

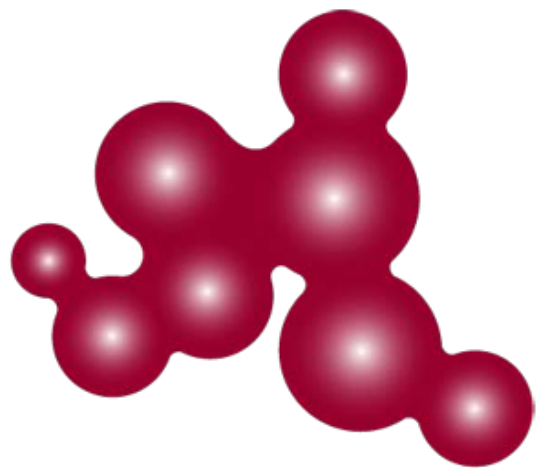
In-Vitro Diagnostics Industry
Code of Practice

Edition 3

February 2018

Administered by IVD Australia

IVD
AUSTRALIA



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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; and
- c. using therapeutic products safely and effectively.

The IVD 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.

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

IVD 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. IVD 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

IVD 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 [AQIS Biosecurity Australia](#), MSAC, and the Department of Health on matters relating to the regulation and reimbursement of IVDs, and to 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 *in vitro* diagnostics industry and ensure that ~~healthcare professionals~~Healthcare Professionals, the Regulator and the Australian community have confidence in their dealings with the industry, and its products.

~~Direct to Consumer A~~ advertisements ~~for those products that are directly sold to Consumers~~ are regulated through the Therapeutic Goods Advertising Code and IVD Australia Members must adhere to this code in respect of these products.

The IVD Australia Code of ConductPractice (the Code) sets out the standards appropriate to the various forms of relationships entered into by IVD 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 IVD 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. IVD Australia Members should also acknowledge that the Code is to be applied in the spirit, as well as in the letter of the Code.

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

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.

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 a mechanism for [Code breaches](#) complaint handling;
- c. To provide a means for the education of Members as to best practice in respect of interaction with Healthcare Professionals and Members' business associates;
- d. To improve compliance by the Australian community in their use of IVD products by providing effective patient protection;
- e. To ensure transparency for the IVD industry in its dealings with Healthcare Professionals; and
- f. To ensure that the reputation of IVD Australia and its Members is upheld at all times.

4. SCOPE

This Code sets out self-regulatory standards that IVD Australia members must follow, and all Industry participants are urged to observe. The Code is compulsory for members of IVD Australia but as a voluntary Industry code it extends to all companies in the IVD 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 IVD Industry Code to apply to the supply of only IVD products. Where there is another therapeutic Industry code that is more relevant in the circumstances, then that code will generally be the more appropriate code.

This Code operates under ~~a set of general~~ the high-level principles that regulate the interaction of ~~Members Industry when interacting in the business environment~~ with Healthcare Professionals.

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 their Members' business associates.

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

- a. All IVD Australia Members; and
- b. All interactions with Healthcare Professionals and ~~Members'~~ business associates.

Any non-Member involved within the IVD 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 as a whole 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 3, Clause 4. Scope

IVD 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.

In February 2017, the APACMed Board revised the Code to no longer permit Members' direct sponsorship of individual HCPs, whether as delegates or faculty, to Third Party Educational Events as of 1 January 2018. Members and third party intermediaries may continue to support HCP training and education provided by third parties through funding of educational grants...

APACMed, Code of Ethical Conduct for Interactions with Health Care Professionals, trifold brochure, page 1.

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. IVD Australia will monitor compliance in Australia with these requirements for twelve months and re-evaluate this position.

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 been invited and paid for to attend meetings (scientific or commercial) organised and branded by the companies themselves. Sponsorship of 3rd party such as for conferences dinners, speakers, is not an issue as the money are given 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.

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*

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, 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

5.6. INTERACTIONS WITH CONSUMERS

~~In general~~Currently, the IVD industry has limited interactions with Consumers. However for certain conditions such as diabetes, pregnancy and obesity, 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, physician or other healthcare professional.

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 Healthcare 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 Healthcare Professional to decide in consultation with the Consumer.
- f. Funding of Health Consumer Organisations - IVD 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, and supporting better outcomes for the Australian community.

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

<http://medicinesaustralia.com.au/files/2010/04/MA-WorkingTogether-TheGuide.pdf>

6.7. INTERACTION WITH HEALTHCARE PROFESSIONALS

The IVD 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 marketing 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.
- 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.

~~d.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 IVD 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

7.8. 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.
- a-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, ~~and the TGAC and all other relevant legislation~~ Therapeutic Goods Advertising Code.

~~8.9.~~ 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. ~~Members are strongly urged to participate in the IVD Australia online code of conduct training program.~~
- 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.

9.10. 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

~~10-11~~ ADMINISTRATION OF THE CODE

Administration of the Code shall be divided between two Committees appointed by the Board of IVD Australia;

- a. Code Administration Committee (CAC) and;
- b. Code Complaints Committee (CCC)

The role of the CAC is to implement and review the Code, to ensure that education on the Code is conducted for, and by, Members, and to report annually on the Code practices, complaints and outcomes.

The role of the CCC is to hear complaints from Members, non-Members and the general public regarding the behaviour of Members and their employees, and to resolve such complaints either by a CCC hearing or via mediation. Appeals against the decision of the CCC will be heard by a separate Appeals Committee set up by the CCC Secretary.

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

~~11-12~~ CODE ADMINISTRATION COMMITTEE

13.1 The CAC shall consist of:

- a. An independent Chair, who is a person with appropriate experience but is not currently employed in the IVD industry;
- b. Three Members from IVD Australia;
- c. Two representatives from Professional Bodies in the *in vitro* diagnostics sector such as RCPA, AACB, AIMS or the Therapeutic Goods Administration and;
- d. One Consumer representative from a health consumer organisation such as Consumers Health Forum.

13.2 A quorum of the CAC shall consist of the Chair and three other Members including at least one external representative. The Committee shall meet at least once per calendar year, although the Chair may request more frequent meetings as required.

13.3 The duties of the CAC shall be to:

- a. Conduct a review of the code at least once every three years to ensure that it continues to reflect community, industry and regulatory standards and values;
- b. Engage industry and key stakeholders in review processes and consult with industry in relation to any proposed amendments;
- c. Prepare amendments to reflect the outcome of review processes;
- d. Submit amendments as determined to the Board of IVD Australia for placement before a meeting of Members for approval;
- e. Ensure that Members and the wider IVD community are advised of all amendments via newsletters and publication on the IVD Australia website;
- f. Review the performance of the Code Complaints procedure and the operation and effectiveness of the Code Complaints Committee;
- g. Collect and disseminate data on the nature and outcomes of Complaints made and interpretations given and report that data to the Board of IVD Australia and to Members and non-Members via the IVD Australia website;
- h. Provide interpretations / guidance documents to assist Members to understand and adhere to the Code;
- i. Refer matters of concern to the CCC for consideration as complaints.

A Member of the Secretariat of IVD Australia shall act as Secretary to the CAC and shall be responsible for the management of the Committee meetings.

~~12.13.~~ CODE COMPLAINTS COMMITTEE

The CCC shall consist of a panel of ~~9~~ - 12 Members from whose number a Committee of four Members shall be drawn to consider and adjudicate a Complaint.

Panellists shall be approved by the Board of IVD Australia on an annual basis and shall be Members or executives of the following:

a. Professional Bodies connected with the IVD industry, such as outlined in clause ~~13~~12.1c;

~~b. Customer Associations;~~

~~e~~b. Government representatives from the Therapeutic Goods Administration or the Department of Health and Aging;

~~e~~c. Consumer Associations, such as the Consumers Health Forum; and

~~e~~d. Members of IVD Australia.

Members of the Committee established to review a complaint shall be selected by the CEO of IVD Australia and must consist of:

(i) An independent Chair, who is a person with appropriate experience but is not currently employed in the IVD industry.

(ii) Three other Members drawn from Clause 1413.a – 1413.d with a spread of representation from the groups.

The Committee must be chosen to avoid conflict of interest for any proposed panellist and no panellist shall sit on a CCC if they have an actual or perceived conflict of interest.

The quorum of a CCC shall consist of the Chair and two other Members including at least one external representative and decisions shall be made by a majority vote of those present.

A Member of the Secretariat of IVD Australia shall act as Secretary to the CCC and shall be responsible for the management of the Committee hearings and the provision of material relating to the Complaint. The Secretary will not, however, participate in the consideration and adjudication of the Complaint, and will not offer any opinion that might influence the Committee in its decision-making.

13.14. COMPLAINTS HANDLING PROCEDURES PUBLISHING OF COMPLAINTS**14.1 Publishing of Complaints**

- a. IVD 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 CCC;
- c. The details published shall not include any confidential information where good reason for withholding the information is provided by either party.
- a-d. The complainant's name will not be published without permission.

14.15. CODE PENALTIES/SANCTIONS AND ENFORCEMENT ACTIONS

a. In order for the Code to achieve/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 CCC. Sanctions will reflect the nature, seriousness and frequency of the breach.

<u>Severity of Breach</u>	<u>Potential Implications</u>
<u>Minor Breach</u>	<p>No safety implications to consumers</p> <p>No effect on how consumers or Healthcare Professionals view the product, its competitors, the industry or its companies</p>
<u>Moderate Breach</u>	<p>No safety implications to consumers</p> <p>Will have adverse impact on the IVD 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</p>
<u>Serious Breach</u>	<p>Safety implications</p> <p>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</p>
<u>Repeat Breach</u>	<p>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</p> <p>May have safety implications</p> <p>Adverse impact on the IVD industry in Australia, such as impact on how consumers or Healthcare Professionals view the product, its competitors, the industry or its companies</p>

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

- i. Censure and/or warning from the CCC. 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 an written assurance regarding ongoing observance of the Code;
- iii. Corrective advertising and /or a retraction to be published as directed by the CCC;
- 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 Committee's deliberations on the IVD Australia website.

b.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 IVD Australia reserves the right, on the recommendation of the CCC, to institute proceedings for the expulsion of such Member under Clause 12c of the IVD Australia Constitution.

15-16. 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 appeal should be in writing and should be submitted to the Secretary of the CCC within 10 working days of receipt of the decision.~~
- ~~e.b.~~ b. The CEO or their delegate shall establish a Code Appeals Committee (AC) to hear the appeal. The Appeals Committee shall consist of:
- i. A qualified Lawyer acting as the Chair;
 - ii. Three other Members drawn from the CCC, none of whom was on the panel that heard the original Complaint;
 - iii. One technical expert in the subject of the complaint, if required.
- ~~e.c.~~ c. Prior to selection, 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;
- ~~e.d.~~ d. The Quorum for the AC is the Chair and two other Members including at least one external representative.
- 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 CCC, together with the appeal papers and any associated response by the Complainant or Respondent, including:
- i. the material that was considered by the CCC 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 CCC.
- h. The findings of the AC are final and binding on the parties.
- ~~i. The CEO or their delegate will provide notification of the outcome of the Appeal to the parties within 10 working days of the conclusion of the Appeal.~~ 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 CCC decision. If unsuccessful in appeal, the Appellant must reimburse IVD 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. IVD 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 IVD 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 IVD 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 IVD Australia, its servants, agents, consultants and all committees established by IVD 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

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 ~~Conduct~~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~~Clause 13.3i~~.

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 <http://www.tga.gov.au/advert/tgac.htm>.

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

Association means IVD Australia Limited (ABN 31 137 771 638).

Authorised Representative means the person nominated by a voting Member of IVD 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 IVD 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 IVD Australia

Code means the IVD Australia Code of ~~Conduct~~ Practice as amended from time to time.

Code Administration Committee (CAC) means the committee established in accordance with [this Code, Clause 12](#) to administer the Code on behalf of the Board.

Code Complaint Committee (CCC) means the committee established in accordance with [this Code clause 13](#) to hear complaints brought under the Code.

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 IVD Australia under the Code.

Complaint means an alleged breach of the Code lodged with IVD Australia under the Code.

Complaints Secretary means the Chief Executive Officer of IVD 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.

IVD Australia means IVD 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 IVD 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 IVD 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](#)

[Complaints Resolution Panel — Recent Panel Determinations](#)

[TGA – Decisions in relation to complaints about advertisements](#)

[Department of Health & Ageing, Regulatory Policy & Governance Division — Codes of Conduct Advisory Group](#)

[Guidelines developed in collaboration between Medicines Australia and the Consumers Health Forum](#)

[IVD Australia Website](#)

[NICNAS Guidelines](#)

[Therapeutic Goods Administration](#)