

Australia New Zealand

Therapeutic Products
Advertising Code

(Draft as at July 2005)

CONTENTS

Throughout the Code, explanatory notes, interpretations and examples are in italics.

PART A

Part A of the Code sets out the common obligations that must be met by advertisers of therapeutic products in Australia and New Zealand and common processes which support the implementation of the Code.

Definitions

Preface

- A1 Object
- A2 Interpretation
- A3 Application
- A4 General processes - public interest criteria, approvals, complaints, appeals
- A5 Failure to comply with the Code

PART B

Part B of the Code sets out the requirements for specific types of advertising of therapeutic products and, to particular audiences. Each Section of Part B is a stand-alone document, which must be read in conjunction with Part A of the Code.

- B1 Advertising medicines to consumers
- B2 Advertising medical devices to consumers
- B3 Advertising therapeutic products to healthcare practitioners

DEFINITIONS

Advertisement	means any communication which promotes or discourages the use, sale or supply of products (whether or not in conjunction with the supply of services, and whether or not the communication identifies particular products or services). (Refer A3)
Advertiser	means any person who, or entity which, communicates, or arranges for the communication of, an advertisement.
Central Approval Officer	means a person employed by an industry association to exercise a delegation to approve advertisements which the Managing Director has granted to that industry association under Section x of the Rules.
Delegated Authority	means any person who is not employed by the Agency or an industry association as an approval officer, to whom the Managing Director has delegated certain limited authority to approve advertisements under Section x of the Rules.
Exempt product	for the purposes of the Code, means a product which does not require a product licence.
Government agency	means any department, ministry, agency, board, organisation, authority, etc of the governments of Australia or New Zealand or international government agencies (such as the Food and Drug Administration (USA)). Refer to the following government internet sites for examples of government agencies - www.gold.gov.au or www.govt.nz
Healthcare practitioner	means (I) for the purposes of determining whether an advertisement is directed to healthcare practitioners, a person who is described in a Schedule (to be developed jointly by Australia and New Zealand) to the Rules and, (II) for the purposes of representations made in advertisements, a person represented so as to be likely to be taken to be a healthcare practitioner.
Label	means a display of printed information upon, or securely affixed to, a container and any primary pack containing the products.
Mainstream media	in relation to an advertisement means: a. any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions; or b. broadcast media where the information is disseminated electronically in a visible or audible form or a combination of such forms; or c. cinematography film; or d. displays about products, including posters: i. in shopping malls (except inside individual shops); ii. in or on public transport; and iii. on billboards.
Presentation	in relation to therapeutic products, means the way in which the products are presented for supply, and includes matters relating to the name of the products, the labelling and packaging of the products

and any advertising or other informational material associated with the products.

Promote

means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.

Restricted medical device

means a medical device which is intended to be administered or used only by a healthcare practitioner.

**Sponsorship
Advertisement**

means a representation that the advertiser (product, brand, company) is sponsoring a person, competition, activity, program or event.

Product licence holder

for the purposes of the Code, means the person who holds the licence for the product, or in the case of an exempt product, the person who is responsible for supplying the product in Australia or New Zealand.

Therapeutic database

means the register of licensed therapeutic products maintained by the Agency (refer Section [insert no] of the Rules).

Therapeutic product

This definition is copied from the

(a) means:

- (i) a product that is represented in any way to be, or that is, whether because of the way in which the product is presented or for any other reason, likely to be taken to be for therapeutic use;
- (ii) an ingredient or component in the manufacture of a product referred to in subparagraph (i) above;
- (iii) a container or part of a container for a product, ingredient or component referred to in subparagraphs (i) or (ii) above; or
- (iv) a product falling within a class of products the sole or principal use of which is, or ordinarily is, a therapeutic use; and

(b) includes:

- (i) a product which the Rules provide shall be treated as a therapeutic product for the purposes of the Agreement; and
- (ii) a product which is declared to be a therapeutic product in an Order made under paragraph 2 of Article 10, but

(c) does not include:

- (i) a product which the Rules provide shall not be treated as a therapeutic product for the purposes of this Agreement; or
- (ii) a product which is declared not to be a therapeutic product in an Order made under paragraph 2 of Article 10.

Therapeutic use

(a) means use in or in connection with:

- (i) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in humans;
- (ii) influencing, inhibiting or modifying a physiological process in humans;
- (iii) testing the susceptibility of humans to a disease or ailment
- (iv) influencing, controlling or preventing conception in humans;
- (v) testing for pregnancy in humans; or
- (vi) the replacement or modification of parts of the anatomy in humans; and

(b) includes any other use which the Rules provide shall be treated as a

³ Refer to the *Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products* at website <http://www.jtaproject.com>

therapeutic use for the purposes of the Agreement³; but

- (c) does not include any use which the Rules provide shall not be treated as a therapeutic use for the purposes of this Agreement.

Verifiable claim

in relation to the advertising of medical devices means any claims that need verification including statements about facts, research results, comparisons, quotes, testimonials, and endorsements or other information about the device not covered under the Therapeutic Products legislation for the essential principles for medical devices.

PREFACE

All products supplied for therapeutic use in Australia and New Zealand must be licensed and entered on the Trans Tasman therapeutic product database, unless exempt.

The advertising of therapeutic products in Australia and New Zealand is controlled by a combination of:

- statutory measures (with both criminal and civil sanctions) enforced by the Agency;
- co-regulatory processes for the approval of advertisements and handling of complaints about advertisements; and
- self-regulation through industry, healthcare professional and media codes of practice or ethics.

Three key *Advertising Principles* are established in the Australian and New Zealand therapeutic products legislation (Act(s)) and provide the foundation for the Australia New Zealand Therapeutic Products Advertising Code (the Code). *Advertising Requirements*, established in the Rules, expand on these principles and are also incorporated in the Code. Other than changes to the *Advertising Principles* and *Advertising Requirements*, which require approval by the Ministerial Council, the Code can be amended by order of the Managing Director of the Agency on the advice of the Advertising Council. The Advertising Council is broadly representative of key stakeholders.

PRINCIPLE 1

Advertisements must comply with the Therapeutic Products Act(s) and Rules and the Therapeutic Products Advertising Code.

Advertisements for therapeutic products must comply with the Code and the therapeutic products legislation developed for the Trans Tasman regulatory scheme.

Therapeutic products that are substances in Schedule 3, or Schedule 4 or Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which are not also in Appendix H (as amended from time to time) or contain substances in those Schedules, cannot be advertised to consumers in Australia, because the therapeutic products legislation as it applies in Australia prevents the advertising of these therapeutic products. The advertising of all Schedule 3 and Schedule 4 products to consumers is allowed in New Zealand, other than those products specifically prohibited by the Misuse of Drugs Act 1975.

Compliance with the requirements of the Code does not absolve product licence holders and other advertisers from the need to comply with other common law and statutory requirements of the country where the advertisement is published, in particular, the trade practices legislation in Australia and New Zealand.

Approval of an advertisement does not guarantee compliance with any legislation.

PRINCIPLE 2

Advertisements must be truthful, balanced and not misleading.

Claims must be valid and have been substantiated.

All claims, not just therapeutic claims, that are made in an advertisement must be truthful, valid and have been substantiated. Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

For example, a claim that a particular therapeutic product is “the most popular” or “the world leader” would need to have been substantiated.

Advertisers should be aware that the Agency, the advertising approval officer and the complaints handling bodies can require the advertiser to produce balanced, comprehensive and credible evidence to support any of the claims or representations made in an advertisement.

PRINCIPLE 3

Advertisements must observe a high standard of social responsibility.

Advertisers have a responsibility to ensure that the content and presentation of their advertisement promotes responsible use through encouraging consumers to select management options wisely, to choose suitable therapeutic products and to use them safely and effectively. In the lawful advertising of prescription medicines (ie as permitted in New Zealand), advertisers should consider the need for consumers readily to access valid, relevant, easily understood information to enable them to make informed healthcare choices in consultation with their healthcare practitioners.

The provisions for compliance with Advertising Principle 1 are to be found in the legislation and the Code

In order to comply with Advertising Principles 2 and 3, the Advertising Requirements, which are established in the Rules, must be observed. These requirements, with explanatory notes, can be found in the sector-specific sections of the Code (i.e. Sections B1, B2, and B3).

PART A

A1. OBJECT

The object of the Code is, through controls on advertising, to:

- safeguard public health and safety;
- protect the public interest; and
- support the quality use of therapeutic products and informed healthcare choices.

The Code sets the standard for the regulation of advertisements for therapeutic products in Australia and New Zealand in order to ensure that the advertising of therapeutic products is socially responsible, does not mislead or deceive and supports consumers:

- selecting management options wisely;
- choosing suitable therapeutic products; and
- using them safely and effectively¹.

The Code provides the minimum advertising standard for the industry codes of practice and healthcare practitioner codes of ethics in Australia and New Zealand.

A2. INTERPRETATION

The Code is the standard applied to all advertisements and in the consideration of approvals, complaints and appeals. In interpreting the Code, the total presentation and context of the advertisement will be considered in terms of the content, as well as the spirit and intent, of the Code.

The conformity of an advertisement with the Code will be assessed in terms of its probable understanding by the reasonable person to whom the advertisement is directed.

A3. APPLICATION

The definition of “advertisement”, in relation to therapeutic products, is broad and includes any form of communication that either directly or indirectly promotes or discourages the use, sale or supply of a therapeutic product. For example, an advertisement about a health service or treatment program that includes a reference to the use, sale or supply of a medicine or medical device is also an advertisement for that medicine or medical device. However, an advertisement for a service, which only incidentally references a type of therapeutic product, is not covered by this definition (e.g. laser hair clinic).

While the definition of “advertisement” is broad, there are a number of exclusions to the definition, as outlined in Section A3.1.

The Code applies to all advertisements for therapeutic products (including products which are exempt from product licensing).

The Code applies to all advertisements directed to consumers and healthcare practitioners.

The Code applies to advertisements disseminated in all forms of media, including, but not limited to:

- Television, radio, cinema;
- Newspapers, consumer magazines, trade / professional journals;
- Outdoor displays e.g. billboards, taxi signs, bus sides, shopping mall displays;
- Direct mail, including addressed and unsolicited mail;
- Catalogues;

¹ Refer Australian National Medicines Policy and National Strategy for Quality Use of Medicines at <http://www.health.gov.au>.

- Point of sale material (eg brochures, pamphlets, posters, displays, shelf-talkers); and
- Websites, e-mails, SMS messages and any other electronic means.

Where an advertisement includes a reference directing consumers to obtain further information (such as a phone number, website, mailing address or book), the information in the referenced material relevant to the advertisement may be taken into account in considering the advertisement.

The oversight of the application of the Code resides with the Advertising Council.

A3.1 Exemptions from the Code

- **Bona fide news, bona fide editorial, bona fide public interest programs and bona fide entertainment programs**

The Code does not apply to bona fide news, bona fide editorials, bona fide public interest programs and bona fide entertainment programs which meet the definition for such material as described in the relevant media industry codes of practice.

News stories, editorial comment and public interest information about therapeutic products are important sources of health information for Australian and New Zealand consumers. Consumers expect that, as distinct from advertisements for therapeutic products where the commercial interest of the advertiser is understood potentially to bias information content, genuine news, editorial and public interest programs comprise independent and objective journalism, free of assertions made by an advertiser/product licence holder. This information thus is expected to be objective and impartial, and commentary/interpretation about the information to be independent of the advertiser. Bona fide entertainment programs are also exempt from the provisions of the Code on this basis.

This exclusion recognises that while the media has the freedom to broadcast or publish news or editorial matter, the broadcast or publication of news, editorial, public interest and entertainment programs is subject to the requirements of relevant industry codes of practice. These codes of practice form part of the regulation of broadcast and print media and draw a distinction between the regulatory treatment of editorial content and that of advertising. This distinction is based principally on whether or not the publisher or broadcaster has received any payment or other valuable consideration in return for the broadcast or publication.

If there is any doubt as to whether material is “editorial” or advertising, the complaint should be submitted through the appropriate media complaints process. Through that complaints process, the material will be assessed for compliance with the appropriate advertising, broadcasting or print code of practice; and, in the case where the material is determined to be advertising, the matter will be referred to the usual central complaints processes for the advertising of therapeutic products.

- **Bona fide education, research and professional advice**

The Code does not apply to:

- bona fide educational material, including material containing scientific information and/or information based on traditional use, prepared by healthcare professionals, academics and other scientists and educators, provided that;

for branded therapeutic products -

the context of the presentation of the material or the material itself does not promote the commercial use, sale or supply of branded therapeutic products and no consideration has been received in return for the public promotion of the branded therapeutic product that is the subject of the educational material;

for generic substances / ingredients or unbranded therapeutic products -

the context of the presentation of the material or the material itself does not promote the commercial use, sale or supply of branded therapeutic products; and any consideration received has been explicitly acknowledged and/or prominently displayed;

or

- private advice provided by healthcare practitioners and retailers or their employees to consumers in the ordinary course of their business;
- or
- communications between consumers.

A3.2 Application of the Code to specific types of advertisements

- **Unbranded advertising**

An unbranded advertisement promotes the use or supply of product by inviting the consumer to seek further information about symptoms or conditions and/or their treatment or management while not referring overtly to any particular branded product. Unbranded advertisements must comply with Advertising Requirements 1, 3, 4, 5, 6 and 8 of the Code.

A typical example of an unbranded advertisement:

"Did you know that there is a new product available for controlling {medical condition}? If you are suffering from {symptoms / conditions} ask your medical practitioner about appropriate treatment options."

- **Generic advertising**

A generic advertisement promotes the benefits of a particular category of therapeutic products, substance, ingredient or medical device component and is not related to any particular branded product. Generic advertisements must comply with Advertising Requirements 1, 3, 4, 5, 6 and 8 of the Code.

A typical example of a generic advertisement:

"Have you considered the benefits of {substance}. Recent research has shown that {substance} in combination with exercise reduces oxidative stress in older adults. Call (phone number) for more information on products which contain this substance."

- **Disease awareness campaigns**

Disease awareness campaigns, comprising information that aims to raise awareness regarding specific diseases, including public health campaigns, must be factual and balanced, and support consumers in making informed healthcare choices.

Disease awareness campaigns must not identify a therapeutic product. Any campaign that directly, or indirectly, promotes the use, sale or supply of therapeutic products is advertising and, therefore, subject to the Code.

Such information usually would focus on encouraging consumers to seek healthcare practitioner advice about the diagnosis, treatment or prevention of a disease or condition.

Advertisers need to be aware that where there is only one therapeutic product available to treat or diagnose the specified disease, or where a new therapeutic product has just been released for the treatment or diagnosis of the disease state, it is possible that information about the disease state, taken in context, could be considered to be unbranded or generic advertising.

Further advice can be sought from the central approvals office in Australia or the central adjudicator in New Zealand.

Where a disease awareness campaign includes material which contains a reference directing consumers to obtain further information (such as a phone number, website, mailing address or book), the information in the referenced material relevant to the campaign material may be taken into account when considering the campaign material.

- **Sponsorship advertisements**

Sponsorship advertisements, in relation to therapeutic products, are any form of communication publicising sponsorship of any person or activity, such as a competition, event or program by a brand name therapeutic product by anyone with a commercial interest in the therapeutic product.

Sponsorship advertisements shall:

- a) clearly and primarily promote the team, individual, competition, event or activity being sponsored;
- b) not contain a direct or implied claim or a sales message for a therapeutic product, other than a brand name, or, in the case of devices, a purpose for use;
- c) not show a therapeutic product or product packaging;
- d) not imitate or use any parts of therapeutic product advertisements from any medium; and
- e) only briefly and in a subordinate way mention or portray the product sponsor's name and/or brand or product name and/or logo, orally or visually.

Sponsorship advertisements (other than advertisements for prescription medicines in New Zealand), which meet the above criteria, are exempt from the mandatory information described under Advertising Requirement 2.

If the brand name of a medicine, medical device or other therapeutic product is used in the sponsorship of a major sporting event (eg "ABC company fun run" or "{product name} fun run"), the billboards at the event and any advertisements for the event that included the brand name of the medicine or device are sponsorship advertisements, provided they meet the above criteria.

- **Reminder advertisements**

Reminder advertisements are advertisements directed to consumers that are designed only to remind the reader of the name of the product or to act as a "lead in" to a full advertisement. They are permitted, provided they do not include both the name of the product and a direct or implied therapeutic claim, and they are linked to "full advertisements" within:

- the same publication (written advertisement); or
- the same program/announcer (spoken advertisement),

as part of a broader campaign.

If these conditions are not met, the full requirements of the Code, including the mandatory information, apply.

Reminder advertisements that are directed to consumers are not permitted for prescription medicines (where prescription products are otherwise permitted to be advertised in New Zealand).

Reminder advertisements in a campaign must not straddle media (i.e. have the main advertisement in one form of media and reminder advertisements in other forms of media).

Any advertisement which contains the name of the product and a therapeutic claim (including where the claim is implied in the product name) is not a reminder advertisement and must meet the full requirements of the Code, including the mandatory information.

- **Presentation**

As part of acceptable presentation (as defined in Rule XX), any written, pictorial or other descriptive matter supplied or displayed with or on any therapeutic product must be truthful, valid and not misleading.

For the purposes of the Code, a label is not an advertisement unless it forms part of an advertisement. For example, where a pack shot is included in an advertisement.

- **Internet advertising**

All advertisements for therapeutic products on Australian or New Zealand websites on the internet must comply with the Code. Any complaint received about an advertisement published on the internet is subject to the usual complaint processes.

Where an Australian or New Zealand website includes an advertisement which has links to other international websites containing advertisements for therapeutic products, the reader must be made aware that they are leaving the Australian / New Zealand website and that other linked advertisements may not comply with the Code.

Where an Australian or New Zealand website is linked to an overseas website, advertisers also are encouraged to alert consumers to the possibility that therapeutic products advertised on the overseas websites may not be available in Australia or New Zealand and, therefore, may not meet Australian/New Zealand regulatory requirements for safety, quality or efficacy.

Where an advertisement includes a reference directing consumers to obtain further information (such as a phone number, website, mailing address or book), the information in the referenced material relevant to the advertisement may be taken into account in considering the advertisement.

Further information on the use of the internet for providing educational material to consumers, including Product Information and Consumer Medicines Information, is included in relevant industry codes of practice.

- **Advertisements for foods or cosmetics in which therapeutic claims are made**

Where an advertisement for a food product contains a claim for therapeutic use, other than a nutrition or health related claim as specifically prescribed by any standard for nutrition, health and related claims in the Food Standards , the product may be declared to be a therapeutic product subject to the full provisions of the therapeutic product legislation, including compliance with the Code and all other regulatory requirements.

Any cosmetic product advertisement which contains a therapeutic claim is subject to the full provisions of the therapeutic products legislation, including compliance with the Code and all other advertising regulatory arrangements.

² Published by Food Standards Australia New Zealand – refer website <http://www.foodstandards.gov.au>

A4. GENERAL PROCESSES

A4.1 Public Interest Criteria

The following public interest criteria are to be applied when making decisions relating to:

- consideration of complaints; and
- Advertising Council recommendations on advertising to vulnerable audiences and restricted representations (refer Advertising Requirement 5 and Advertising Requirement 8) made in relation to products or classes of products, including:
 - (a) consumers', or certain groups of consumers', vulnerability when:
 - faced with having a disease, condition, ailment or defect,
 - seeking to manage a condition (eg pregnancy), or
 - seeking to avoid a disease, condition, ailment or defect.
 - (b) for non-prescription medicines, the likelihood that the audience has the knowledge and maturity to self-diagnose and self-manage the condition(s) for which the products are to be advertised;
 - (c) the likelihood that advertising of the products to the likely audience could reasonably be expected to deliver to them health benefits or improvements to their quality of life;
 - (d) whether a representation would be likely to result in consumers not seeking timely professional advice where appropriate (such as where timely professional advice is important to prevent negative health consequences or serious deterioration or progression of disease);
 - (e) whether a representation would be likely (alone or through repetition or together with other references) to have a negative impact on public health (or to have an adverse effect on persons other than those to whom the advertisement is directed); and
 - (f) such other aspects of the public interest as may appear to be appropriate.

For non-prescription medicines:

The World Health Organization notes that responsible self-medication can:

- help prevent and treat symptoms and ailments that do not require medical consultation;
- reduce the increasing pressure on medical services for the relief of minor ailments, especially when financial and human resources are limited;
- increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult; and
- enable patients to control their own chronic conditions.

For medical devices:

Paragraphs (a) and (b) of the public interest criteria are not relevant in the context of determining whether a restricted medical device should be able to be advertised (refer Part B2 - Requirement 8).

Additionally, applications to advertise a restricted medical device also must address the following points:

- Whether the content of the advertisement is balanced and adequately references warnings, contra-indications and risks particularly for those devices used in invasive procedures;
- Whether the advertisement is likely to arouse preconceived expectations of the outcomes;
- Whether the advertisement clearly identifies the important role of the healthcare practitioner and the advice he/or she provides; and
- Whether the advertisement could be construed to claim or imply that the use of the device or procedure is suitable in all cases.

A4.2 Approval of advertisements

Advertisements for medicines directed to consumers

Advertisements which appear in mainstream media, other than the internet, must be approved by the Central Approvals Officers in Australia or New Zealand for compliance with the Code prior to publication or broadcast. This is a requirement under the Joint Therapeutic Product Rules. A fee is payable on the basis of the time taken to approve the advertisement as outlined in the Joint Therapeutic Product Rules for fees and charges.

Advertisements for medical devices directed to consumers

Advertisements for medical devices which:

- contain a verifiable claim; or
- promote a restricted medical device;

must be approved by the Central Approvals Officers in Australia or New Zealand for compliance with the Code prior to publication or broadcast. This is a requirement under the Joint Therapeutic Product Rules.

Revisions to advertisements which have been approved by the Central Approvals Officers

Product licence holders and other advertisers which have a properly qualified and trained employee or consultant (acting under contract) to consider and approve advertisements are encouraged to apply for accreditation as a Delegated Authority (DA) to approve advertisements or revisions of advertisements which have already been approved by either the Central Approvals Officers in Australia or New Zealand.

Applications to become a Delegated Authority are considered by the Advertising Council (or a relevant sub-committee) which then makes recommendations to the Agency. The DA is issued with a unique number which is recognised by the media for the purposes of placing the advertisement. The responsibility for assessing advertisements is vested only with that person. The DA can call the Central Approvals Office free of charge for advice, if necessary.

For further details refer to

Advertisements for therapeutic products directed to healthcare practitioners

These advertisements do not require approval in Australia. In New Zealand, approval through the Central Approvals Office in New Zealand is strongly encouraged, on a self-regulatory basis.

Whether or not requiring approval, all advertisements for therapeutic products in Australia and New Zealand, including advertisements for therapeutic products on the internet, must comply with the Code.

An approval number must be stand-alone, located in the bottom right hand corner of a print media or internet advertisement and able to be read easily from a normal viewing distance.

The process for the approval of advertisements is set out in the Rules. Irrespective of the country in which the approval is granted, the approval applies to advertisements communicated in any media in either Australia or New Zealand, other than advertisements for prescription and certain non-prescription medicines directed to consumers that may only be advertised in New Zealand.

Withdrawal of approval

An approval for an advertisement can be withdrawn by an approvals officer or the Agency as a result of an upheld complaint or legislative change.

Seeking prior approval for the use of certain restricted representations for medicines or restricted medical devices

For an application for approval for the use of a restricted representation or a restricted medical device:

- for medicines, to refer directly or by implication to serious diseases, conditions, ailments or defects in an advertisement, or,

➤ for medical devices that are intended to be used and/or administered solely by healthcare practitioners,
the approval decision will take into consideration the public interest criteria listed in section A4.1.

A4.3 Complaints

Complaints about advertisements thought to be in breach of the Therapeutic Products Act(s) or Rules, including the Advertising Principles, Advertising Requirements and the Code, can be lodged² with:

- the Central Complaints Panel in New Zealand, for advertisements published or broadcast in New Zealand; or
- the Central Complaints Panel in Australia, for all advertisements published or broadcast in Australia, through the Central Support Unit.

The functions and powers of the Central Complaints Panels established in Australia and New Zealand are set out in the Rules.

In support of a fair and transparent complaints system, anonymous complaints are not accepted.

New Zealand

Any person can submit a complaint about an advertisement to the Central Complaints Panel in New Zealand. The Chair of the Panel has the discretion to withhold the name of the complainant. Complaints that are submitted by consumers or competitors about advertisements directed to healthcare practitioners, which do not involve matters of serious public health and safety, may be referred to the appropriate industry sector panel for consideration. If the complainant wishes to pursue the complaint, the industry sector panel may apply a charge.

Australia

Any person can submit a complaint about an advertisement to the Central Complaints Panel in Australia. So as not to act as a disincentive for the making of complaints, where the complainant is a consumer, the complainant's name is withheld from the other party and from public release. The Central Complaints Panel handles all complaints about advertisements directed to consumers, and complaints involving matters of serious public health and safety. Complaints that are submitted by consumers or competitors about advertisements directed to healthcare practitioners, which do not involve matters of serious public health and safety, are referred to the appropriate industry sector panel for consideration. If the complainant wishes to pursue the complaint, the industry sector panel may apply a charge.

A4.4 Review and Appeals

Review of a decision not to approve an advertisement or to withdraw an approval

If an advertisement is not approved or approval is withdrawn, a request to review the decision can be submitted to the Managing Director (refer Rule {insert Rule number}) to reconsider the merits of the decision to refuse approval in Australia and New Zealand.

The request for review can be considered by a senior delegate of the Managing Director, who was not involved in the initial decision making process.

The initial decision will stand until the decision is varied or revoked.

The request must be made within 30 days after the notice of the decision and the applicant must, at the same time, send a copy of the request to the Advertising Council. In reviewing the decision, the Managing Director may take into account any recommendation made by the Advertising Council.

Appeal of a decision not to approve an advertisement or withdraw an approval

² Lodgement should preferably be in writing. However, where this is not possible, complaints will still be accepted provided that the identity of the complainant can be confirmed and the exact nature of the complaint.

Where the applicant is dissatisfied with the decision of the Managing Director, an application can be made to the Trans Tasman Review Tribunal that will provide an independent merits review of the Agency's regulatory decisions.

Appeal of a decision made in dealing with complaints about advertisements

Australia

If the Central Complaints Panel (Australia) decides that an advertisement breaches the therapeutic products legislation, including the Code, the Panel can order certain action/s be taken by the advertiser/product licence holder, such as withdrawal of the advertisement, publication of a retraction or correction, withdrawal of a representation and/or impose penalties. If the order is not complied with within 14 days, the Panel may make recommendations to the Agency to pursue regulatory or court action. In extreme cases, regulatory action to remove the product from the market may be necessary.

Both parties to the complaint can request that the Managing Director review the determination of the complaint and any orders issued against the advertiser/product licence holder. If either party is still dissatisfied with the internal review, an appeal can be made to the Trans Tasman Review Tribunal, which will be drawn from a merits review panel.

The matter may also be taken to the Federal Court of Australia or the courts of an Australian State or Territory.

New Zealand

If the Central Complaints Panel (New Zealand) decides that an advertisement breaches the therapeutic products legislation, including the Code, the Panel can request that the advertiser/product licence holder withdraw the advertisement. If the request is not complied with within 14 days, the Panel may refer the matter to the Agency to pursue regulatory or court action. In these circumstances, regulatory action to remove the product from the market may be necessary.

Either party to the complaint may request that the Advertising Standards Complaints Appeal Board (ASCAB) review the determination of the complaint and, if dissatisfied with that review, a request can be made for an internal review by the Managing Director of the Agency. If either party is still dissatisfied, an appeal can be made to the Trans Tasman Review Tribunal which will be drawn from a merits review panel.

The matter may also be taken to the New Zealand court.

A5 - FAILURE TO COMPLY WITH THE CODE

Non-compliance with the Code is an offence under Section X of the Trans Tasman Therapeutic Products Act(s). Regulatory action also can be taken by the Agency under Section X of the Rules to suspend or cancel a product licence for breaches of the Code.

Compliance with the Code is encouraged through broad stakeholder representation on the Advertising Council, the consultative processes in place for any proposed changes to the Code and education programs run by the peak therapeutic products and advertising/media industry associations in Australia and New Zealand.

To deal with non-compliance with the Code, a range of administrative sanctions and criminal penalties can be applied by the Agency. A range of enforcement tools is necessary to ensure that the regulatory response is commensurate with the seriousness of the offence and recognises that, in many cases, minor offences can be resolved without the need for punitive action. Often this range is considered in terms of a pyramid with the lower levels based on advice and persuasion to prompt a voluntary response. The next level involves the issuances of formal directions to undertake certain action/s and/or infringement notices, which are intended to be a light punitive action where there is a clear breach of a non-serious nature. Where there is the need to escalate the matter, regulatory action can be taken to suspend or cancel a product licence. At the top of the pyramid is criminal prosecution, which would apply only to the most serious breaches or repeat offenders.

PART B1

ADVERTISING MEDICINES TO CONSUMERS

The advertising of prescription medicines, and certain non-prescription medicines, directly to consumers is prohibited in Australia (refer B1-23). In New Zealand, advertising of all legally supplied medicines directed to consumers is permitted, subject to compliance with this Code, other than those which contain controlled drugs which are not exempted or partially exempted controlled drugs, as defined in the *Misuse of Drugs Act 1975*. Where the Researched Medicines Industry Association of New Zealand (RMI) Code of Practice contains additional requirements or limitations for the advertising of prescription medicines, advertisers must comply with these provisions.

Requirement 1

Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.

An advertisement must not contain an offer of a sample for medicines without approval from the Agency.

Advertisements must not encourage consumers to purchase or use quantities of a medicine that may exceed, or is not appropriate for, their needs.

In determining whether or not an advertisement is likely to encourage a consumer to use a medicine inappropriately or excessively, all circumstances relating to the advertisement will be taken into account, including the target audience and, where appropriate, the following factors:

- *the nature of the advertisement;*
- *the nature and quantity of the medicine offered as part of a price promotion or required to be purchased as a condition of entry to a competition;*
- *prizes offered in association with the medicine;*
- *the risk of the medicine advertised; and*
- *the design/conditions of any competition.*

An exemption may be granted by the Agency to allow the advertising of a sample of a medicine on a case by case basis where this is considered to be consistent with the policy on Quality Use of Medicines and in the public interest. An example of a product category that meets the public interest criteria to allow approval for advertising of samples is sunscreen preparations.

Requirement 2

Advertisements must contain the mandatory information to encourage responsible use.

Any advertisement for a medicine must include all of the required statements in paragraphs (a) to (e), other than where:

- the advertisement does not contain a therapeutic claim and displays only the brand/name/picture of the medicine or the name of the product licence holder and/or the price and/or point of sale; or
- the advertisement is an unbranded, or a reminder, or a sponsorship advertisement.

All required statements in paragraphs (a) to (e) must be prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or be heard and understood.

For all required statements, other than 'Always read the label', words conveying the same meaning may be used.

(a) (i) Advertisements to consumers for medicines must contain:

- the trade name; and
- indications consistent with those included in the product licence database of therapeutic products maintained by the Agency; and
- where the advertising of prescription medicines is permitted in New Zealand, a list of the active ingredients; and
- for all medicines (except for prescription medicines where they may be advertised in New Zealand) the following mandatory statement:

ALWAYS READ THE LABEL

- and the following statement or words with the same meaning:

USE ONLY AS DIRECTED

- and the following statement, or words with the same meaning, where relevant to the product i.e. if the indication is for symptomatic relief, or a similar indication.

IF SYMPTOMS PERSIST SEE YOUR HEALTHCARE PRACTITIONER

- (ii) If the medicine, when used according to the directions:

- has known serious adverse effects (in terms of severity and clinical importance); or
- is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI),

an appropriate warning of those effects must be given.

(Where a warning which reflects the regulatory requirements for the label or the Consumer Medicine Information (CMI) refers to a serious disease, disorder, or condition an approval for use of a restricted representation as per Requirement 8 of the Code is not required).

(The IAC recommends the development of common sense guidelines during the implementation period, with appropriate input by relevant expert committees, to provide parameters for the inclusion of warnings relating to the severity and the clinical importance of adverse effects and contraindications appropriate for the category of product).

- (iii) Additional mandatory statements based on the scheduling classification of the therapeutic product, as follows:

- If it is a restricted/pharmacist only medicine (New Zealand) or Schedule 3 and listed in Appendix H, SUSDP (Australia), the words:

YOUR PHARMACIST'S ADVICE IS REQUIRED; or AVAILABLE ONLY FROM YOUR PHARMACIST

- If it is a Schedule 4 (prescription medicine) able to be advertised in New Zealand:

PRESCRIPTION MEDICINE, CONSULT YOUR DOCTOR [OR OTHER PRESCRIBER] TO SEE IF THIS MEDICINE IS RIGHT FOR YOU

- For New Zealand, if there is a charge for a prescription medicine in excess of the standard prescription fee, this should be indicated, e.g.

A CHARGE APPLIES, CONSULT YOUR DOCTOR OR PHARMACIST

- (iv) Where an advertisement is for the sale or supply of therapeutic products by mail order, direct mail, or the internet, the advertisement must contain, in addition to the above:

- any mandatory advisory statements required to be included on the product label, prominently displayed on each page that features the relevant medicine/s;
- if the medicine, when used according to the directions:
 - has known serious adverse effects (in terms of severity and clinical importance); or
 - is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI);

an appropriate warning of those effects must be given.

(Where a warning reflects the regulatory requirements for the label of the Consumer Medicine Information (CMI), an approval for use of a restricted representation as per Requirement 8 of the Code is not required);

- a full list of the active ingredients.
(Where the product name is also the single active ingredient, the pack shot displaying the product name will be sufficient to meet this requirement).
- (b) Where the advertising of prescription medicines is permitted (New Zealand), consumers must be notified that additional product information can be obtained, and the methods for doing so. Such information shall include the name and quantities of the active ingredients, authorised uses, appropriate precautions, contra-indications, and adverse reactions. *Various acceptable methods include, but are not limited to, instructions for consumers to contact their doctor, pharmacist or healthcare practitioner; referring consumers to the labelling of the product or the Consumer Medicine Information; provision of a toll-free telephone number; the advertiser's internet website address; the advertiser's postal address; reference to the Consumer Medicines Information, where applicable, and referring consumers to advertisements with full information appearing concurrently in other media.*
- (c) In addition to the requirements specified above, analgesics require the following statement:
- INCORRECT USE COULD BE HARMFUL**
- An advertisement for analgesics must not represent that:
- (a) analgesic consumption is safe; and/or
 - (b) analgesics will relax, relieve tension, sedate or stimulate.
- (d) An advertisement for vitamins must not represent that vitamin supplements:
- are a substitute for good nutrition or a healthy diet; and/or
 - are superior to, or more beneficial than, dietary nutrients or that normal health may be affected by not taking vitamin supplements.
- (e) Advertisements for medicines containing claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, must have an appropriate balance between those claims and references to a healthy energy-controlled diet and physical activity.

Requirement 3

To assist consumers to make informed decisions, advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated and:

- a) for medicines – must be consistent with the indications included on the product licence database of therapeutic products maintained by the Agency; and**
- b) for exempt therapeutic products – must be compliant with the Code.**

Product licence holders / advertisers are required to hold appropriate, balanced, comprehensive and credible evidence to support advertised claims. That is, when the claim is considered in the overall context of all information available at the time of advertising, it is, on balance, substantiated. Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

Evidence may be requested to verify any claim included in an advertisement. Where the advertiser is not a product licence holder, the advertiser should have access to this evidence.

For advertising claims for therapeutic use, the product licence holder / advertiser must hold information or evidence to substantiate any indication for use. Depending on the class of the products, this evidence must either have been evaluated by the Agency or subject to self-certification by the product licence holder as part of product licensing requirements.

Other advertising claims, such as product presentation, marketing or commercial claims, also must be valid and have been substantiated.

The term 'valid' embraces the concepts of safe and effective use of medicines. It can apply in the broader context to any marketing claim contained within an advertisement.

The term 'balance' embraces the overall balance within an advertisement of representations, risks and benefits.

Any therapeutic indication referred to in unbranded or generic advertising must have been substantiated. In this case, Requirements 3(a) and 3(b) are not relevant.

If a product licence holder ceases to supply/import/manufacture or export particular medicines, that product licence holder may request that the product licence be cancelled. Subject to relevant Australian government legislation, New Zealand government legislation and Australian state/territory legislation, where the cancelled product can continue to be lawfully supplied by a retailer (who is not also the product licence holder) directly to consumers, the product may be advertised for supply subject to compliance with the Code.

Requirement 4

Advertisements must not directly nor by implication, omission, ambiguity, exaggerated claim or comparison:

- (a) mislead or deceive, or be likely to mislead or deceive; or**
- (b) abuse trust, or exploit lack of knowledge; or**
- (c) exploit the superstitious or, without justifiable reason, play on fear or cause distress.**

The protection of public health and safety, in terms of quality, safety and efficacy of the advertised product (including performance claims) is the focus of this Requirement. The Australian Competition and Consumer Commission (Australia) and Commerce Commission (NZ) also have responsibility for laws prohibiting misleading or deceptive conduct and false and misleading representations (including advertising). These agencies deal with broader matters through the administration of relevant trade practices legislation. The Agency will liaise with the Australian Competition and Consumer Commission and the Commerce Commission in New Zealand where there is any potential regulatory overlap.

R4.1 An advertisement must not:

- i) contain any claim, statement or implication that the product is safe or that its use cannot cause harm or that it has no side effects or risks associated with its use;
- ii) contain any claim, statement or implication that the product is effective in all cases of a condition;
- iii) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- iv) contain any matter which is likely to lead persons to believe that:
 - they are suffering from a serious ailment, or
 - harmful consequences may result from the therapeutic product not being used.

Claims as described in iv) may be restricted representations. Where appropriate, and if claims made in an advertisement are consistent with public health messages, an exemption from iv) may be granted. Approval for the use of a restricted representation, as per Requirement 8 of the Code, may need to be sought. An example of a product category that meets the public interest criteria to allow approval for restricted representations is sunscreen preparations for skin cancer prevention.

R4.2 Comparative advertising

Comparative advertising must be balanced and must not be misleading, or likely to be misleading, either about the product advertised or any therapeutic products, or classes of therapeutic products, with which comparison is made.

Comparative advertisements must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence.

Where medicines whose market entry indications are compared with other medicines whose market entry indications have been evaluated by the Agency, the advertiser must, upon request, be able to produce evidence to substantiate the comparison.

In comparing products, advertisements must not discourage consumers from taking medicines prescribed by a healthcare practitioner.

R4.3 Scientific information

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

Using complex scientific terminology in advertisements is likely to exploit the average consumer's lack of scientific knowledge to understand the true meaning of what is being said in the advertisement.

Extracts from scientific studies must not be ambiguous or mislead as to the content or results of the study or the performance of the medicine. Inserting selected abstracts from scientific papers or medical reports, which do not accurately reflect the results of the study or report, into an advertisement, has the potential to be ambiguous and may mislead by omission or implication. Titles of publications, or parts thereof, must not contravene the Code.

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, where that product licence holder directly, or indirectly, has commercial interest in the medicine or its ingredients.

Requirement 5

Advertisements must not unduly glamorise products or prey on the vulnerability of particular audiences.

Examples of potentially vulnerable audiences include, but are not limited to:

- *minors (people under 18 years of age)*
- *older people*
- *people with mental health problems*
- *people with impaired hearing/vision*
- *people with chronic or serious illness or long term or permanent disability*
- *people for whom English is a second language*

In considering the compliance of an advertisement directed to any of the potentially vulnerable groups listed above, the public interest criteria (refer Section A4.1) will be applied.

Requirement 6

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and is not presented as an endorsement of a product.

Unless prohibited by **endorsed** sector codes, advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the name of the endorser and acknowledgement of any valuable consideration.

Examples which would be taken to represent an endorsement by a government agency and therefore are prohibited include:

- *“approved by the Agency” (or any other terminology in the trans Tasman legislation which implies approval)*
- *“recommended by the Australian Sports Commission”*
- *“supported by the National Science and Technology Centre”*

Examples of statements which would not be considered to imply an endorsement include:

- *Entered into the product licence database of therapeutic products*
- *Manufactured in a GMP licensed premise*
- *Manufacturing Licence No. (****)*

Examples which would be taken to represent an endorsement by a healthcare practitioner (as defined under Part A4 of the Code) and would be permitted subject to certain disclosure requirements include:

- pictorial images of healthcare practitioners promoting a medicine,
- using the name of a healthcare practitioner to promote the medicine, or
- stating or implying that a healthcare practitioner, uses, recommends or was involved in the testing or development of a medicine.

Note: An approvals officer may request provision of a statutory declaration as authentication of an endorsement by an individual healthcare practitioner.

Hospitals or other facilities providing healthcare services

Facilities that provide health care or healthcare services include centres that are delivering healthcare services on a commercial or public health basis. For example hospitals, general practice, dentistry, community-based office practices, day-surgery centres, domiciliary nursing services, other healthcare providers, and other community services such as needle exchanges, ambulance services and mobile medical services.

Examples of an endorsement by a healthcare facility or service include:

- advertising to consumers that a healthcare facility or service has a contract to use a specific medicine,
- promoting sponsorship of healthcare facilities or services by a brand name medicine,
- suggesting a healthcare facility or service prefers a particular brand of medicine, or
- suggesting a healthcare facility or service was involved in the development, testing or manufacture of the medicine being advertised.

Requirement 7

Testimonials in advertisements, where not prohibited by law, must comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable consideration.

The use of testimonials in advertisements to promote medicines is acceptable, other than for prescription products directed to consumers (New Zealand), provided the testimonial:

- is genuine;
- complies with the Code;
- is current;
- has been authenticated;
- presents the typical case, not the exceptional; and
- contains an acknowledgement of any valuable consideration.

The advertising approval officer, at the time of assessing an advertisement for approval for publication, will request evidence of the above, including that it is typical, and is entitled to require a signed statutory declaration, and/or a copy of the signed testimonial, from the person making the testimony. If the substance of the testimonial in the advertisement has been altered from the original testimony, the advertisement may not be approved for publication.

“Current” means that the content of a testimonial must be up to date and hold true at the time of the publication of the advertisement.

“Typical” means that which reflects the characteristics of a group. i.e. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

Requirement 8

Advertisements directed to consumers must not refer directly or by implication to serious diseases, conditions, ailments or defects without approval from the Agency.

Unless prior approval has been obtained (refer Part A4.2) advertisements directed to consumers must not contain a restricted representation. This means that they must not (either expressly or by implication) refer to the self-diagnosis of, or the treatment, management, prevention or cure of, serious forms of diseases, conditions, ailments or defects which are those diseases, conditions, ailments or defects (or symptoms of the aforementioned) which are generally accepted as not being suitable for treatment, management, prevention or cure by consumers.

PROHIBITIONS

1. *In Australia, it is prohibited to advertise directly to consumers, prescription medicines (i.e. containing Schedule 4 or 8 substances), and non-prescription medicines containing Schedule 3 substances that do not appear in Appendix H to the Standard for Uniform Scheduling of Drugs and Poisons, (as amended from time to time), including medical devices which contain those substances. The prohibition does not apply where the Australian Commonwealth, States and Territories governments include information about specific products in public health education initiatives such as vaccination campaigns.*
2. *In New Zealand, advertisements for Class A, Class B and Class C controlled drugs which are not exempted or partially exempted controlled drugs, as defined in the Misuse of Drugs Act 1975, may only be directed to healthcare practitioners and in appropriate media.*

PART B2

ADVERTISING MEDICAL DEVICES TO CONSUMERS

Requirement 1

Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.

Advertisements must not encourage consumers to purchase or use quantities of a medical device that may exceed, or be inappropriate for, their needs.

There is a range of ways in which advertisements for medical devices could encourage excessive or inappropriate use. One such example would be the encouraging of prolonged self-administration of a medical device, which could result in delay of persons seeking advice from a health care practitioner and/or mask the symptoms of a more serious disease; for example, an advertisement that encourages repeated and/or prolonged use of a peripheral nerve stimulator for pain relief.

In determining whether or not an advertisement is likely to encourage a consumer to use medical devices inappropriately or excessively, all circumstances relating to the advertisement will be taken into account, including the target audience and, where appropriate, the following factors:

- *the nature of the advertisement;*
- *the nature and quantity of therapeutic products:*
 - *offered as part of a price promotion;*
 - *offered as samples or giveaways; or*
 - *required to be purchased as a condition of entry to a competition;*
- *prizes offered in association with therapeutic products;*
- *the risk of the therapeutic products advertised;*
- *the design/conditions and promotion of any competition;*
- *the instructions for use, or advice, regarding the appropriate use of a medical device.*

Requirement 2

Advertisements must contain the mandatory information to encourage responsible use.

Any advertisement for medical devices must include all of the required statements in paragraphs (a) to (e), other than where:

- the advertisement does not contain a therapeutic claim or intended purpose for use and displays only the brand/name/picture of the medical device and/or the price and/or point of sale; or
- the advertisement is an unbranded, or a reminder, or a sponsorship advertisement.

All required statements in paragraph (a) must be prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood.

(a) Advertisements to consumers for medical devices must contain the following statements:

- the trade name;
- the intended purpose consistent with that included in the product licence database of therapeutic products maintained by the Agency. [Until 2007, where there is no intended purpose on the database, the purpose must be consistent with the manufacturer's intended purpose for use]; and
- the following mandatory statement (except where the advertisement is for a health service or treatment program that includes a reference to the use or administration of a particular device as part of that service or treatment):

ALWAYS READ THE LABEL

and/or, where appropriate,

FOLLOW THE INSTRUCTIONS (or words to that effect)

If the medical device has contraindications or specific warnings that may affect the safe use of the device, which are reflected in the regulatory requirements for the product label or in the patient information, an appropriate warning must be given (where a warning includes a reference to a restricted medical device as part of the regulatory requirements for the label, approval to reference that restricted medical device is not required).

For example, if:

- an electronic medical device is likely to interfere with a cardiac pacemaker; and/or
 - the use of a particular medical device is contraindicated for specific medical conditions;
- then these warnings should appear in the advertisement for the devices.

Requirement 3

To assist consumers to make informed decisions, advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated and:

- a) for medical devices – must be consistent with the manufacturer’s intended purposes included on the product licence database for therapeutic products maintained by the Agency; and**
- b) for exempt therapeutic products – must be compliant with the Code.**

Product licence holders / advertisers are required to hold appropriate, balanced, comprehensive and credible evidence to support advertised claims. That is, when the claim is considered in the overall context of all information available at the time of advertising, it is, on balance, substantiated. Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

Evidence may be requested to verify any claim included in an advertisement. Where the advertiser is not a product licence holder, the advertiser should have access to this evidence. That is, the product licence holder / advertiser must hold information or evidence to substantiate any intended purpose included on the database for therapeutic products. Depending on the class of the products, this evidence will either have been evaluated by the Agency or have been subject to self-certification by the product licence holder as part of product licensing requirements.

Other advertising claims, such as product presentation, marketing or commercial claims, also must be valid and have been substantiated.

The term ‘valid’ embraces the concepts of responsible and judicious use of products. It can apply in the broader context to any marketing claim contained within an advertisement.

The term ‘balance’ embraces the overall balance within an advertisement of representations, risks and benefits.

Any purpose of use referred to in unbranded or generic advertising must be consistent with the manufacturer’s purpose for use and have been substantiated. In this case, Advertising Requirements 3(a) and 3(b) are not relevant.

If a product licence holder ceases to supply/import/manufacture or export particular medical devices, that product licence holder may request that the product licence be cancelled. Subject to relevant Australian government legislation, New Zealand government legislation and Australian state/territory legislation, where the cancelled product can continue to be lawfully supplied by a retailer (who is not also the product licence holder) directly to consumers, the product may be advertised for supply subject to compliance with the Code. Healthcare practitioners may continue to advertise the use (but not supply) of a cancelled medical device to consumers in relation to the health service being promoted.

If a medical device has not been evaluated by the Agency (eg class I, class IIa and some class IIb devices), the advertising approval officer may require the product licence holder / advertiser to produce evidence to show how the therapeutic claims made in the advertisement fit in with the manufacturer’s purpose of use (as reflected in the therapeutic product database, where applicable), prior to approving an advertisement for publication.

Requirement 4

Advertisements must not directly nor by implication, omission, ambiguity, exaggerated claim or comparison:

- (a) mislead or deceive, or be likely to mislead or deceive; or**
- (b) abuse trust, or exploit lack of knowledge; or**
- (c) exploit the superstitious or, without justifiable reason, play on fear or cause distress.**

The protection of public health and safety, in terms of quality, safety and efficacy of the advertised product (including performance claims), is the focus of this Requirement. The Australian Competition and Consumer

Commission (Australia) and Commerce Commission (NZ) also have responsibility for laws prohibiting misleading or deceptive conduct and false and misleading representations (including advertising). These agencies deal with broader matters through the administration of relevant trade practices legislation. The Agency will liaise with the Australian Competition and Consumer Commission and the Commerce Commission in New Zealand where there is any potential regulatory overlap.

R4.1 An advertisement must not:

- i) contain any claim, statement or implication that the product is safe or that it cannot cause harm or that it has no side effects or risks associated with its use;
- ii) contain any claim, statement or implication that the product is effective in all cases of a condition;
- iii) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- iv) contain any matter which is likely to lead persons to believe that;
 - they are suffering from a serious ailment, or
 - harmful consequences may result from the therapeutic product not being used.

Claims as described in iv) may be restricted representations. Where appropriate, and if claims made in an advertisement are consistent with public health messages, an exemption from iv) may be granted. Approval for the use of a restricted representation, as per Advertising Requirement 8 of the Code, may need to be sought. An example of a product category that meets the public interest criteria to allow approval for restricted representations is condoms for the reduction of the risk of transmission of sexually transmitted diseases.

R4.2 Comparative advertising

Comparative advertising must be balanced and must not be misleading, or likely to be misleading, either about the product advertised or any therapeutic products, or classes of therapeutic products, with which comparison is made.

Comparative advertisements must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence.

Where therapeutic products whose market entry indications, or purpose of use, are compared with other therapeutic products whose market entry indications have been evaluated by the Agency, the advertiser must, upon request, be able to produce evidence to substantiate the comparison.

In comparing products, advertisements for medical devices must only make comparisons between products with a similar intended purpose of use.

R4.3 Scientific information

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

Using complex scientific terminology in advertisements is likely to exploit the average consumer's lack of scientific knowledge to understand the true meaning of what is being said in the advertisement.

Extracts from scientific studies must not be ambiguous or mislead as to the content or results of the study or the performance of the medical device. Inserting selected abstracts from scientific papers or medical reports, which do not accurately reflect the results of the study or report, into an advertisement, has the potential to be ambiguous and may mislead by omission or implication. Titles of publications, or parts thereof, must not contravene the Code.

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, where that product licence holder directly, or indirectly, has a commercial interest in the medical device or its components.

Requirement 5

Advertisements must not unduly glamorise products or prey on the vulnerability of particular audiences.

Examples of potentially vulnerable audiences include, but are not limited to:

- *minors (people under 18 years of age)*
- *older people*
- *people with mental health problems*
- *people with impaired hearing/vision*
- *people with chronic or serious illness or long term or permanent disability*
- *people for whom English is a second language*

In considering the compliance of an advertisement directed to any of the potentially vulnerable groups listed above, the public interest criteria (refer A4.1) will be applied.

Medical devices that are considered to meet the public interest criteria for advertising to minors (ie people under 18 years of age) include:

- *tampons*
- *condoms and personal lubricants*
- *bandages and dressings*
- *devices for management of chronic conditions under medical supervision (where reference to these chronic conditions includes a reference to a restricted representation additional requirements apply - see Advertising Requirement 8).*

Requirement 6

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and is not presented as an endorsement of a product.

Unless prohibited by **endorsed sector codes, advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the name of the endorser and acknowledgement of any valuable consideration.**

Examples which would be taken to represent an endorsement by a government agency, and therefore are prohibited, include:

- *“approved by the Agency” (or any other terminology in the trans Tasman legislation which implies approval)*
- *“recommended by the Australian Sports Commission”*
- *“supported by the National Science and Technology Centre”*

Examples of statements which would not be considered to imply an endorsement, and therefore are permitted, include:

- *Entered into the product licence database of therapeutic products*
- *Manufactured in a GMP licensed premise*
- *Manufacturing Licence No. (****)*
- *Product is CE marked*

Examples which would be taken to represent an endorsement by a healthcare practitioner (as defined under Part A4 of the Code), and are permitted subject to certain disclosure requirements, include:

- *pictorial images of healthcare practitioners promoting a medical device,*
- *using the name of a healthcare practitioner to promote the medical device, or*
- *stating or implying that a healthcare practitioner, uses, recommends or was involved in the testing or development of a medical device.*

Note: An approvals officer may request provision of a statutory declaration as authentication of an endorsement by an individual healthcare practitioner.

Hospitals or other facilities providing healthcare services

Facilities that provide health care or healthcare services include centres that are delivering healthcare services on a commercial or public health basis. For example hospitals, general practice, dentistry, community-based office practices, day-surgery centres, domiciliary nursing services, alternative health providers, and other community services such as needle exchanges, ambulance services and mobile medical services.

Examples of an endorsement by a healthcare facility or service which would be prohibited include:

- *advertising to consumers that a healthcare facility or service has a contract to use a specific medical device,*
- *promoting sponsorship of healthcare facilities or services by a brand name medical device,*
- *suggesting a healthcare facility or service prefers a particular brand of medical device, or*
- *suggesting a healthcare facility or service was involved in the development, testing or manufacture of the medical device being advertised.*

Requirement 7

Testimonials in advertisements, where not prohibited by law, must comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable consideration.

The use of testimonials in advertisements to promote medical devices is acceptable provided the testimonial:

- *is genuine;*
- *complies with the Code;*
- *is current;*
- *has been authenticated;*
- *presents the typical case, not the exceptional; and*
- *contains an acknowledgement of any valuable consideration.*

The advertising approval officer, at the time of assessing an advertisement for approval for publication, will request evidence of the above, including that it is typical and is entitled to require a signed statutory declaration, and/or a copy of the signed testimonial, from the person making the testimony. If the substance of the testimonial in the advertisement has been altered from the original testimony, the advertisement may not be approved for publication.

“Current” means that the content of a testimonial must be up to date and hold true at the time of the publication of the advertisement.

“Typical” means that which reflects the characteristics of a group. i.e. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

Requirement 8

Advertisements directed to consumers must not refer directly or by implication to medical devices, or procedures involving medical devices, that are intended to be used and/or administered solely by healthcare practitioners, without approval from the Agency.

Medical devices that can be administered or used only by healthcare practitioners (“restricted medical devices”) are prohibited from being advertised to consumers unless:

- the advertisement does not specifically reference a particular branded product; or
- prior approval has been obtained (refer Section A4.2).

For example:

- *advertising to consumers of a brand named active implantable drug infusion device, which is implanted into the patient by a surgeon for relief of chronic pain, is prohibited.*

An application for an exemption to advertise direct to consumers, a medical device, or procedure using a medical device that is used and/or administered by a healthcare practitioner should address the public interest criteria outlined in Section A4.1.

PART B3

ADVERTISING THERAPEUTIC PRODUCTS TO HEALTHCARE PRACTITIONERS

Preface

The Advertising Principles and relevant Advertising Requirements included in this part of the Code apply specifically to advertisements for therapeutic products that are directed solely to healthcare practitioners.

PART A of the Code applies to the advertising of therapeutic products directed both to consumers and to healthcare practitioners.

All advertising directed to healthcare practitioners must encourage the responsible and quality use of therapeutic products. Because healthcare practitioners have expert and professional knowledge in their relevant fields, and are able to discriminate between information of value and advertising hyperbole, not all of the Advertising Requirements in Sections B1 and B2 (i.e. advertising directed to consumers) apply. There is no requirement for pre-approval of advertisements directed to healthcare practitioners.

The following requirements for advertising to healthcare practitioners have been developed jointly by the relevant industry associations in Australia and New Zealand with reference to their existing codes of practice. These requirements will continue to be reflected in the industry association codes. Where applicable, the requirements are the same as those for advertising to consumers.

While the Australia New Zealand Therapeutic Products Advertising Code sets the minimum standard for advertising requirements, additional requirements may be applied to particular industry sectors through the industry association codes. These additional requirements can be found in the individual industry association codes, which also provide additional guidance on the application of these requirements.

NOTE: Some requirements that are applicable to advertising directed to consumers do not apply to advertising directed to healthcare practitioners. To retain the consistency of numbering, these parts have been noted as being intentionally blank.

Requirement 1

Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.

Requirement 2

Advertisements must contain the mandatory information to ensure responsible use.

Each industry code details how compliance with Advertising Requirements 2 and 3 is achieved. For example, sections 2 and 3 of the Medicines Australia Code of Conduct and section 6.2 of the Researched Medicines Industry Association of New Zealand Code of Practice cover the requirements for prescription medicines advertisements directed to health care practitioners.

In the Australian Self-Medication Industry Code of Practice, section 5.5 identifies the specific information that must be included in advertisements directed to healthcare practitioners.

Requirement 3

Advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated, and:

a) for medicines:

must be consistent with the approved Product Information, or other substantiation of efficacy provided by the product licence holder to the Agency;

b) for medical devices:
must be consistent with the manufacturer's intended purposes, included on the product licence database for therapeutic products maintained by the Agency; and

c) for exempt therapeutic products:
must be compliant with the Australia New Zealand Therapeutic Products Advertising Code.

Industry association codes provide guidance and examples on how to comply with this Advertising Requirement.

For example, for prescription medicines promoted to healthcare practitioners, all claims must be balanced, accurate, correct, fully supported by the Product Information (PI), literature or Data on File, or an appropriate industry source, where these do not conflict with the Product Information (refer section 1 of the Medicines Australia Code and section 4.3 of the Researched Medicines Industry Association of New Zealand Code of Practice).

For non-prescription therapeutic products, information and therapeutic claims must be current, accurate, balanced and must not mislead either directly, by implication, or by omission (refer section 5 of the ASMI Code, Principle 2 of the NZSMI Code of Practice and section 7.3 of the CHC Code of Practice).

Requirement 4

Advertisements must not directly nor by implication, omission, ambiguity or comparison mislead or deceive, or be likely to mislead or deceive.

Claims and representations made in advertisements must be truthful and have been substantiated.

R4.1 An advertisement must not:

- i) contain any claim, statement or implication that the product is safe or that its use cannot cause harm or that it has no side effects or risks associated with its use;
- ii) contain any claim, statement or implication that it is effective in all cases of a condition;
- iii) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;

R4.2 Comparative advertising

Comparative advertising must be balanced and must not be misleading, or likely to be misleading, either about the product advertised or any therapeutic products, or classes of therapeutic products, with which comparison is made.

Comparative advertisements must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence.

Where therapeutic products whose market entry indications, or purpose of use, are compared with other therapeutic products whose market entry indications have been evaluated by the Agency, the advertiser must, upon request, be able to produce evidence to substantiate the comparison.

R4.3 Scientific information

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

Extracts from scientific studies must not be ambiguous or mislead as to the content or results of the study or the performance of the therapeutic product. Inserting selected abstracts from scientific papers or medical reports, which do not accurately reflect the results of the study or report, into an advertisement, has the potential to be ambiguous and may mislead by omission or implication. Titles of publications, or parts thereof, must not contravene the Code.

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, where that product licence holder directly, or indirectly, has a commercial interest in the product or its ingredients or components .

R4.4 Substantiating Data

Any information used to support a claim must include sufficient detail, and be of adequate quality, to allow evaluation of the validity of results and hence of the claim.

Requirement 5

Advertisements must not unduly glamorize products.

Requirement 6

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and cannot be misconstrued as an endorsement of a product.

Advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not in any way imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the name of the endorser and acknowledgement of any valuable consideration.

Exclusions from this requirement are:

- *reference to the conduct of clinical trials and any funded research; and*
- *any statement about listing on the Australian Pharmaceutical Benefits Scheme (PBS), or by the New Zealand Pharmaceutical Management Agency (PHARMAC), or other government health funding body.*

Examples of an endorsement by a government agency which would be prohibited include:

- *“approved by the Agency”*
- *“recommended by the Australian Sports Commission”*
- *“supported by the National Science and Technology Centre”*

Healthcare practitioners:

Examples which would be taken to represent an endorsement by a healthcare practitioner (as defined under Part A4 of the Code) and permitted subject to certain disclosure requirements, include:

- *pictorial images of healthcare practitioners promoting a therapeutic product,*
- *using the name of a healthcare practitioner to promote the therapeutic product, or*
- *stating or implying that a healthcare practitioner, uses, recommends or was involved in the testing or development of a therapeutic product.*

Hospitals or other facilities providing healthcare services

Facilities that provide health care or healthcare services include centres that are delivering healthcare services on a commercial or public health basis.

For example hospitals, general practice, dental services, community-based office practices, day-surgery centres, domiciliary nursing services, alternative health practices or centres, and other community services such as needle exchanges, ambulance services and mobile medical services.

Industry codes of practice address appropriate transparency requirements in relation to the funding of research by product licence holders.

Requirement 7

Testimonials in advertisements, where not prohibited by law, must comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable consideration.

The use of testimonials in advertisements to promote therapeutic products is acceptable, provided the testimonial:

- *is genuine;*
- *complies with the Code;*
- *is current;*
- *has been authenticated; and*
- *presents the typical case, not the exceptional.*

The advertising approval officer in New Zealand, at the time of assessing an advertisement for approval for publication, will request evidence of the above, including that it is typical and is entitled to require a signed statutory declaration, and/or a copy of the signed testimonial, from the person making the testimony. If the substance of the testimonial in the advertisement has been altered from the original testimony, the advertisement may not be approved for publication.

“Current” means that the content of a testimonial must be up to date and hold true at the time of the publication of the advertisement. “Typical” means that which reflects the characteristics of a group. i.e. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

Requirement 8 – this part is intentionally blank

The following requirement is applicable only to the advertising of therapeutic products directed to healthcare practitioners

Requirement 9 (medicines)

All communications made by product licence holders (or their representative) must comply with the Code. Where the product being advertised is a finished product, therapeutic claims for unlicensed products and unapproved indications must not be made, unless the product is exempt from product licensing.

Whenever a therapeutic claim is made for a product for which a product licence is required, the licence applicant (or their representative) must offer the approved Product Information, or other data used by the product licence holder as the basis for obtaining the product licence.

Whenever a therapeutic claim is made for:

- **an active ingredient that may be used in the manufacture of therapeutic products; or**
- **a product which is exempt from product licensing;**

the data used by the supplier to verify the claim must be offered by the licence applicant (or their representative).

Advertisements directed to healthcare practitioners for extemporaneously compounded therapeutic products (as finished goods which are exempt from product licensing) are required to comply with the Code.

Active ingredients are exempt from product licensing but may be advertised to healthcare practitioners to be used in extemporaneous compounding of finished products. Any factual new information on the benefits of a particular active ingredient can be provided as educational material or bona fide research, which is exempt from the Code (refer Section A3.1).

Requirement 9 (devices)

The representation of medical devices/diagnostics included on the product licence database for therapeutic products maintained by the Agency must be consistent with the manufacturer’s intended purposes and be consistent with the essential principles for the product.

When requested, the product licence holder (or their representative) must be able to supply a copy of the product licence holder’s product information consistent with the manufacturer’s intended purpose and essential principles. Claims outside the manufacturer’s intended purpose and essential principles must not be made.

For non-therapeutic claims the product licence holder must hold substantiating data to support the claims.