified;

d. The term “new” may only be used in the first 12 months of promotion;

e. Products and services of other companies or the medical or scientific opinions of Healthcare Professionals should not be disparaged, compared unfairly or treated with disrespect, either directly or by implication. Comparison must be in the context of peer-reviewed publications available in the public domain. Members must be able to substantiate all claims made through reliable, readily available, medical or scientific evidence; and

f. Promotional activities must not be designed or presented in ways that reflect poorly on or reduce confidence in the Pathology Technology Industry.

### 7.9 Company Commissioned Articles (CCA)

a. A Company Commissioned Article must be clearly identified as such.

b. The Sponsor must be clearly identified at either the top or the bottom of the article.

c. Where a CCA is used solely for the purpose of supporting a claim, including a comparative claim, the claim must be referenced accurately. Information in the referenced article must be up-to-date. The referenced article must be produced on request within 21 days.

### 7.10 Competitions

Members may conduct competitions for Healthcare professionals directly or through a third party that comply with the following provisions:

a. The competition must be based entirely on medical or other specialist healthcare knowledge or on the acquisition of such knowledge;

b. All competition prizes must be directly relevant to the practice of medicine or other specialist field of healthcare and be of minimal monetary value or be an item of an educational nature;

c. Entry to the competition must not be dependent on the ordering, recommendation, use, testing, purchase, sale or prescribing of a product; and

d. The conduct of the competition must comply in all respects with all relevant laws and regulations

### 7.11 Market Research

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

a. The market research is clearly identified as such and does not promote a product or reward the participants;

b. Any compensation for Healthcare Professionals is kept to a minimum, is reasonable and commensurate with the amount of work performed; and

c. Where the market research includes a competition or a prize, it complies with clause 7.10

## 8. SOCIAL MEDIA

a. This section applies to advertising on websites (including e-Newsletters accessible via the internet), podcasts and social media directed to Healthcare Professionals.

b. All use of social media by Members in the promotion of IVD products to Healthcare Professionals must comply with the requirements of clause 7.8.

c. Content distributed via social media that directly or indirectly promotes the use of a product shall be considered to be an advertisement and must therefore conform to this Code, the TGAC and all other relevant legislation.

## 9. COMPANY REPRESENTATIVES

a. Members should ensure that Company Representatives are adequately trained and possess appropriate technical knowledge to present information on the company's products in an accurate and responsible manner.

b. Members should also ensure that Company Representatives are aware of the provisions of the Code and have been trained in ethical and professional behaviour in the performance of their duties.

c. Company Representatives must conduct themselves at all times in an ethical and professional manner. They must not offer any inducement or payment or engage in unconscionable behaviour in their dealings with Healthcare Professionals. They must ensure that their meetings are conducted in a professional manner and that their behaviour is at all times reasonable and responsible. The company representative must respect and adhere to workplace policy and expectations of the healthcare professional and/or healthcare organisation or institution. Company Representatives must ensure that their behaviour does not, or does not appear to, compromise the independence or professional integrity of any other Healthcare Professional.

## 10. SHAREHOLDINGS AND/OR OTHER FINANCIAL INTERESTS HELD BY HEALTHCARE PROFESSIONALS IN MEMBER COMPANIES

a. Where a Healthcare Professional owns a material or significant interest in a Member Company, the Member 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 an IVD is made consistent with ensuring the best health outcomes of the Consumer.

b. A Healthcare Professional who owns an interest in a Member Company must disclose that interest to a Consumer where the Healthcare Professional recommends a product that is marketed by that Member.

# Part C

# Administration of the Code

# 11. ADMINISTRATION OF THE CODE

The Code shall be administered by the Code Commissioner, as appointed by the Board of Pathology Technology Australia;

The Code Commissioner administers the Code in conjunction with the Board of Directors. This includes periodic review of the Code, review of the education materials supporting the code and reporting to the reporting annually on Code practices, complaints and outcomes.

The Code Commissioner will accept and hear complaints from Members, non-Members and the public regarding the behaviour of Members and their employees, and to resolve such complaints either by a hearing or via mediation. Appeals against the decision of the Code Commissioner will be heard by the Executive members of the Board of Directors plus the CEO.

**The formal procedures for conduct of complaints and appeals shall be determined by the Board of Pathology Technology Australia and reviewed from time to time to reflect best industry practice. The procedure shall be disseminated to members and published on the Pathology Technology Australia website on the page dedicated to the Code of Practice.**

# 12. CODE COMMISSIONER APPOINTMENT

## 12.1 Appointing the Code Commissioner

The CEO and Board of Pathology Technology Australia shall be responsible for appointing a suitable Code Commissioner. The Code Commissioner as far as possible will have the following attributes:

a. An independent Commissioner, who is not currently employed by a member or non-member company in the Pathology Technology supply sector;

b. Must have deep knowledge of compliance requirements in the healthcare sector;

c. Has previous experience in business in healthcare;

d. And, preferably has training in compliance accreditation or assessment and or business compliance training.

## 12.2 Term of the Code Commissioner

The term of appointment shall be for two years, following which the Board can extend the appointment two years at a time.

# 13. CODE COMMISSIONER DUTIES

The Code Commission shall be responsible for the following:

- Review of the Pathology Technology Australia Code of Conduct once every 2 years. If not meeting industry best practice, shall suggest revision to the Board.
- Accept and investigate all complaints of Code violations. Refer these to the Board for any remediation action, once investigated.

- Be available to assess member company Codes to determine if they meet thresholds set in the Pathology Technology Australia Code.
- Contribute a Code of Conduct report to Pathology Technology Australia's Annual Report. This report should cover a summary of any complaints investigated during the year and a summary of any review activities.
- Report to the Board of Directors on Code activities at least once per year.
- Liaise with the CEO on training or remediation requirements for member companies.

# 14. PUBLISHING OF COMPLAINTS

## 14.1 Publishing of Complaints

a. Pathology Technology Australia shall publish the outcomes of every (and only) upheld complaints after the complaint (and appeal, where relevant) is finalised.

b. The details published shall include a minimum of:

   i. the name of the product and parties identified in the complaint (except where the Complainant has requested that their name be withheld);

   ii. the nature of the complaint;

   iii. the breaches of the Code that have been determined by the complaints process or by subsequent appeal;

   iv. the sanctions, if any, imposed by the Code Commissioner;

c. The details published shall not include any confidential information where good reason for withholding the information is provided by either party.

d. The complainant's name will not be published without permission.

# 15. CODE SANCTIONS AND ENFORCEMENT ACTIONS

a. In order for the Code to maintain credibility with and compliance by signatories and to engender stakeholder confidence in the industry and its Code, it is necessary that commercially significant sanctions be available to the Code Commissioner. Sanctions will reflect the nature, seriousness and frequency of the breach.

| **Severity of Breach** | **Potential Implications** |
|---|---|
| **Minor Breach** | No safety implications to consumers<br>No effect on how consumers or Healthcare Professionals view the product, its competitors, the industry or its companies |
| **Moderate Breach** | No safety implications to consumers<br>Will have adverse impact on the Pathology Technology Industry in Australia, such as impact on the perceptions of the consumer or Healthcare Professionals regarding the product, its competitors, the industry or its companies |
| **Serious Breach** | Safety implications<br>Major adverse impact on the complementary healthcare industry in Australia, such as a major impact on how consumers or Healthcare Professionals view the product, its competitors, the industry or its companies |
| **Repeat Breach** | When the same or a similar breach is repeated in the promotion of either a particular product, or any product of a company, which had been found to be in breach of the Code within the preceding 24 months<br>May have safety implications<br>Adverse impact on the Pathology Technology Industry in Australia, such as impact on how consumers or Healthcare Professionals view the product, its competitors, the industry or its companies |

b. Where the Code Commissioner finds that a Member has breached the Code, the Commissioner must apply one or more of the following sanctions:

i. Censure and/or warning from the Commissioner. This may include a notification to Professional Associations of the nature of the breach;

ii. Written provision of an assurance from the offending party that they will institute immediate action to remedy the breach, and a written assurance regarding ongoing observance of the Code;

iii. Corrective advertising and /or a retraction to be published as directed by the Code Commissioner;

iv. Destruction of offending material such as advertisements, pamphlets or brochures;

v. In the event of serious and/or repeated breaches, a monetary fine to a maximum of $75,000;

vi. Publication of the result of the Commissioner's deliberations on the Pathology Technology Australia website.

**c.** In the event of continued or repeated breaches of the Code by a Member or failure to comply with an imposed sanction, the Board of Pathology Technology Australia reserves the right, on the recommendation of the Code Commissioner, to institute proceedings for the expulsion of such Member under Clause 12c of the Pathology Technology Australia Constitution.

# 16. APPEALS

## 16.1 The Appeals Committee

a. A Member who has been found to have breached the Code, or a Complainant who has had a Complaint dismissed, shall have the right to appeal against the findings or any sanctions imposed.

b. The CEO or their delegate shall convene the Executive of the Board of Directors, plus a qualified Lawyer to act as Chair of the Appeal Committee (AC) to hear the appeal.

c. Prior to convening the AC, the CEO or their delegate must determine if any proposed Member has an actual or perceived conflict of interest. No panellist may sit on AC if he or she has a conflict of interest or perceived conflict of interest in the subject matter or with a party that is the subject of the appeal;

d. The entire AC must be present to hear and adjudicate any deliberations for an appeal.

e. The AC must make decisions by a majority of its Members.

f. The AC must consider only the matter that was previously submitted to the Code Commissioner, together with the appeal papers and any associated response by the Complainant or Respondent, including:

   i. the material that was considered by the Code Commissioner in the matter;

   ii. the appeal papers and any response from the respondent to the appeal; and

   iii. any additional material which the AC reasonably believes will assist in its deliberations.

g. The AC may not consider whether the appellant company has breached sections of the Code that were not considered by the Code Commissioner.

h. The findings of the AC are final and binding on the parties.

i. The deliberations of the AC are confidential and must not be disclosed by any party or by a Member of the AC.

j. The Appellant may be required to lodge a bond if financial penalty was imposed in the original Code Commissioner decision. If unsuccessful in appeal, the Appellant must reimburse Pathology Technology Australia for its costs including out-of-pocket expenses, legal costs and reasonable expenses associated with the determination of the Appeal, unless the AC determines otherwise. Alternatively, the AC may require such costs to be shared by the parties in proportions determined by the AC.

# 17. DISCLAIMER

a. This Code is not intended to provide, nor shall it be construed as legal advice.

b. Where there is any conflict or inconsistency between the provisions of this Code and any Commonwealth, State or Territory legislation or instruments, that legislation or instrument will take precedence over this Code.

c. Pathology Technology Australia and all committees established under this Code will at all times seek to exercise their powers and functions hereunder in a fair, impartial and objective manner for the benefit of

no one Member, but rather for the overall greater good and benefit of the Pathology Technology Industry and the wider community generally.

d. The rules of conduct and the standards of good practice imposed upon Members by this Code are fair and reasonable and are otherwise necessary for this Code to achieve its objectives.

e. The powers granted to Pathology Technology Australia and the committees established under this Code, particularly but without limitation as they are related to complaints handling, sanctions, enforcement action and appeal procedures, are fair and reasonable and otherwise necessary for this Code to achieve its objectives.

f. All Members are deemed to have released Pathology Technology Australia, its servants, agents, consultants and all committees established by Pathology Technology Australia under this Code from all claims, demands, actions, suits or proceedings which a Member might otherwise have brought or have been entitled to bring against all or any of the released parties, for or in relation to any act or omission taken by one or more of them, in the exercise of their functions or duties under this Code.

# Part D

# Vendor Credentialing

## 18. VENDOR CREDENTIALING TO AS 5182:2018

a) The vendor credentialling concept was first discussed in 2016. Pathology Technology Australia (Then known as IVD Australia) engaged fully in the establishment of the Standards Australia process to create AS5182:2018 Vendor Credentialing for Health Facilities.

The Australian Standard 5182:2018 sets out the expectations for vendors and service providers, their employees and contractors, entering Australian Health Facilities. A link to the Standard is provided in the resources in Part E of this Code.

At that time PTA engaged with a number of state health authorities and facilities to reach an agreement whereby members of PTA had automatic vendor credentialing recognition. This was by members signing onto and adhering to our Code of Conduct and the requirements on the Standard. It soon became clear that Vendor Credentialing was a very low priority for state health facilities and there was not recognition or standardisation amongst states on their approach.

However, recently, 2 states have established relationships with third party service providers who have offered to run state-wide vendor credentialling services. These providers charge a fee to vendors for this service, and it is anticipated that vendors will need to pay a similar fee in each jurisdiction where these services are offered.

b) PTA and MTAA have agreed to establish our own vendor credentialing processes, to AS5182:2018, via our respective Codes of Conduct, to and certify our members accordingly.

Members who have employees engaged in activities that require them to attend customer sites, especially healthcare facilities, should be familiar with the Standard (see Compliance AS:2018 and Monitoring, below).

## 19. MEMBER OBLIGATIONS UNDER AS 5182:2018

a) When joining Pathology Technology Australia, members agreed to observe and adhere to this Code of Conduct, which now includes the obligations under AS5182:2018.

The objective of the Standard is to provide the following benefits for healthcare providers:

i. Appropriately safeguard the health and safety of patients, residents, and staff.

ii. Ensuring that vendor representatives attending restricted areas of healthcare facilities have the appropriate immunisations, background, education and training.

iii. Minimize the risk associated with allowing vendor representatives to visit restricted areas.

    a. Manage vendor credentialing in an efficient and cost-effective manner.

iv. The objective of the Standard is to provide the following benefits for

    Vendors:

v. Vendor complies with terms and conditions of their customer's contract

vi. Vendor has a single periodic credentialing attestation requirement for all healthcare organisations who adopt the Standard

b) Independent of the Obligations set out in AS 5182:2018, members must also undertake to ensure their employees comply with any and all state, territory and commonwealth mandates for vaccination against communicable infections. As part of the certification process, members will be required to confirm the

vaccination status of their employee base in customer facing positions. Proof of vaccination status (as and when required by state, territory and commonwealth authorities) must be available and provided on request as part of the accreditation and certification process.

## 20. COMPLIANCE WITH AS 5182:2018 AND MONITORING

An online training program is provided for members to download and provide to their employees.

Employees shall complete training and certify their understanding and willingness to comply with the Standard. As part of this Code, members will provide opportunities for employees to complete the training and monitor completion. Members will provide employees with a "Certification of Adoption" form which the employee will sign-off once training is completed.

A copy of the Certification of Adoption form is included in the resources in Part E.

Members shall provide a copy of the completed form to the PTA Secretariat and retain a copy in their employee's file.

## 21. MEMBER ACCREDITATION CERTIFICATES AND CARDS

Upon receipt of the completed Certification of Adoption form, PTA will provide a certification card (either virtual, physical or both) to the member for use as and when required to enter a healthcare facility.

This certification may need to be renewed on a periodic basis, according to the Standard and the jurisdictional requirements. The certification card will link the employee with the company and should be returned to the company upon cessation of employment.

# Part E

# Appendices to the Code

# APPENDIX 1: INTERPRETATION AND DEFINITIONS

## Interpretation

a. The CEO or their delegate is authorised to provide advice to Members on the interpretation of the Code of Practice and its application to actual or proposed activities. The CEO may seek an opinion from the Chair, individual Members of CAC or a meeting of CAC convened for this purpose before providing advice to the Member. The provision of such advice does not exempt the Member or the situation from subsequently being subject to a complaint.

b. The CEO shall provide a report to each CAC meeting on all requests for advice received from Members, the nature of the advice given and any other relevant information. The CAC will review the advice and, where considered appropriate, will endorse the advice given for incorporation into explanatory notes to the Code. Explanatory notes will be issued within one month following their endorsement by the CAC.

c. Members who have received an interpretation of the Code and have chosen to act in contravention of the advice given may be referred by the CAC to the CCC by lodgement of a Complaint in accordance with the published Code Complaint Procedures.

## 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, paragraph, schedule or annexure of the Code and a reference to the Code includes a reference to a schedule or annexure;

d. A reference to a $ amount is a reference to an amount of Australian currency;

e. The meaning of general words is not limited by specific examples introduced by including, for example or similar expressions;

f. Headings are for reference only and do not affect interpretation;

g. If there is a conflict between a definition in the Code and the definition of a similar term in the Therapeutic Goods Act (Cth) 1989 or its regulations, the legislative definition shall take precedence.

h. This edition of the Code replaces and supersedes all previous editions or drafts of the Code.

# Definitions

**Advertisement**, in relation to a Product, includes any statement, pictorial representation or design, however made, that is intended whether directly or indirectly to promote the use or supply of a Product and/or a service offered in relation to a product.

**Advertising Code** means the Therapeutic Goods Advertising Code as amended. This is available on the Therapeutic Goods Administration (TGA) Website at https://www.tga.gov.au/publication/therapeutic-goods-advertising-code.

**Appeals Committee** means the Code Complaints Appeals Committee established in accordance with Clause 17 to hear appeals.

**Association** means Pathology Technology Australia Limited (ABN 31 137 771 638).

**Authorised Representative** means the person nominated by a voting Member of Pathology Technology Australia Limited under its Constitution to represent and vote on behalf of that voting Member.

**Australian Register of Therapeutic Goods (ARTG)** means the database of therapeutic goods maintained by the Therapeutic Goods Administration pursuant to the Therapeutic Goods Act 1989 (Cth) as amended.

**Board** means the Board of Directors of Pathology Technology Australia Limited.

**Breach** means a failure to comply with of any provision of the Code.

**Chief Executive Officer (CEO)** means a person appointed to that role by the Board of Pathology Technology Australia

**Code** means the Pathology Technology Industry Code of Practice as amended from time to time.

**Code Commissioner** means a person appointed by the Board of Directors with the relevant experience and understanding to review advise on and adjudicate the Code of Conduct.

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

**Company Representative** means a representative from a Member company or from a non-Member company that has agreed to comply with the code

**Complainant** means a person who lodges a complaint with Pathology Technology Australia under the Code.

**Complaint** means an alleged breach of the Code lodged with Pathology Technology Australia under the Code.

**Complaints Secretary** means the Chief Executive Officer of Pathology Technology Australia or their delegate responsible for the administration of a Complaint under the Code.

**Conference faculty** means a healthcare or commercial organisation responsible for the program and educational content of the meeting.

**Consultant** means a Healthcare professional who is engaged by a Member to act as a consultant to the Member.

**Consumer** means any person who may undergo a diagnostic procedure in which an *in vitro* diagnostic Product may be used or who may acquire an *in vitro* diagnostic Product for their own use in relation to their own health, but does not include a Healthcare Professional.

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

**Disease Education Activity** means any activity engaged in by a Member with the purpose of educating a consumer or consumers about a particular disease or condition.

**Education and Training** means the provision of educational material, product specifications, lectures and /or training sessions in relation to IVD products.

**Entertainment** includes sporting event, musical or other forms of entertainment.

**Healthcare Professional** means any pathologist or other medical practitioner, scientist, nurse, pharmacist, physiotherapist, chiropractor, osteopath, psychologist, dietician, acupuncturist, herbalist, naturopath, traditional herbalist or Chinese herbalist or a person who has current Membership of an Australian Professional Association or any person who is undertaking training to gain admittance to an Australian Professional Association or any person who is an employee of an Institution as defined.

**Hospitality** means the provision of accommodation, food and/or beverage.

**Industry** means that sector of the Healthcare industry that is engaged in the manufacture, import, distribution, maintenance, servicing or repair of *in vitro* diagnostic reagents or instruments or services.

**Institution** means an institution, corporation, government body agency or committee or any other organisation engaged in the purchase or other acquisition, supply or distribution, assessment, funding or recommendation in relation to *in vitro* diagnostic medical devices, in the administration or regulation of healthcare or medical products, or in the provision of information or education in relation to medical products.

***In vitro* Diagnostic (IVD) Medical Device** means any medical device that is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system whether used alone or in combination with another diagnostic product, intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of:

a. Giving information about a physiological or pathological state or congenital abnormality;

b. Determining safety and compatibility for, or with a potential recipient; or

c. Monitoring therapeutic measures.

**Pathology Technology Australia** means Pathology Technology Australia Limited (ABN 31 137 771 638).

**Laws and Regulations** means any law or regulation in force in Australia to which any act or omission the subject of the Code applies, including the Therapeutic Goods Act (Cth) 1989 as amended.

**Market Research** means the gathering of data on the scope or demographics of a market and its components including the needs of customers.

**Member** means any company, including its employees, that is a Member of Pathology Technology Australia, or any other person or company from the Industry who submits to the Complaints process and outcomes in accordance with the provisions of the Code.

**Member Representative** means any person or entity engaged to act for, employed by or retained for the purpose of advancing the interests of a Member.

**Minor Breach** means there are no safety implications to consumers, no effect on how consumers or Healthcare Professionals view the product, its competitors, the industry or its companies.

**Moderate Breach** means there are no safety implications to consumers, but it will impact on the perceptions of the consumer or Healthcare Professionals regarding the product, its competitors, the industry or its companies.

**Product** means an *in vitro* diagnostic (IVD) medical device.

**Product Demonstration** means a demonstration of the operation of a Product and includes any discussion regarding the Product features, benefits and performance and/or terms of sale of a Product.

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

**Promotion** means any activity that directly or indirectly promotes or encourages the use, acquisition, or supply of an IVD by purchase, sale or otherwise, or discourages such use, acquisition or supply of a competing IVD, and includes the publication or dissemination of an Advertisement.

**Regulator** means a government agency performing a statutory regulatory function, including but not limited to, the Therapeutic Goods Administration.

**Repeat Breach** means the same or a similar breach is repeated in the promotion of either a particular product, or any product of a company, which had been found to be in breach of the Code within the preceding 24 months. There may be/are safety implications and/or an adverse impact on the Pathology Technology Industry in Australia.

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

**Serious Breach** means there may be/are safety implications and/or a major adverse impact on the complementary healthcare industry in Australia, and it will have a major impact on how consumers or Healthcare Professionals view the product, its competitors, the industry or its companies.

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

**Sponsor**, in relation to an IVD, means the holder of an Australian Register of Therapeutic Goods (ARTG) entry in relation to that Product.

**Third Party Educational Conference** means a conference or event sponsored or conducted by or on behalf of a Professional Association that is independent, of an educational, scientific or policymaking nature and is for the genuine purpose of promoting scientific or medical knowledge or the delivery of effective healthcare.

**Trade Display** means a physical display of a Product or an advertisement or Educational Material about a Product, where-so-ever presented.

**Training Organisation** means any laboratory, hospital, Institution or organisation that provides training to Healthcare Professionals.

# APPENDIX 2: REFERENCES

AS 3806-2006 Australian Standard ™ Compliance Programs

Australian Competition & Consumer Commission (ACCC) Guidelines for Developing Effective Voluntary Industry Codes of Conduct, February 2005

Australian Competition & Consumer Commission (ACCC) Guide to unconscionable conduct, May 2008

Medicines Australia Code of Conduct

MTAA Code of Practice

Therapeutic Goods Act 1989

Therapeutic Goods Regulations 1990

Therapeutic Goods (Medical Devices) Regulations 2002

Therapeutic Goods Advertising Code 2015

Working Group on Promotion of Therapeutic Products, Report to Parliamentary Secretary Catherine King

MedTech Europe Code of Ethical Business Practice

ACAPMed Code of Ethical Conduct for Interactions with Health Care Professionals

# APPENDIX 3: RESOURCES

ACCC information on misleading & deceptive conduct

TGA – Decisions in relation to complaints about advertisements

Guidelines developed in collaboration between Medicines Australia and the Consumers Health Forum

Pathology Technology Australia Website

Therapeutic Goods Administration

Therapeutic Goods Administration Advertising Hub