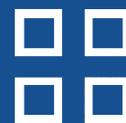




– Code of Practice New Zealand Dental Industry

The purpose of the New Zealand Dental Industry Code of Practice is to ensure that the selection of diagnostic and treatment pathways by dental professionals is made free of any undue influence on the part of the dental industry.

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medical technology
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Introduction

The purpose of the Code is to ensure high ethical interactions and socially acceptable behaviour within the Dental Industry and ensure the Oral Healthcare Professional, the Regulator and the New Zealand community can have confidence in their dealings with the Dental Industry and its Products and services.

The Code is not intended to supplant or supersede New Zealand law, regulations or professional codes including those that may be applied to individual companies.

The Code represents an act of self regulation in the first instance. NZDI (New Zealand Dental Industry) Members should also acknowledge that the Code is to be applied in the spirit as well as the letter of the Code.

Any business that is not an NZDI Member 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 Dental Industry as a whole if it is to maintain the confidence of all the stakeholders that it serves.

Many Member businesses may have internal Codes of Conduct prescribed by their parent organisations. This Code is not intended to override the provisions of any internal code, should that mandate a higher level of performance of a stricter code of behaviour.

There are several industry codes applying to different therapeutic sectors. It is the intention that the Code applies to the supply of Dental Technology Products. Where there is another therapeutic industry code that is more relevant then that code will generally be the more appropriate code.

Faye P Sumner

Chief Executive Officer
October 2017

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Section 1 – Principles

- 1.1 It is intended that the scope of the Code will cover the following:
 - 1.1.1 All NZDI Members;
 - 1.1.2 Any business, whether or not a Member, that exhibits at a trade show, exhibition or similar event convened by NZDI; and
 - 1.1.3 Any non-Member business that voluntarily accepts and observes the Code.
- 1.2 The Code operates under a set of general principles that regulate the interaction of Members with Dental Professionals. These principles are:
 - 1.2.1 Members must at all times comply with the provisions of all relevant legislation;
 - 1.2.2 Members must not engage in unethical behaviour, misleading or deceptive conduct, or unfair or unconscionable practices; and
 - 1.2.3 Members must always respect the ethical requirements and codes of practice which apply to Dental Professionals by their Professional Association.
- 1.3 The Dental Industry, sector more broadly, 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;
 - 1.3.1 That a Dental Professional should choose suitable Therapeutic Products only if this is considered necessary and in the patient's best interest;
 - 1.3.2 Therapeutic Products should be used safely and effectively;
 - 1.3.3 Diagnostic and treatment options should be selected by Dental Professionals wisely, based on the best available evidence and the patient's needs, free from any undue influence on the part of the Dental Industry;
 - 1.3.4 Decisions by Dental Professionals concerning treatment and / or diagnostic pathways are made independently of any inappropriate inducement or offer by the Dental Industry.
- 1.4 NZDIG CPC Committee will collaborate with relevant stakeholders in code creation, updating, education, monitoring and compliance.

Compliance Guidance —

The NZDI Code of Practice applies to any Member business and in addition to any business (whether or not a Member) that exhibits at a trade show convened by NZDI. The latter outcome is achieved as accepting the Code is a standard condition of participation at a trade show / exhibition managed by NZDI.

NZDI members should also acknowledge that the Code is to be applied in the spirit, as well as in the letter of the Code. In this context, members are encouraged not to apply their own interpretation, but seek guidance from NZDIG CPC Committee as to whether their marketing and promotional activities are consistent with the outcomes in this document.

Section 2 – Gifts & Inducements

- 2.1 Consistent with Clause 1.3.3, a Member must not inappropriately influence a Dental Professional's selection of diagnostic and / or treatment pathways as a result of offering a Gift.

Gifts —

- 2.2 At no time may a Member offer a Gift:
- 2.2.1 In connection with the ordering, purchase or supply of a Therapeutic Product; or
 - 2.2.2 When it is in the form of cash / negotiable instruments / gift card (redeemable for anything other than a Therapeutic Product) / monetary equivalents, except when the benefit is applied against a Commercial Account.
- 2.3 A Member may offer a Gift where:
- 2.3.1 It is offered independently of the ordering, purchase or supply of a Therapeutic Product; and
 - 2.3.2 It does not exceed NZ\$75 (GST Excluded) as at 1 January 2018, adjusted annually in accordance with *New Zealand Consumer Price Index*, and offered only once in any four week period.
- 2.4 The following are not considered to be Gifts:
- 2.4.1 Therapeutic Products, or any other dental product used on and / or for patients in the delivery of dental care, in reasonable quantities for demonstration or evaluation purposes.
 - 2.4.2 Additional Therapeutic Products, or any other dental product used on and / or for patients in the delivery of dental care, offered in any quantity when offered in connection with the ordering, purchase or supply of Therapeutic Products (e.g. buy ten get one free).
 - 2.4.3 Additional Therapeutic Products, or any other dental product used on and / or for patients in the delivery of dental care, offered in connection with a reward / loyalty type promotion as this is deemed to be a legitimate type of commercial discount.
 - 2.4.4 Any discount / rebate paid against the commercial account (having regards for Clause 2.2.2).
- 2.5 The offer of registration to a CPD Activity is not considered to be a Gift; however, any such offer must be made in a manner consistent with Clause 3.

Compliance Guidance —

As noted in the principles, the expectation of this Code is that businesses in the dental industry will undertake no promotional activity that would encourage a dental professional to do other than select diagnostic and treatment options wisely based on the best available evidence and the consumer's needs.

The practical outcome is that there should be no inducement, such as offering a gift, that may affect the decision of a dental professional as to which is the appropriate diagnostic or treatment pathway for a patient.

A member should not be seen to undermine the principles for good oral hygiene.

A Therapeutic Product includes any product falling within the definition of goods set out in the NZ Medicines Act 1981. As a general rule, this means that the Code applies to promotional activities for:

- Instruments and equipment;
- Medicines and disinfecting products;
- Imaging and diagnostic equipment;
- Materials used for restorative / cosmetic purposes;
- Materials used in surgery.

The provision of Therapeutic Product (and other dental product) samples to Dental Professionals for evaluation purposes is deemed to be a legitimate marketing activity [Clause 2.4.1]. Similarly the supply of additional Therapeutic Products offered in connection with the ordering, purchase or supply of Therapeutic Products (e.g. buy ten get one free) is deemed to be a legitimate type of commercial discount [Clause 2.4.3].

With reward / loyalty type schemes these can operate only when the benefit to the healthcare professional is additional Therapeutic Products [Clause 2.4.3] or a discount / rebate [Clause 2.4.4]. In any other circumstances a reward / loyalty type scheme would be viewed as incompatible with Clause 2.2.1.

It is important to note that some forms of gifts / inducements are legitimate as they are considered to be normal commercial activities. These include discounts, rebates applied against a customer's account and provision of free samples, or additional products of Therapeutic Products (only) supplied when ordering, for example the 'buy ten get one free' type of promotion.

Competitions —

- 2.6 A Member may conduct competitions where:
- 2.6.1 The conduct of the competition must comply in all respects with all relevant laws and regulations; and
 - 2.6.2 The entry to any competition conducted by a Member must not be dependent on the ordering, purchase, supply, recommendation, use, testing or prescribing of a Therapeutic Product.

Compliance Guidance —

A Member may conduct a business card draw, raffle or similar promotion so long as in order to enter the competition the Dental Professional does not need to buy a Therapeutic Product.

In organising a competition Members should abide by the relevant New Zealand legislation. As a general rule government regulations require that competitions be held entirely by chance.

Section 3 – Education & Training

- 3.1 Consistent with Clause 1.3.3, a Member must not inappropriately influence a Dental Professional's selection of diagnostic and / or treatment pathways through the conduct of education and training programs.

CPD Activities —

- 3.2 Members may offer CPD Activities to Dental Professionals to facilitate the safe and effective use of Therapeutic Goods where:
- 3.2.1 The CPD Activity is delivered by staff with the appropriate qualifications and expertise to deliver the training;
- 3.2.2 The CPD Activity should be conducted in clinical, laboratory, conference or other settings, which are conducive to the educational nature of the CPD Activity and to the effective transmission of the knowledge, as well as allowing for any "hands on" component; and
- 3.2.3 Any CPD Activity offered by Members where Therapeutic Goods are demonstrated and / or made available for sale should not be in a venue, where it can be reasonably argued, was selected due to its recreational, entertainment facilities.
- 3.3 Any CPD Activity offered to Dental Professionals associated with Therapeutic Goods must be offered in accordance with NZDA guidelines and policies.

Hospitality & Travel Within New Zealand —

- 3.4 Members may provide attendees with reasonable Hospitality in connection with the CPD Activity. The Hospitality must be incidental to the main purpose of the training, reasonable in cost and extent, and provided only to the Dental Professionals involved in the CPD Activity.
- 3.5 Members may pay for the Travel for a Dental Professional to attend a CPD activity.
- 3.6 Members shall not provide or pay for Travel and / or Hospitality for a Dental Professional's partner or guest.

Hospitality & Travel Overseas —

- 3.7 Where a Member offers a CPD Activity overseas, and where attendance is paid for by the Member, it must be offered subject to the following criteria:
- 3.7.1 It must be demonstrated that by, the nature of the CPD Activity, it was not available in New Zealand;

Compliance Guidance –

The dental industry invests heavily in training and educating Dental Professionals to ensure that they use the products in the optimal manner.

To this end there is extensive training and education conducted by businesses for the benefit of Dental Professionals and ultimately for enhanced patient outcomes.

In conducting the education and training businesses need to ensure that the focus of the relationship is educative and not an opportunity to provide inappropriate Hospitality.

Training and education includes both formal, structured sessions and the in-service instruction that occurs in a healthcare setting. It can also include working with Dental Professionals to better understand the product and patient benefit to be derived from the product.

Any Hospitality must be appropriate in value. This will vary from CPD activity to CPD activity. With every event however the business must determine if the event is lavish or excessive, even if the business has not itself organised the event.

Training should be held at a venue deemed appropriate for the professional standing of the professional which is an appropriate location for education purposes. **The physical attractiveness of the venue or available sporting or leisure facilities should not be a primary determinant factor in venue selection.** The primary considerations in choice of a venue for any training should be whether it provides an environment that is conducive to the effective transmission of knowledge and would be perceived by an ordinary Member of the public to be conducive to learning.

If, as part of the sale of Therapeutic Goods, training is overseas this must only be done in a context where it must be demonstrated that by, the nature of the CPD Activity, it was not available in New Zealand.

As to what constitutes Hospitality and Travel (including accommodation) refer to the definitions in Section 15.

- 3.7.2 The duration of the trip should only be sufficient for the Dental Professional to attend the CPD Activity;
- 3.7.3 Any Hospitality should be incidental to the primary purpose of the trip; and
- 3.7.4 Members shall not provide or pay for Travel and / or Hospitality for a Dental Professional's partner or guest.

Section 4 – Sales & Promotional Events

- 4.1 Consistent with Clause 1.3.3, a Member must not inappropriately influence a Dental Professional's selection of diagnostic and / or treatment pathways through the conduct of sales and promotional events.

Client Meetings —

- 4.2 Where it is deemed necessary for Member employees to meet with Dental Professionals to discuss product features, conduct negotiations, arrange sales and deliveries, such meetings:
- 4.2.1 Should be held in a dental practice / medical institution, the Member's business premises, a meeting venue or other appropriate facility.
- 4.2.2 The Member may, with the agreement of the Dental Professional, provide Hospitality; however, such Hospitality should be incidental to the purpose of the meeting.
- 4.3 Members may provide or pay for the Travel of a Dental Professional.
- 4.4 Members shall not provide or pay for Travel and / or Hospitality for a Dental Professional's partner or guest.

Product Demonstrations & Sales Events —

- 4.5 Where it is deemed necessary for Member employees to meet with Dental Professionals to showcase products, demonstrate product features, conduct negotiations and arrange sales (e.g. a product demonstration or trade show), such meetings:
- 4.5.1 Should be held at the supplier's business premises, a training facility, laboratory, conference / exhibition venue or other appropriate facility.
- 4.5.2 Should not be in a venue, where it can be reasonably argued, was selected due to its recreational, entertainment facilities.
- 4.5.3 Members may, with the agreement of the Dental Professional, provide or pay for reasonable Hospitality for attendees; and
- 4.5.4 Members may provide or pay for the Travel for a Dental Professional.
- 4.5.5 Members shall not provide or pay for Travel and / or Hospitality for a Dental Professional's partner or guest.
- 4.6 If product demonstrations and sales events are represented to have a CPD component, this must be offered in accordance with Section 3.

Compliance Guidance —

A meeting with a Dental Professional, practice manager, buyer or procurement manager may review product specifications and review the commercial arrangements as part of the interaction.

A **Client Meeting** is deemed to be where sales staff or management of a Member will meet with a dental professional to discuss products, sales / contracts or the commercial relationship between the Member and the Dental Professional's own practice / business.

A **Product Demonstration** or **Sales Event** is deemed to be an opportunity for one or more Dental Professionals to review products, test products and negotiate prices. Such events are typically product 'launch' events, visits to a showroom or a trade show.

Any Hospitality must be reasonable and a business must ensure that the interaction is not simply a social interchange funded by the business. **It is not possible for a business simply to invite a Dental Professional out for a meal** unless otherwise provided for in this Code.

The primary requirement is that any Hospitality is reasonable and subordinate in focus to the primary intent of the meeting. In assessing whether Hospitality is reasonable, businesses should consider not only the financial cost but whether an ordinary Member of the public would consider the venue and Hospitality arrangements to be reasonable.

As to what constitutes Hospitality and Travel (including accommodation) refer to the definitions in Section 15.

Section 5 – Consulting Agreements

- 5.1 Consistent with Clause 1.3.3, a Member must not inappropriately influence a Dental Professional's selection of diagnostic and / or treatment pathways through consulting agreements.
- 5.2 Dental Professionals may serve as consultants to Member businesses, 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.
- 5.3 Consulting arrangements must be in written form, signed by all parties to the consulting agreement and specify all services 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.
- 5.4 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.
- 5.5 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 Therapeutic Products or services which consultants may use for, or in, their own business or place of employment.
- 5.6 Compensation should be paid based on services actually provided and must be in accordance with applicable legislation, including tax legislation.
- 5.7 Members may pay for reasonable expenses incurred by consultants including Travel, 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.
- 5.8 All Consulting Agreements should be appropriately documented and acknowledged where appropriate.

Compliance Guidance —

A consulting agreement is a legitimate way to engage with a Dental Professional for the purposes of seeking their professional opinion. The remuneration must be documented and be consistent with standard professional rates.

In order to meet the requirements of Clause 5.3, a detailed formal contract may not be required; however, the documentation must be sufficient to clearly detail the arrangements that pertain to the agreement.

Section 6 – Donations & Grants

- 6.1 Consistent with Clause 1.3.3, a Member must not inappropriately influence a Dental Professional's selection of diagnostic and / or treatment pathways through the provision of donations or grants; and
- 6.1.1 A receipt must be provided by the entity receiving the donation / grant and kept by the Member; and
- 6.1.2 Donations of cash must only be made to Registered Charitable Institutions or Educational Institutions able to receive them in a context that deems them to be a deductible gift for taxation purposes.

Charitable Donations Of Products / Services —

- 6.2 Members may make donations of products / services for charitable purposes to support delivery of dental and oral healthcare services in the community; however a donation must not be made in order to induce the use of a product or service.
- 6.3 Donations of products / services greater than \$250 (GST Excluded) in value as at 1 January 2018, adjusted annually in accordance with the New Zealand Consumer Price Index, must only be made when:
- 6.3.1 Provided to Registered Charitable Institutions or Educational Institutions that are not-for-profit in nature; or
- 6.3.3 The Member is able, upon request, to provide MTANZ with a statutory declaration that the donation was made in good faith on the basis the products / services were to be used for non-profit purposes.

Research —

- 6.4 Members may make donations of cash grants for education or research purposes, where:
- 6.4.1 The donation or cash grant is made to a Registered Charitable Institution or Research Institution.
- 6.4.2 The donation or cash grant is made to a Registered Charitable Institution or Research Institution that uses the proceeds to support one or more students, residents, fellows and participants in a program offered by an Educational Institution.

Compliance Guidance —

If a member business is simply meeting a request for a dentist to provide a small quantity of therapeutic products to support a volunteer effort, the Member may be asked to provide NZDIG with a statutory declaration to attest that these goods were indeed provided without charge for charitable purposes in the event that a Complaint is received (Clause 6.3.3).

Each business is encouraged to make publicly available on its website, a list of organisations to which it provides financial support and / or significant direct / indirect non-financial support. The list should be updated on an annual basis.

- 6.4.3 Members may make 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 donor. Members may also make grants to support public education of patients or the wider community in respect of important healthcare topics.

Section 7 – Event Sponsorship

- 7.1 Consistent with Clause 1.3.3, a Member must not inappropriately influence a Dental Professional's selection of diagnostic and / or treatment pathways through the sponsorship of a CPD Activity, a charity / fundraising event or a social event.
- 7.2 The Member should receive and keep a formal agreement that clearly sets out the support to be provided by the Member and the benefits that the Member may receive.
- 7.3 It is important to note that Section 7 does not encompass sponsorship of events outside the dental sector.

Hospitality Sponsorship —

- 7.4 Members may only provide donations or cash grants to support sponsorship of a Hospitality at a social / networking event (where the audience is predominately Dental Professionals) where the event is convened by a Professional Association, Charitable Institution or not-for-profit Educational Institution.

Conference Sponsorship —

- 7.5 Members may choose to support CPD Activities in a number of ways which is permitted when:
 - 7.5.1 The CPD Activity is convened by a Professional Association, Registered Charitable Institution or a not-for-profit Educational Institution; or
 - 7.5.2 It has been convened by a for-profit provider and the program meets the guidelines on CPD Activities; and
 - 7.5.3 Any Hospitality at the event is incidental to the event's CPD focus.

Speaker Sponsorship —

- 7.6 Members may make grants to Conference Organisers for reasonable honoraria, and reasonable Travel and Hospitality and meals for Dental Professionals or other individuals who are bona fide conference speakers.
- 7.7 Members may pay for the Travel and Hospitality of a Dental Professional that is a conference speaker where this forms part of a sponsorship agreement.

Travel Grants —

- 7.8 Members may provide financial support to the Conference organisers to cover costs such as reasonable Travel for Dental Professionals (including students), where the conference is primarily dedicated to objective medical and scientific educational activities. The Conference organisers should be responsible for and control the program content, educational methods and materials used.

Compliance Guidance —

It is standard practice for Members to sponsor conferences and events and this is encouraged. It is important that the sponsorship, whether by way of cash payments or in-kind, are provided directly to the organising body (that must be an independent legal entity) and not directly to the Dental Professional.

Businesses should use simple agreements with Dental Professionals to ensure that all parties are clear on the purpose of the event and what will be provided. An agreement is not required for an event that is reasonable in size, such as a short seminar. In these circumstances the program or agenda is sufficient as evidence of the agreed scope of services.

This Section does not apply to the sponsorship of events outside the dental sector [Clause 7.3] that may, for example, include Sponsorship of a sporting team / event.

As to what constitutes Hospitality and Travel (including accommodation) refer to the definitions in Section 15.

Section 8 – Hospitality

- 8.1 Consistent with Clause 1.3.3, a Member must not inappropriately influence a Dental Professional's selection of diagnostic and / or treatment pathways through the offering of Hospitality.
- 8.2 Members may only provide Hospitality to Dental Professionals where:
- 8.2.1 It is permitted under Clause 3.4, Clause 4.2.2 or Clause 4.5.3; and
- 8.2.2 It is offered independently of the purchase, ordering of a Therapeutic Product; and
- 8.2.3 The venue meets accepted standards as regards to community standards and values; and
- 8.2.4 The value of the Hospitality is such that it meets community standards and values insofar as appropriate to the standing of the Dental Professional.
- 8.3 Hospitality offered independently of a CPD Activity or sales and promotional event should not include Travel.

Compliance Guidance —

It's not uncommon for businesses in the dental industry to meet with a Dental Professional over lunch or dinner; however, the Code places limitations on the extent of this Hospitality.

The term "Hospitality" is defined in Clause 14.1.22 and is taken to mean the provision of food and / or beverages and entertainment (e.g. a play, concert, sporting event, etc). Circumstances where it is possible to provide a Dental Professional with Hospitality include:

- A CPD event [Clause 3.4]
- A client meeting [Clause 4.2]
- Product demonstration / sales event [Clause 4.5]

In these circumstances, it is not possible to take a Dental Professional to lunch or dinner for a social occasion (e.g. a Christmas celebration, it's their birthday or for a general catch-up) [Clause 8.2]

Any Hospitality must be reasonable in nature.

In assessing whether Hospitality is reasonable, businesses should consider not only the financial cost but whether an ordinary Member of the public would consider the venue and Hospitality arrangements to be reasonable.

With respect to community standards, this is taken to preclude entertainment of a nature that may reflect badly on either the dental profession or dental industry, such as taking a Dental Professional to a gentlemen's club.

Section 9 – Advertising

- 9.1 In advertising their products and services to Dental Professionals, Members must ensure that the advertisements and related promotional literature does not incorporate an offer that is inconsistent with this Code.
- 9.2 In advertising their Therapeutic Products to Dental Professionals, Members must ensure that the advertisements and related promotional literature (excluding brand name reminders) must contain the Member's name and the brand name of the Therapeutic Product.

General Advertising Obligations —

- 9.4 All advertisements will be consistent with the requirements of the Advertising Standards Authority Therapeutic Health & Advertising Code and any other statutory obligations that may pertain to product sales

NOTE: NZDIG CPC Committee will not consider complaints alleging a breach of the ASA's Code, they must be referred to the appropriate authority.

Comparative —

- 9.5 Any product comparison of Therapeutic Products offered by a competitor must only be made using data / evidence contained in a peer-reviewed academic journal or similar publication.
- 9.6 A claim that a Member has unfairly disparaged the product of another is considered to be a commercial dispute and outside the scope of this Code.

NOTE: NZDIG CPC Committee will not consider complaints alleging a breach of the ASA's Code, they must be referred to the appropriate authority.

Commissioned Articles —

- 9.7 Business commissioned articles concerning Therapeutic Products written by, or including comment from, a Dental Professional can be produced by a Member in circumstances where they:
- 9.7.1 Are clearly identified as such; and
- 9.7.2 The Member is clearly identified at either the top or the bottom of the article; and
- 9.7.3 It must carry a statement that makes it clear the author was paid to write the article.

Compliance Guidance —

This section of the Code applies to advertisements directed exclusively to Dental Professionals and those with responsibility for the purchasing of medical devices. However, advertisements directed to consumers are regulated by the Advertising Standards Authority rather than this Code.

Compliance with the Code does not absolve Members and other advertisers from the need to comply with other common law and statutory requirements, in particular the framework set out by the Consumer Guarantees Act and Fair Trading Act

Advertisers have a responsibility to ensure the content and presentation of their advertisement and promotional material promotes the quality use of Therapeutic Products through encouraging the Dental Professionals to select, for their patients, appropriate management options, suitable products and then to use those products safely and effectively.

All claims, not just therapeutic claims, which are made, must be truthful, valid and not misleading.

A claim that a Member has unfairly disparaged the product of another is considered to be a commercial dispute and outside the scope of this Code, thus parties are expected to resolve the matter amicably without recourse to this Code.

Complaints that allege an advertisement is false or misleading should be directed to the NZ ASA.

Section 10 – Consumer Interaction

- 10.1 When interacting with Consumers Members must be aware that they have obligations under the *Consumer Act* policies and guidelines.

Consumer Advised To Seek Professional Guidance —

- 10.2 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 Dental Professional that is, where required, registered with the NZ Dental Council. Such a Dental Professional may be employed by the Member.

Oral Health Promotion —

- 10.3 Disease education activities for Consumers relating to Therapeutic Products may provide information, promote awareness and educate the public about health, disease and their management, however:
- 10.3.1 A disease education activity may make reference to the availability of different options for diagnosis or treatment but may not direct the Consumer to purchase a specific Therapeutic Products.
- NOTE:** NZDIG CPC Committee will not consider complaints alleging a breach of this Clause, they must be referred to the appropriate authority.
- 10.3.2 The emphasis of the disease education activity should be on the condition and its recognition rather than on the specific Therapeutic Products. Appropriate treatment for an individual Consumer following use of an over-the-counter Therapeutic Products is for the Dental Professional to decide in consultation with the Consumer.

Company Representatives — General

- a. A Company must:
- (i) ensure that its Company Representatives are fully aware of the provisions of the Code; and
 - (ii) provide ongoing training to Company Representatives on compliance with the provisions of the Code.
- b. A Company should ensure that its Company Representatives at all times:
- (i) maintain a high standard of ethical conduct and professionalism;
 - (ii) conduct themselves in a manner that complies with the Code;

Compliance Guidance —

In general, the dental industry has limited interactions with consumers but in certain areas such oral healthcare, goods are available for general sale / self-selection by patients.

The scope of this Code are those products intended by the manufacturer or supplier for the purpose of Providing Care by a Dental Professional that is a medical device as defined by the NZ Medicines Act 1981. In this context, over-the-counter products supplied by a Member do not fall within the scope of this Code, however Members do have certain obligations that are set out in Clause 10.2.

In order to ensure that the Code is well-understood within a company, the employees and agents who have primary contact with healthcare professionals and others with product-purchasing authority must be fully trained in the Code and its provisions. It is preferable that all employees within the medical technology industry receive at least broad training on the Code and the need for ethical and professional dealings.

A company has the responsibility of ensuring adequate awareness of the Code and its provisions. A company should also ensure that employees understand the nature of the professional relationship with healthcare professionals to ensure that there is no inappropriate behaviour that might compromise the professional independence of the healthcare professional.

NZDIG CPC Committee conduct regular Code of Practice workshops to assist educating new company representatives and updating existing company representatives on Code of Practice developments.

- (iii) act in a manner that does not compromise, appear to compromise or appear likely to compromise the professional behaviour or independence of a Dental or Oral Health Professional; and
 - (iv) act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.
- c. A Company should ensure that a Company Representative who attends procedures at the invitation of a Dental or Oral Health Professional complies with all relevant institutional requirements, standards, codes and all relevant Laws and Regulations.

Code Training

A Company should ensure that every Company Representative undertakes an education program that complies with NZDI guidelines.

It is recommended Representatives employed in a role which involves promotional activities on behalf of the Company undertakes an education program on the Code of Practice approved by NZDI:

- (i) within the first six months of employment in the role; and
- (ii) as a refresher program at no less frequency than once every three years.

Compliance Guidance —

If there are significant changes to the Code of Practice, it is expected that Company Representatives will receive training on the changes.

Section 11 – Complaints Committee

11.1 Code of Practice Committee — General

The Code of Practice Committee (CPC) is established to supervise the administration of the Code and is responsible to the MTANZ Board.

11.2 Composition of CPC

CPC shall be made up of:

- a. A minimum of two members from NZDIG Executive Committee who are MTANZ members;
- b. Two NZDI Dental Members who are MTANZ members;
- c. A representative from the New Zealand Dental Association;
- d. And, a representative from MTANZ.

11.3 Role of CPC

CPC is responsible for the review and evaluation of the Code and its administration. To achieve this, CPC must:

- a. conduct regular internal and external reviews of the Code in accordance with clause 11.5 to ensure it continues to reflect community, industry and regulatory standards and values;
- b. consult with key stakeholders if it is considered that more than minor amendments are required;
- c. submit all proposed amendments to the NZDIG Executive Committee for approval;
- d. publicise all amendments in accordance with clause 11.5;
- e. oversee the effective operation and administration of the complaints handling procedures;
- f. collate statistical data of complaints received and their outcomes; and
- g. conduct a regular review and analysis of complaints and Industry issues they may raise and make recommendations to the Board.

11.4 CPC procedures

CPC must operate in accordance with the following procedures:

- a. Elect a Chair from within the group;
- b. CPC must meet at a minimum once per year. The Chair may request more frequent meetings on an as needs basis;

Compliance Guidance —

The structure of the administrative provisions of the Code is to provide for a committee established for complementary purposes:

Code of Practice Committee - member-based committee which reviews Code implementation and education and reports annually on Code complaints and outcomes.

- c. Decisions of CPC must be made by a majority vote of its members;
- d. A quorum of four NZDI members must participate in each CPC meeting.

11.5 Reviews

- a. External reviews of the Code must be carried out once every five years or more frequently if so determined by CPC.

For the purposes of conducting an internal review, CPC may seek comment or submissions from Companies and other relevant stakeholders.

11.6 Publicising the Code

- a. CPC should identify and recommend to the NZDIG the optimal means for the Association to promote the Code to Companies, the Industry, Dental & Oral Health Professionals, Regulators and other relevant stakeholders and participants in the healthcare and dental industry.
- b. NZDIG must ensure that the Code is available on the MTANZ website at all times and encourage Companies to reference and provide links to the Code on their own websites.
- c. NZDIG must encourage Companies to promote the Code on a regular basis.

11.7 Reporting

Each year CPC should provide a written report on the administration of the Code for inclusion in the MTANZ Annual Report;

MTANZ to include any Code complaints in the regular Board meeting papers.

Section 12 – Complaints Management

12.0 General

- a. Companies should take all measures reasonably required to ensure compliance with the Code by Company Representatives. Companies should adopt effective compliance programs by issuing written policies and procedures, conducting training programs and implementing clear procedures, controls and enforcement mechanisms.
- b. Companies are encouraged to inform all customers, Institutions and Dental & Oral Health Professionals of the requirements of the Code.
- c. A Complaint regarding promotional activities by a Company or an interaction with a Dental & Oral Health Professional, should be dealt with company to company contact, in the first instance.;
- d. If, following intercompany dialogue, the complaint remains unresolved, a complainant may lodge a complaint with the NZDIG Code of Practice committee;
- e. The COP committee should evaluate the complaint and make recommendations or action to the NZDIG Board;
- f. In support of a fair and transparent complaints system, anonymous Complaints are not accepted;
- g. Notwithstanding the obligations on NZDIG to report on the outcome of Complaints as provided in the Code, all information about a Company, a Complainant, and the subject matter of a Complaint, must be kept confidential by NZDIG until all avenues of appeal are exhausted.

12.1 Complaint Handling Procedures

12.1.1 Complaints by Consumer or Non-Industry Complainant

The following applies to a Complaint to be made by a Consumer or Non-Industry Complainant.

- a. Before lodging a Complaint, the party wishing to complain is encouraged (but not required) to seek to resolve the issue the subject of the Complaint with the Company whose behaviour has given rise to the Complaint.
- b. For privacy purposes, and to avoid any disincentive for making a Complaint, the Complainant may apply to the NZDIG to have the Complainant's name withheld from the Respondent and from public release.

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Complainants are encouraged to first approach the company whose behaviour is complained of to attempt to address the behaviour. If the complainant is not satisfied that the behaviour has been addressed then a complaint may be lodged with NZDIG.

The Code requires industry participants to attempt to resolve issues before resorting to the complaints process. Non-industry complainants are also encouraged to raise issues with a company before lodging a complaint. However as it might be more difficult for a non-industry person to raise a matter directly with a company (whether as a consumer, healthcare professional or other healthcare participant), the Code provides that a non-industry complainant may bring a complaint without first taking the step of contacting the company whose behaviour is complained of.

The Code provides for a mediation process which is more appropriate than a formal complaint process. It is open to the parties to a complaint to request mediation as the means to resolve the issue.

12.1.2 Complaints by an Industry Complainant

Before lodging a Complaint, an Industry Complainant should seek to resolve the issue the subject of the Complaint, directly with the Company whose behaviour has given rise to the Complaint. The Industry Complainant may not make a Complaint unless the parties have been unable to satisfactorily resolve the issue.

12.2 Complaints General

- a. The following applies to all Complaints. A Complaint should be in writing with supporting material and:
 - (i) state the nature of the conduct, state the provision of the Code alleged to have been breached and the reasons for asserting a breach has occurred;
 - (ii) where relevant, provide supporting scientific or other technical data;
- b. If the Complaint is brought by an Industry Complainant on the basis that the Company has not provided substantiation of a claim, the Complainant must provide evidence to support its allegations.
- c. NZDIG will acknowledge a complaint, whether concerning a Company or a non-member, in writing within seven working days of its receipt and deal with the complaint expeditiously.
- d. NZDIG should forward a copy of the Complaint to the Chief Executive Officer of the Respondent within seven working days of receiving the Complaint. The Respondent should respond in writing to NZDIG within 10 working days.
- e. NZDIG should provide the Complainant with a copy of the Respondent's response and invite the Complainant to reply in writing within 10 working days. NZDIG should provide the Respondent with a copy of the Complainant's reply within 5 working days.
- f. If a Complaint is upheld, the Respondent must reimburse NZDIG, as applicable, its secretariat costs and out-of-pocket expenses associated with the determination of the Complaint, unless the NZDIG Board determines otherwise.

Section 13 – Code Penalties

13.1 Classification of Breaches

Where a breach of the Code has been established, before determining any sanction, the NZDIG Board must first classify the severity of the breach, in accordance with the classification set out below.

Minor Breach: a breach of the Code that has no safety implications and will have no adverse effect on how Dental & Oral Health Professionals or the general public view the Medical Technology the subject of the Complaint, similar products or the Industry.

Moderate Breach: a breach of the Code with no safety implications but which will adversely impact on the perceptions of Dental & Oral Health Professionals or the general public regarding the Medical Technology the subject of the Complaint, similar products or the Industry.

Severe Breach: a breach of the Code that has safety implications or will have a major adverse impact on how Dental & Oral Health Professionals or the general public view the Medical Technology the subject of the Complaint, similar products or the Industry.

Repeat Breach: when a Company commits the same or similar breach of the Code to a breach found against the Company within the preceding 24 months.

Serial breach: when a company breaches the code, and that company has been found to have breached the code on not less than two previous occasions in the preceding 24 months.

13.2 Available Sanctions and Reporting

Where the NZDIG CPC committee has judged that the company has breached the Code it shall refer to the complaint to the MTANZ Board with any recommended sanctions or actions. The MTANZ Board may choose to apply the following sanctions:

- a. A requirement that the Company take immediate action to discontinue or modify any practice which is determined to constitute a breach of the Code, in which event the Company should confirm in writing to MTANZ that it has taken the required action within 10 working days of receipt of the decision;
- b. A requirement that the Company recall and destroy any offending material in which event the Company must confirm in writing to the MTANZ, within 10 working days of receipt of the decision, that it has taken the required action;

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The Code determines the outcome of a complaint in two parts. The first is to determine if there has been a breach and to classify the seriousness of the breach. The second part is to assess the applicable sanction for the breach that has been determined.

- c. Suspension or expulsion of the Company from MTANZ in a manner consistent with the MTANZ Constitution;
- d. Publication of the name of the company and the breach of the Code on the MTANZ website;
- e. Publication of the name of the company and the breach of the Code in the MTANZ Annual Report;
- f. Notification of any unethical business behaviour to any private or public procurement agency.
- g. Notification to the NZ Dental Association by way of a paid advertisement in the NZDA News for 2 consecutive publications.
- h. Notification to the NZ Dental Council.
- i. Exclusion from Dental Expo.

Section 14 – Interpretation

Interpretation —

Meanings —

- 14.1 In the Code when the following words are capitalised they are intended to have the following definition:
- 14.1.1 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 includes a service offered in relation to a product.
 - 14.1.2 Advertising Standards Authority (ASA) The Advertising Standards Authority (ASA) self-regulate advertising in New Zealand. Advertising Codes of Practice provide the rules by which all advertisements in all media should comply.
 - 14.1.3 Association means the Medical Technology Association of New Zealand Dental Industry Group
 - 14.1.4 Authorised Officer means the Chief Executive Officer or his delegate.
 - 14.1.5 MTANZ Board means the Board of Directors of Medical Technology Association of New Zealand.
 - 14.1.6 Breach means a failure, as determined by the NZDIG CPC, to comply with of any provision of the Code.
 - 14.1.7 Code means this NZ Dental Industry Code of Practice as amended from time to time.
 - 14.1.8 NZDIG New Zealand Dental Industry Group as elected by the Dental Industry Members.
 - 14.1.9 NZDIG CPC means the committee established in accordance with Clause 11.1 to administer the Code on behalf of the Board.
 - 14.1.10 NZDIG CPC means the committee established in accordance with Clause 13.3 to hear complaints brought under the Code.
 - 14.1.11 Complainant means a person who lodges a complaint with NZDIG under the Code.
 - 14.1.12 Complaint means a complaint lodged with NZDIG CPC Committee under the Code.
 - 14.1.13 Commercial Account is the trade account, line of credit or other transactional record used by a Member for the purposes of recording sales and invoicing a Healthcare Professional for the purchase of Therapeutic Products.

- 14.1.14 Secretary means the Authorised Officer or his delegate responsible for the administration of a Complaint or appeal under the Code.
- 14.1.15 Consultant means a Dental Professional who is engaged by a Member to act as a consultant to the Member.
- 14.1.16 CPD Activity is any event, seminar, course, conference or similar continuing professional development program that permits a Dental Professional to meet their obligations set out in the *NZDA Guidelines*.
- 14.1.17 Dental Professional is any individual registered by the NZ Dental Council, or any national board within the framework, to provide dental care, oral health care, medical care or patient diagnostic services. It may also include an individual responsible for procuring Therapeutic Products.
- 14.1.18 Oral Healthcare Professional means any registered dentist, dental specialist, dental therapist, dental hygienist, oral health therapist, clinical dental technician and student of dental or oral health care in addition to any individual in a profession falling within the responsibility of a national Board operating under the auspices of the Dental Council of New Zealand. This definition includes a person under the direction and control of a Oral Healthcare Professional.
- 14.1.19 Oral Health Promotion Activity means any activity engaged in by a Member with the purpose of educating a consumer or consumers about a particular disease or condition.
- 14.1.20 Educational Institution is a not-for-profit provider of vocational and / or tertiary education accredited by government to issue NZQA qualifications.
- 14.1.21 Entertainment includes sporting event, musical or other forms of entertainment.
- 14.1.22 Gift is any good offered to a Dental Professional unless otherwise excluded under Clause 2.4.
- 14.1.23 Hospitality means the provision of food and / or beverages and Entertainment (e.g. a play, concert, sporting event, etc).

- 14.1.24 Market Research means the gathering of data on the scope or demographics of a market and its components including the needs of customers.
- 14.1.25 Member means any: Business, including its employees, which is a Member of MTANZ; any other person or business from the industry who submits to the complaints process and outcomes in accordance with the provisions of the Code; and any business that has contracted with MTANZ to participate as an exhibitor at trade show or similar event.
- 14.1.26 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 pursuant to any agreement between the representative and the Member.
- 14.1.27 New Zealand Dental Association (NZDA) is the professional association for New Zealand dentists.
- 14.1.28 New Zealand Dental Council is a regulatory authority created by the Health Practitioners Competence Assurance Act 2003. The oral health practitioners regulated under the Dental Council are dentists, dental specialists, dental therapists, dental hygienists, clinical dental technicians, dental technicians, and orthodontic auxiliaries.
- 14.1.29 Product means any good falling within the scope of Clause 16.2.38.
- 14.1.30 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.
- 14.1.31 Professional Association means a clinical or other professional body representing Dental Professionals or other healthcare professionals.
- 14.1.32 Promotional Activity means any activity that directly or indirectly promotes or encourages the use, acquisition, or supply of a dental by purchase, sale or otherwise, or discourages such use, acquisition or supply of a competing dental, and includes the publication or dissemination of an advertisement.

- 14.1.33 Registered Charitable Institution is a charity or not-for-profit organisation registered with the New Zealand Charities Commission.
- 14.1.34 Respondent means, in relation to a complaint, the Member (as defined in Clause 16.2.29) whose conduct is the subject of the complaint.
- 14.1.35 Therapeutic Product/s refers to a medical device as defined by the NZ Medicines Act 1981.
- 14.1.36 Trade Display means a display of a product or an advertisement or educational material about a product, where-so-ever presented.
- 14.1.37 Travel is transportation by airline, overseas / interstate passenger liner but does not mean transportation by public transport (e.g. buses, metropolitan train, local water ferry, etc), taxi, hire car or limousine; and also overnight accommodation.

Specific References —

- 14.2 In the Code:
- 14.2.1 The singular includes the plural and vice versa and a gender includes other genders;
- 14.2.2 Another grammatical form of a defined word or expression has a corresponding meaning;
- 14.2.3 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 include a reference to and schedule or annexure;
- 14.2.4 A reference to a \$ amount is a reference to an amount of New Zealand currency;
- 14.2.5 The meaning of general words is not limited by specific examples introduced by including, for example or similar expressions and;
- 14.2.6 Headings are for reference only and do not affect interpretation;
- 14.2.7 This edition of the Code replaces and supersedes all previous editions or drafts of the Code.

End.

This Compliance Guidance does not form part of the Code and may be amended by the Authorised Officer as circumstances require.