

Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006

The Ministerial Council established under 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, done at Wellington on 10 December 2003, makes the following Rule.

Dated 2006

[DRAFT ONLY – NOT FOR SIGNATURE]

Minister for Health and Ageing
Australia

Minister of Health
New Zealand

CONSULTATION DRAFT ONLY

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Part 1 Preliminary

1.01 Name of Rule

This Rule is the *Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006*.

1.02 Commencement

This Rule commences on [^date].

1.03 Definitions

(1) In this Rule:

accepted industry sector code of conduct means an industry sector code of conduct accepted by the Authority under section 2.03.

advertisement, in relation to a therapeutic product, means any communication that promotes or discourages the use, sale or other supply of the product, whether or not the communication is in conjunction with the supply of a service or identifies the particular product or service, but does not include:

- (a) a product label; or
- (b) a communication of any of the following kinds:
 - (i) corrective advertising;
 - (ii) a retraction;
 - (iii) bona fide news, a bona fide editorial or a bona fide public interest or entertainment program;
 - (iv) bona fide educational, research or professional advice.

Advertising Code means the Australia New Zealand Therapeutic Products Advertising Code mentioned in section 2.01.

advertising industry body means an association or other body or organisation involved in the advertising industry in Australia or New Zealand.

approval number, in relation to an approved advertisement, has the meaning given by section 3.07.

approved advertisement means an advertisement approved, or taken to be approved, under Division 3.2.

Central Complaints Panel or ***Panel*** means a Central Complaints Panel constituted under Part 5.

consumer means a person who is not a healthcare practitioner.

export-only therapeutic product means a therapeutic product that is intended to be exported to a country that is not Australia or New Zealand, and will not be supplied in Australia or New Zealand.

healthcare practitioner means any:

- (a) chiropractor, dental practitioner, dietitian, medical practitioner, nurse, optometrist, osteopath, pharmacist, physiotherapist, podiatrist, psychologist, scientist working in a medical laboratory or veterinary surgeon; or
- (b) acupuncturist, herbalist, homoeopathic practitioner, naturopath, nutritionist, or practitioner of traditional Chinese medicine or other traditional medicine; or
- (c) person who:
 - (i) has current membership of an Australian or New Zealand healthcare practitioner professional body that complies with subsection (2); and
 - (ii) has the necessary or appropriate qualifications and training for membership of that body.

industry sector code of conduct has the meaning given by section 2.03.

public interest criteria means public interest criteria of a kind mentioned in paragraph 2.01 (3) (b).

restricted medical device means a medical device that is intended to be used or administered by a healthcare practitioner.

restricted representation means a representation that refers directly or indirectly, or by implication, to a serious disease, disorder, condition, ailment or defect.

therapeutic products industry includes the following sectors:

- (a) the prescription medicines industry;
- (b) the over-the-counter medicines industry;
- (c) the complementary medicines industry;
- (d) the medical devices industry.

therapeutic products industry body means an association or other body or organisation representing the therapeutic products industry in Australia or New Zealand.

verifiable claim, in relation to an advertisement for a medical device, means a claim about the medical device in the advertisement that requires verification, including any of the following:

- (a) a statement about facts;
- (b) research results;
- (c) a comparison;
- (d) a quote;
- (e) a testimonial;
- (f) an endorsement;

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- (g) other information about the device that is not required to be provided with the device under Part 3 (Information to be provided with medical devices) of Schedule 1 to the Medical Devices Rule.
- (2) For subparagraph (c) (i) of the definition of *healthcare practitioner* in subsection (1), a healthcare practitioner body complies with this subsection if it has:
 - (a) a certification system that incorporates:
 - (i) appropriate standards of training for membership, established via a consultative process with the healthcare profession and endorsed by the relevant educational or industry authorities; and
 - (ii) an established, transparent procedure for assessing practitioner qualifications; and
 - (iii) effective incentives to ensure practitioners seek and maintain certification; and
 - (iv) annual requirements for continuing professional development as a condition of continued certification; and
 - (b) a code of ethics with which certified practitioners agree to comply; and
 - (c) effective procedures for receiving, investigating and resolving complaints; and
 - (d) an established disciplinary system for enforcing proper conduct and continuing professional development requirements, that is able to investigate and apply sanctions where necessary, together with a process for appeals; and
 - (e) effective incentives for compliance with codes of practice as well as sanctions for non-compliance with standards of practice and other membership requirements; and
 - (f) external scrutiny and involvement of experts who are not members of the profession, to promote transparency, accountability and credibility.

Note Other terms and expressions used in this Rule are defined, for the purposes of the Rules generally, in the Administration and Interpretation Rule. The Administration and Interpretation Rule also indicates terms that are defined in the Agreement, or that are defined by reference to their definition in other Rules. A term defined in the Agreement has the same meaning when used in a Rule: see subsection 1.01 (2) of Part 1 of Schedule 1 to the Administration and Interpretation Rule.

Terms and expressions defined or referred to in the Administration and Interpretation Rule include:

Agreement	medical practitioner
approved form	Scheduling Standard
Authority Gazette	serious (disease etc)
dental practitioner	working day
expert advisory committee	

Terms defined in the Agreement and used in this Rule include:

Authority	Rule
manufacture	supply

Order therapeutic product
promotion therapeutic use.

1.04 Object of this Rule

The object of this Rule is to regulate the advertising of therapeutic products with the aims of:

- (a) safeguarding public health and safety; and
- (b) protecting the public interest; and
- (c) supporting the quality use of therapeutic products and informed healthcare choices.

1.05 Rule does not apply to advertisements for export-only products

This Rule does not apply to an advertisement for an export-only therapeutic product.

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Part 2 Advertising standards and codes of conduct

2.01 Determination of advertising standards

- (1) The Authority, by Order, may determine that matters specified in the Order constitute a standard (to be known as the *Australia New Zealand Therapeutic Products Advertising Code*) in respect of advertisements relating to therapeutic products.
- (2) The Advertising Code must incorporate the following principles (the *Advertising Principles*) relating to the advertising of therapeutic products:
 - **PRINCIPLE 1 — Advertisements must comply with the Australian Act, the New Zealand Act, the Advertising Rule and the Advertising Code**
 - **PRINCIPLE 2 — Advertisements must be truthful, balanced and not misleading. Claims must be valid and must have been substantiated**
 - **PRINCIPLE 3 — Advertisements must observe a high standard of social responsibility.**
- (3) In addition, the Advertising Code must incorporate:
 - (a) the requirements (the *Advertising Requirements*) set out in Schedule 1, being requirements relating to compliance with the Advertising Principles; and
 - (b) public interest criteria for determining whether an advertisement complies with Principle 3 of the Advertising Principles.
- (4) Without limiting the matters that may be specified in the Order, the Advertising Code may include provisions explaining or clarifying the Advertising Principles and the Advertising Requirements.
- (5) The Advertising Code may:
 - (a) make different provision for different kinds or classes of advertisements and therapeutic products; and
 - (b) exclude specified kinds or classes of advertisements or therapeutic products from the application of the Code.

Note For the publication, operation and disallowance of Orders, see:

- (a) in Australia — [Division 2 of Part 2] of the Australian Act; and
- (b) in New Zealand — [Part 2] of the New Zealand Act.

2.02 Advertisements to comply with Advertising Code

An advertisement relating to a therapeutic product must comply with the Advertising Code.

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Note Compliance with the Advertising Code is central to the regulation of advertising under the Scheme. A number of sanctions (both criminal and civil) relating to breaches of the Code by advertisers are in Part [] of the Australian Act and Part [] of the New Zealand Act. Compliance with the Code is also a requirement for the approval of advertisements under Part 3 of this Rule and is a statutory condition of a product licence in respect of a therapeutic product (see Division 3.7 of the Medicines Rule and Division 4.3 of the Medical Devices Rule).

2.03 Industry sector codes of conduct

- (1) In this section:
industry sector code of conduct means a set of principles and practices (whether referred to as a code of conduct or a code of practice) that:
 - (a) relates to the advertising and promotion of therapeutic products; and
 - (b) is applicable to a particular sector of the therapeutic products industry in Australia or New Zealand.
- (2) A therapeutic products industry body that has established an industry sector code of conduct may apply to the Authority for acceptance by the Authority of the code in so far as it relates to the advertising and promotion of therapeutic products.
- (3) An application must be in writing and must be accompanied by a copy of the code.
- (4) The Authority must consider an application made in accordance with this section and, subject to subsection (5), may accept the code for the purposes of the Rules.
- (5) The Authority must not accept the code unless it is satisfied that the code is consistent with the Advertising Code.
- (6) In deciding whether to accept or refuse to accept the code, the Authority must take into consideration any advice or recommendation of the Advertising Council relating to the code.
- (7) Within 20 working days after making its decision in respect of an application under this section, the Authority must give the applicant written notice of the decision.
- (8) If the Authority's decision is to refuse to accept the code, the notice must:
 - (a) give the Authority's reasons for the refusal; and
 - (b) inform the applicant, in accordance with section 7.04, of the applicant's right to have the Authority's decision reviewed.

Note 1 For the review process generally, see Part 7.

Note 2 Compliance with an accepted industry sector code of conduct may be made a condition of a product licence in respect of a therapeutic product. See Division 3.7 of the Medicines Rule and Division 4.3 of the Medical Devices Rule.

Part 3 Advertisements directed to consumers — particular requirements

Division 3.1 General

3.01 Application of this Part

This Part does not apply to an advertisement directed solely to healthcare practitioners.

Division 3.2 Advertisements requiring Authority approval

Subdivision 3.2.1 General

3.02 Interpretation for this Division

(1) In this Division:

applicant means an applicant for approval of an advertisement under this Division.

approval holder, in relation to an approved advertisement, means the person to whom notice of approval of the advertisement was given.

mainstream media means any:

- (a) magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions; or
- (b) cinematography film; or
- (c) display (including posters) about products:
 - (i) in shopping malls (except inside an individual shop); or
 - (ii) in or on public transport; or
 - (iii) on billboards; or
- (d) means by which information is disseminated electronically in a visible or audible form or in a combination of such forms, other than:
 - (i) the Internet; or
 - (ii) electronic mail; or
 - (iii) narrowcast transmission; or
 - (iv) a short message service (SMS), being a system enabling the transmission of short text messages from a digital mobile telephone to another digital mobile telephone; or

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- (v) a multimedia messaging service (MMS), being a system enabling the transmission of visual communication, voice communication or electronic mail from a digital mobile telephone to:
 - (A) another digital mobile telephone; or
 - (B) an electronic mail address.

narrowcast transmission means a system by which information is disseminated electronically in a visible or audible form or in a combination of such forms:

- (a) the reception of which is limited:
 - (i) by being targeted to special interest groups; or
 - (ii) by being intended only for limited locations (for example, arenas or business premises); or
 - (iii) by being provided during a limited period or to cover a special event; or
 - (iv) because it provides programs of limited appeal; or
 - (v) for some other reason; and
 - (b) that complies with any determinations or clarifications under section 19 of the *Broadcasting Services Act 1992* of Australia in relation to subscription narrowcasting services or open narrowcasting services within the meaning of section 17 or 18, respectively, of that Act.
- (2) For this Division, an advertisement is taken to be published, or intended to be published, in mainstream media if it is inserted within the pages of an item mentioned in paragraph (a) of the definition of **mainstream media** in subsection (1) that is published, or is intended to be published.

3.03 Application of Division

- (1) Subject to section 3.01 and to subsection (2), this Division applies to:
 - (a) an advertisement for a medicine that is published or broadcast, or intended to be published or broadcast, in any mainstream media; and
 - (b) an advertisement for a medical device that is published or broadcast, or intended to be published or broadcast, in any media if:
 - (i) the device is a restricted medical device; or
 - (ii) the advertisement contains a verifiable claim.

Note for paragraph (1) (a) Advertisements inserted within the pages of a magazine or newspaper for consumers may come within this paragraph. See subsection 3.02 (2).

- (2) This Division does not apply to an advertisement mentioned in paragraph (1) (a) or (b) that consists only of the following information:
 - (a) the brand name of the product; or
 - (b) the price of the product; or
 - (c) the type or style of the product; or
 - (d) a photographic or other reproduction of the product that does not contain any claim for therapeutic use in relation to the product; or

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- (e) the locations or times at which the product is offered for sale or other supply; or
 - (f) any other information reasonably necessary to identify the person offering the goods for sale or other supply.
- (3) This Division also applies to an advertisement for a medicine or a medical device that is declared by the Authority, under section 3.19, to be an advertisement for which approval under this Division is required.

Note For criminal and civil penalties relating to the publication or broadcast of advertisements requiring approval under this Division, see:

- (a) for Australia — [sections] of the Australian Act; and
- (b) for New Zealand — [sections] of the New Zealand Act.

Subdivision 3.2.2 Approval of advertisements

3.03A Requirement for approval of advertisements

- (1) A person must not publish or broadcast, or cause to be published or broadcast, an advertisement to which this Division applies unless the Authority has approved the advertisement under this Division.
- (2) If:
- (a) an advertisement relates to a therapeutic product of a kind mentioned in [paragraph 332CO (1) (d) or paragraph 332CP (d)] of the Australian Act; and
 - (b) the Authority, by Order, declares that it is necessary to publish or broadcast the advertisement, or advertisements of that kind, in the interests of public health;
- the Authority is taken to have approved the advertisement under this Division.

Note for subsection (2) This provision will enable the advertising of therapeutic products that normally cannot be advertised in Australia where there is a need to promote their availability, for example, to treat a disease or condition of public health significance.

3.04 Applications for approval

- (1) An application for an approval of an advertisement to which this Division applies must be:
- (a) made to the Authority in an approved form; and
 - (b) signed by or on behalf of the applicant.
- (2) An application is not effective unless:
- (a) the application complies with subsection (1); and
 - (b) the prescribed application fee has been paid.

3.05 Approval of advertisements

Advertisements for medicines

- (1) If an application in respect of an advertisement for a medicine is an effective application under section 3.04, the Authority must approve the advertisement if the Authority is satisfied that it:
 - (a) complies with the Advertising Code; and
 - (b) does not contain a restricted representation (other than a restricted representation the use of which has been approved under section 4.05 or permitted under section 4.10); and
 - (c) does not contain a presentation of the medicine that is not acceptable within the meaning of section 1.06 of the Medicines Rule and the Advertising Code.

Advertisements for medical devices

- (2) If an application in respect of an advertisement for a medical device is an effective application under section 3.04, the Authority must approve the advertisement if the Authority is satisfied that it:
 - (a) complies with the Advertising Code; and
 - (b) does not contain a reference to a restricted medical device (other than a reference approved under section 4.14).
- (3) If the Authority is not satisfied as to a matter set out in subsection (1) or (2), as the case requires, the Authority must refuse to approve the advertisement.
- (4) The Authority may impose conditions on an approval.
- (5) Unless earlier revoked, an approval expires at the end of 2 years after the date on which it is given, or taken to have been given, under this Subdivision.

3.06 Notice of approval or refusal to approve an advertisement

- (1) The Authority must give written notice to the applicant of the approval of, or of the refusal to approve, an advertisement.
- (2) If written notice is not given to the applicant within 60 days after the day on which the application was made (or within such longer period as the Authority specifies by written notice to the applicant within that period), the Authority is taken to have approved the advertisement at the end of the period.
- (3) If an approval is subject to conditions, the conditions must be set out in the notice.
- (4) A notice of refusal to approve an advertisement must:
 - (a) give the Authority's reasons for the refusal; and

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- (b) inform the applicant, in accordance with section 7.04, of the applicant's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

3.07 Distinguishing numbers for approved advertisements

- (1) The Authority must allocate a distinguishing number (the *approval number*) to each approved advertisement.
- (2) The Authority must inform the applicant of the approval number at the time of giving notice of approval of the advertisement.

3.08 Variation of conditions of approval

- (1) The Authority, by written notice to an approval holder, may vary any condition of approval of an approved advertisement.
- (2) The notice must:
 - (a) give the Authority's reasons for the variation; and
 - (b) inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

3.09 Suspension of approval

- (1) The Authority, by written notice to an approval holder, may suspend the approval of an approved advertisement if the Authority is satisfied that:
 - (a) there are grounds for revocation of the approval under section 3.10; and
 - (b) it is likely that the approval holder will, within the period of the suspension, be able to take the action necessary to ensure that the advertisement complies with the requirements of the Australian Act, the New Zealand Act, this Rule and the Advertising Code.
 - (2) The notice of suspension:
 - (a) must give the reason for the suspension; and
 - (b) must specify the period of the suspension (being a period not longer than 3 months); and
 - (c) may include conditions to be complied with by the approval holder as a prerequisite to a decision whether to withdraw the suspension; and
 - (d) must inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.
- Note* For the review process generally, see Part 7.
- (3) The suspension of an approval takes effect:
 - (a) on the day on which the notice is given to the approval holder; or
 - (b) if a later day is specified in the notice — on that day.

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- (4) The Authority may withdraw the suspension of an approval before the expiry of the period of suspension if the Authority is satisfied that:
 - (a) the ground for the suspension no longer applies; and
 - (b) the conditions (if any) imposed under paragraph (2) (c) have been complied with; and
 - (c) there are no other grounds for suspension.
- (5) The suspension of an approval under this section does not affect the Authority's power to revoke an approval under section 3.10.

3.10 Revocation of approval

- (1) The Authority, by written notice to an approval holder, may revoke the approval of an approved advertisement if the Authority is satisfied that:
 - (a) information given by the applicant in the application was false or incorrect and the Authority or a Review Tribunal relied on the information in deciding to approve the advertisement; or
 - (b) there has been a breach of a condition of approval; or
 - (c) a person has contravened an offence provision or civil penalty provision of the Australian Act or New Zealand Act in relation to the publication or broadcast of the advertisement; or
 - (d) because of a change to the facts or circumstances existing when the advertisement was approved, the advertisement no longer complies with the Australian Act, the New Zealand Act, this Rule or the Advertising Code; or
 - (e) because of a change to the Advertising Code, the advertisement no longer complies with the Code; or
 - (f) the advertisement does not comply with a requirement of the Advertising Code for a reason other than paragraph (d) or (e); or
 - (g) if the advertisement is for a medicine — the advertisement contains a presentation of the medicine that is not acceptable within the meaning of section 1.06 of the Medicines Rule and the Advertising Code.
- (2) The notice under subsection (1) must:
 - (a) give the Authority's reasons for the decision; and
 - (b) inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.
- (3) The revocation of an approval takes effect:
 - (a) on the day on which the notice is given to the approval holder; or
 - (b) if a later day is specified in the notice — on that day.

Note For the review process generally, see Part 7.

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Subdivision 3.2.3 Delegation of powers relating to approvals

3.11 Delegation of powers to Authority employees

- (1) The Managing Director, by instrument in writing, may delegate all or any of the Authority's powers or functions under Subdivision 3.2.2 to an employee of the Authority.
- (2) The Managing Director may at any time revoke a delegation under this section.
- (3) In exercising a delegated power or performing a delegated function a delegate must comply with any directions of the Managing Director.

3.12 Delegation of powers to external delegates

- (1) The Managing Director, by instrument in writing, may delegate all or any of the Authority's powers or functions under Subdivision 3.2.2 to:
 - (a) a therapeutic products industry body or advertising industry body; or
 - (b) a person involved in the therapeutic products industry, advertising industry or media industry in Australia or New Zealand.
- (2) A delegation under this section may be in respect of advertisements:
 - (a) for any kind or class of therapeutic products; or
 - (b) for a specified kind or class of therapeutic products; or
 - (c) that are minor revisions of approved advertisements.
- (3) For paragraph (2) (c), an advertisement is a *minor revision* of an approved advertisement if the only changes to the approved advertisement are:
 - (a) straightforward and do not result in a substantial modification of the advertisement; or
 - (b) intended to reflect a new advertising campaign for the advertised product that does not substantially depart from existing advertising.

Examples for paragraph (3) (a)

Examples of changes to an approved advertisement that may come within paragraph (3) (a) are a change of price or pack, or permissible sales promotion.

- (4) In exercising a delegated power or function under this section, a delegate must comply with any written directions of the Managing Director.
- (5) Subject to this Division, a delegation under this section remains in force for the period stated in the instrument of delegation.

3.13 Applications for external delegations

- (1) An application for a delegation to be made under section 3.12 must:
 - (a) be made to the Authority in an approved form; and
 - (b) nominate the person who is to be, or is to exercise the powers of, the delegate; and

- (c) be signed on or on behalf of the applicant.
- (2) An application is not effective unless:
 - (a) the application complies with subsection (1); and
 - (b) the prescribed application fee has been paid.

3.14 Consideration of applications

- (1) The Managing Director must consider an effective application under section 3.13 for a delegation and may, subject to this section, grant the application and make the delegation.
- (2) The Managing Director must not make a delegation under paragraph 3.12 (1) (a) to an industry body unless the Managing Director is satisfied that the delegated power will be exercised, on behalf of the industry body, by a person who:
 - (a) is employed, or engaged as a consultant, by the industry body; and
 - (b) has the necessary skills, qualifications and experience; and
 - (c) is a fit and proper person;to exercise the delegated power.
- (3) The Managing Director must not make a delegation under paragraph 3.12 (1) (b) to a person unless the Managing Director is satisfied that the person:
 - (a) has the necessary skills, qualifications and experience; and
 - (b) is a fit and proper person;to exercise the delegated power.
- (4) In considering whether to make a delegation, the Managing Director must take into account any recommendation of the Advertising Council relating to the proposed delegation.

3.15 Conditions on external delegations

- (1) It is a condition of a delegation made under section 3.12 that the delegate:
 - (a) keep records of advertisements approved or refused approval under the delegation for a period of at least 3 years; and
 - (b) make such records available to the Authority, without charge, on request.
- (2) The Managing Director, in writing, may impose other conditions on the exercise of a power under the delegation if the Managing Director considers it is necessary, in the interests of public health and safety, or in the public interest generally, to do so.

Section 3.16

3.16 Revocation of external delegations

- (1) The Managing Director, by written notice to the delegate, may revoke a delegation made under section 3.12 if the Managing Director is satisfied that:
 - (a) the delegate has not exercised the delegated power in accordance with this Rule; or
 - (b) the delegate has contravened a condition of the delegation; or
 - (c) in the case of a delegation under paragraph 3.12 (1) (a), the delegated power is no longer being exercised by a person who complies with the requirements of subsection 3.14 (2); or
 - (d) in the case of a delegation under paragraph 3.12 (1) (b), the delegate no longer meets the requirements of subsection 3.14 (3).
- (2) In addition, the Managing Director, by written notice to the delegate, may revoke a delegation made under paragraph 3.12 (1) (b) if:
 - (a) the delegate is employed, or is engaged as a consultant, by an entity that is involved in the therapeutics products industry, advertising industry or media industry in Australia or New Zealand; and
 - (b) the Managing Director is satisfied that, since the delegation was made, the entity has failed to comply on more than 1 occasion with the Advertising Code in respect of the publishing or broadcasting of advertisements for therapeutic products.
- (3) In considering whether to revoke a delegation, the Managing Director may take into account any advice of the Advertising Council with respect to the proposed revocation.
- (4) The notice under subsection (1) or (2) must give the Authority's reasons for the decision.

3.17 Delegation to Chair of Central Complaints Panel

- (1) The Managing Director, by instrument in writing, may delegate to the Chair of a Central Complaints Panel the Authority's power to do one or both of the following:
 - (a) suspend the approval of approved advertisements under section 3.09;
 - (b) revoke the approval of approved advertisements under section 3.10.
- (2) A power delegated under subsection (1) must not be exercised in respect of an advertisement except upon the consideration by the Central Complaints Panel concerned of a complaint about the advertisement.
- (3) The Managing Director may at any time revoke a delegation under this section.
- (4) In exercising a delegated power under this section the delegate must comply with any directions of the Managing Director.

Division 3.3 Advertisements not requiring Authority approval

3.18 Authority may request information from advertisers

- (1) This section applies to a person who:
 - (a) publishes or broadcasts, or causes to be published or broadcast; or
 - (b) is about to publish or broadcast, or cause to be published or broadcast; an advertisement for a medicine or a medical device, not being an advertisement to which Division 3.2 applies.
- (2) The Authority, by written notice, may require a person to whom this section applies to give to the Authority:
 - (a) within such reasonable time (being not less than 10 working days) as is specified in the notice; and
 - (b) in such form as is specified in the notice; all of the material relating to the advertisement.
- (3) The Authority must not impose a requirement under this section in respect of an advertisement except for the purpose of ensuring that the advertisement complies with the Australian Act, the New Zealand Act, this Rule and the Advertising Code.

Note Failure to comply with a notice given under this section may give rise to a civil penalty, or to the imposition of a penalty by notice as an alternative to civil proceedings. See:

- (a) for Australia — [section [] and Division 3 of Part 3] of the Australian Act; and
- (b) for New Zealand — [sections [] and []] of the New Zealand Act.

3.19 Authority may declare that advertisements require approval

- (1) This section applies to a person if the Authority is satisfied that the person:
 - (a) has failed to comply with the requirements of a notice given to the person under section 3.18 in respect of an advertisement; or
 - (b) has published or broadcast, or caused to be published or broadcast, at least 2 different advertisements (not being advertisements for which approval was required under Division 3.2) that did not comply with the Australian Act, the New Zealand Act, this Rule or the Advertising Code.
- (2) The Authority, by notice in writing to the person, may declare that:
 - (a) all advertisements for medicines or medical devices that the person is to publish or broadcast, or is to cause to be published or broadcast; or
 - (b) if a particular kind of such advertisements is specified in the notice — all advertisements of that kind;are, for the period specified in the notice or, if no period is specified, until the notice is revoked, advertisements that require an approval under Division 3.2.

Part 4 General restrictions on advertising

Division 4.1 False or misleading representations

4.01 False or misleading representations — direction not to publish or broadcast

If the Authority is satisfied that a representation in an advertisement about a therapeutic product is false or misleading, the Authority may, by notice in writing given to the person apparently responsible for publishing or broadcasting the advertisement, direct that person not to publish or broadcast, or cause to be published or broadcast, an advertisement containing that representation (whether express or implied) about that product.

Note Failure to comply with a direction given under this section may give rise to a criminal or civil penalty, or to the imposition of a penalty by notice as an alternative to criminal or civil proceedings. See:

- (a) for Australia — [sections 326CP and 327CP and Division 3 of Part 3] of the Australian Act; and
- (b) for New Zealand — [sections [] and []] of the New Zealand Act.

Division 4.2 Use of restricted representations

4.02 Definitions

In this Division:

applicant means an applicant for the use of a restricted representation in an advertisement about a therapeutic product.

approval holder, in relation to a restricted representation, means the person to whom notice of approval of the use of the restricted representation was given.

Note Restricted representation is defined in section 1.03.

4.03 Use of restricted representations

A person must not use a restricted representation in an advertisement about a therapeutic product unless the Authority:

- (a) has approved its use under section 4.05; or
- (b) has permitted its use under section 4.10.

Note For criminal and civil penalties relating to the use of restricted representations, see:

- (a) for Australia — [sections] of the Australian Act; and
- (b) for New Zealand — [sections] of the New Zealand Act.

4.04 Applications for approval of use of restricted representation

- (1) An application to the Authority for approval of the use of a restricted representation must:
 - (a) be in writing; and
 - (b) address the public interest criteria set out in the Advertising Code; and
 - (c) be signed by or on behalf of the applicant.
- (2) An application is not effective unless:
 - (a) the application complies with subsection (1); and
 - (b) the prescribed application fee (if any) has been paid.

4.05 Approval of restricted representation

- (1) If an application for approval of the use of a restricted representation is an effective application under section 4.04, the Authority must approve the use of the restricted representation if the Authority is satisfied that the representation:
 - (a) is accurate and balanced; and
 - (b) is not misleading or likely to be misleading; and
 - (c) satisfies the public interest criteria set out in the Advertising Code.
- (2) Otherwise, the Authority must refuse to approve the use of the restricted representation.
- (3) The Authority may impose conditions on an approval.
- (4) In deciding whether to approve or refuse to approve the use of a restricted representation, the Authority must take into consideration:
 - (a) any advice or recommendation of the Advertising Council; and
 - (b) any advice of any other expert advisory committee; and
 - (c) the public interest criteria set out in the Advertising Code.
- (5) The Authority must publish notice of the granting of an approval in the Authority Gazette.

4.06 Notice of approval or refusal

- (1) The Authority must give written notice to the applicant of the approval of, or of the refusal to approve, the use of a restricted representation.
- (2) If written notice is not given to the applicant within 60 days after the day on which the application was made (or within such longer period as the Authority specifies by written notice to the applicant within that period), the Authority is taken to have approved the use of the restricted representation at the end of the period.
- (3) If an approval is subject to conditions, the conditions must be set out in the notice.

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- (4) A notice of refusal to approve the use of a restricted representation must:
 - (a) give the Authority's reasons for the refusal; and
 - (b) inform the applicant, in accordance with section 7.04, of the applicant's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

4.07 Variation of conditions of approval

- (1) The Authority, by written notice to an approval holder, may vary any condition of approval of the use of a restricted representation.
- (2) The notice must:
 - (a) give the Authority's reasons for the variation; and
 - (b) inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

4.08 Suspension of approval

- (1) The Authority, by written notice to an approval holder, may suspend the approval of the use of a restricted representation if the Authority is satisfied that:
 - (a) there are grounds for revocation of the approval under section 4.09; and
 - (b) it is likely that the approval holder will, within the period of the suspension, be able to take the action necessary to ensure that the advertisement satisfies the requirements for approval under subsection 4.05 (1).
- (2) The notice of suspension:
 - (a) must give the reason for the suspension; and
 - (b) must specify the period of the suspension (being a period not longer than 3 months); and
 - (c) may include conditions to be complied with by the approval holder as a prerequisite to a decision whether to withdraw the suspension; and
 - (d) must inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

- (3) The suspension of an approval takes effect:
 - (a) on the day on which the notice is given to the approval holder; or
 - (b) if a later day is specified in the notice — on that day.
- (4) The Authority may withdraw the suspension of an approval before the expiry of the period of suspension if the Authority is satisfied that:
 - (a) the ground for the suspension no longer applies; and

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- (b) the conditions (if any) imposed under paragraph (2) (c) have been complied with; and
 - (c) there are no other grounds for suspension.
- (5) The suspension of an approval under this section does not affect the Authority's power to revoke an approval under section 4.09.

4.09 Revocation of approval

- (1) The Authority, by written notice to the approval holder, may revoke the approval of the use of a restricted representation if:
- (a) the Authority is satisfied that information given by the applicant in the application was false or incorrect and the Authority or a Review Tribunal relied on the information in deciding to approve the use of the representation; or
 - (b) the Authority is satisfied that there has been a breach of a condition of the approval; or
 - (c) additional information about the safety of the therapeutic product concerned becomes available and the Authority is satisfied that, if the information had been available at the time of the approval, the Authority would not have approved the use of the restricted representation.
- (2) The notice under subsection (1) must:
- (a) give the Authority's reasons for the decision; and
 - (b) inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

4.10 General permission to use restricted representation

The Authority, by notice in writing published in the Authority Gazette, may permit the use of a restricted representation in advertisements about:

- (a) all therapeutic products; or
- (b) a kind or class of therapeutic products specified in the notice.

Division 4.3 References to restricted medical devices

4.11 Definitions

In this Division:

applicant means an applicant for approval of a reference to a restricted medical device in an advertisement.

approval holder, in relation to a reference to a restricted medical device in an advertisement, means the person to whom notice of approval of the reference was given.

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Note Restricted medical device is defined in section 1.03.

4.12 References to restricted medical devices

An advertisement about a therapeutic product must not contain a reference to a restricted medical device unless the Authority has approved the reference under this Division.

Note For criminal and civil penalties relating to advertisements that contain references to a restricted medical device, see:

- (a) for Australia — [sections] of the Australian Act; and
- (b) for New Zealand — [sections] of the New Zealand Act.

4.13 Applications for approval of a reference to a restricted medical device

- (1) An application for approval of a reference to a restricted medical device in an advertisement must be:
 - (a) made to the Authority in an approved form; and
 - (b) signed by or on behalf of the applicant.
- (2) An application is not effective unless:
 - (a) the application complies with subsection (1); and
 - (b) the prescribed application fee has been paid.

4.14 Approval of a reference to a restricted medical device

- (1) If an application for approval of a reference to a restricted medical device is an effective application under section 4.13, the Authority must approve the reference if the Authority is satisfied that the reference:
 - (a) is accurate and balanced; and
 - (b) is not misleading or likely to be misleading; and
 - (c) satisfies the public interest criteria set out in the Advertising Code in relation to the advertising of medical devices and, in particular, restricted medical devices.
- (2) Otherwise, the Authority must refuse to approve the reference.
- (3) The Authority may impose conditions on an approval.
- (4) In deciding whether to approve or refuse to approve a reference to a restricted medical device, the Authority must take into consideration:
 - (a) any advice or recommendation of the Advertising Council; and
 - (b) any advice of any other expert advisory committee; and
 - (c) any public interest criteria mentioned in the Advertising Code.
- (5) The Authority must publish notice of the granting of an approval in the Authority Gazette.

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4.15 Notice of approval or refusal

- (1) The Authority must give written notice to the applicant of the approval of, or of the refusal to approve, a reference to a restricted medical device.
- (2) If written notice is not given to the applicant within 60 days after the day on which the application was made (or within such longer period as the Authority specifies by written notice to the applicant within that period), the Authority is taken to have approved the reference at the end of the period.
- (3) If an approval is subject to conditions, the conditions must be set out in the notice.
- (4) A notice of refusal to approve a reference to a restricted medical device must:
 - (a) give the Authority's reasons for the refusal; and
 - (b) inform the applicant, in accordance with section 7.04, of the applicant's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

4.16 Variation of conditions of approval

- (1) The Authority, by written notice to an approval holder, may vary any condition of approval of a reference to a restricted medical device.
- (2) The notice must:
 - (a) give the Authority's reasons for the variation; and
 - (b) inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

4.17 Suspension of approval

- (1) The Authority, by written notice to an approval holder, may suspend the approval of a reference to a restricted medical device if the Authority is satisfied that:
 - (a) there are grounds for revocation of the approval under section 4.18; and
 - (b) it is likely that the approval holder will, within the period of the suspension, be able to take the action necessary to ensure that the advertisement satisfies the requirements for approval under subsection 4.14 (1).
- (2) The notice of suspension:
 - (a) must give the reason for the suspension; and
 - (b) must specify the period of the suspension (being a period not longer than 3 months); and
 - (c) may include conditions to be complied with by the approval holder as a prerequisite to a decision whether to withdraw the suspension; and

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- (d) must inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

- (3) The suspension of an approval takes effect:
 - (a) on the day on which the notice is given to the approval holder; or
 - (b) if a later day is specified in the notice — on that day.
- (4) The Authority may withdraw the suspension of an approval before the expiry of the period of suspension if the Authority is satisfied that:
 - (a) the ground for the suspension no longer applies; and
 - (b) the conditions (if any) imposed under paragraph (2) (c) have been complied with; and
 - (c) there are no other grounds for suspension.
- (5) The suspension of an approval under this section does not affect the Authority's power to revoke an approval under section 4.18.

4.18 Revocation of approval

- (1) The Authority, by written notice to the approval holder, may revoke the approval of a reference to a restricted medical device if:
 - (a) the Authority is satisfied that information given by the applicant in the application was false or incorrect and the Authority or a Review Tribunal relied on the information in deciding to approve the reference; or
 - (b) the Authority is satisfied that there has been a breach of a condition of the approval; or
 - (c) additional information about the restricted medical device becomes available and the Authority is satisfied that, if the information had been available at the time of the approval, the Authority would not have approved the reference.
- (2) The notice under subsection (1) must:
 - (a) give the Authority's reasons for the decision; and
 - (b) inform the approval holder, in accordance with section 7.04, of the approval holder's right to have the Authority's decision reviewed.

Note For the review process generally, see Part 7.

Part 5 Complaints about advertisements

Division 5.1 General

5.01 Definitions

In this Part:

complaint means a complaint about an advertisement made to a Central Complaints Panel under section 5.22.

relevant Act means:

- (a) in relation to a complaint made to the Central Complaints Panel for Australia — the Australian Act; and
- (b) in relation to a complaint made to the Central Complaints Panel for New Zealand — the New Zealand Act.

Division 5.2 Central Complaints Panels

5.02 Establishment of Central Complaints Panels

There are to be constituted, in accordance with this Division:

- (a) a Central Complaints Panel in respect of complaints about advertisements that are to be considered in Australia (the *Central Complaints Panel for Australia*); and
- (b) a Central Complaints Panel in respect of complaints about advertisements that are to be considered in New Zealand (the *Central Complaints Panel for New Zealand*).

5.03 Function of Central Complaints Panel

The function of a Central Complaints Panel is:

- (a) to receive and consider complaints about advertisements under Division 5.3; and
- (b) to take action and to make recommendations in accordance with that Division.

5.04 Pool of potential Panel members

- (1) The Ministerial Council may appoint in writing persons as potential members of a Central Complaints Panel on the recommendation of the Authority.

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- (2) A person recommended by the Authority for appointment must have expertise or experience in Australia or New Zealand in 1 or more of the following fields:
 - (a) public health;
 - (b) healthcare practice;
 - (c) advertising;
 - (d) therapeutic products;
 - (e) regulatory matters;
 - (f) the therapeutic products industry;
 - (g) consumer issues;
 - (h) Australian or New Zealand law.
- (3) In particular, in recommending persons for appointment, the Authority must have regard to the requirements for the constitution of a Panel set out in this Division.
- (4) In recommending persons for appointment the Authority must also consider any advice given to the Authority by the Advertising Council.
- (5) Subject to this Division, an appointment under this section is for the term stated in the appointment.
- (6) The term stated in the appointment must not be longer than 5 years from the date of the appointment.
- (7) A person cannot be appointed for more than 2 consecutive terms.
- (8) A person may resign as a potential Panel member by signed notice of resignation given to the Ministerial Council.

5.05 Appointment of Principal Members of Panels

- (1) The Ministerial Council must appoint:
 - (a) a person appointed under section 5.04 as the Principal Member of the Central Complaints Panel for Australia; and
 - (b) a person appointed under section 5.04 as the Principal Member of the Central Complaints Panel for New Zealand.
- (2) A person appointed under paragraph (1) (a):
 - (a) must have expertise or experience in Australia in the field of:
 - (i) public health, with experience in community practice in a healthcare profession; or
 - (ii) consumer issues; and
 - (b) must not be associated with any sector of the therapeutic products industry, the advertising industry or the media industry.

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- (3) A person appointed under paragraph (1) (b):
 - (a) must have expertise or experience in New Zealand in the field of:
 - (i) corporate or public sector governance; or
 - (ii) consumer issues; and
 - (b) must not be associated with any sector of the therapeutic products industry, the advertising industry or the media industry.
- (4) Subject to this Division, the appointment of a Principal Member is for the term stated in the appointment.
- (5) The term stated in the appointment must not be longer than 3 years from the date of the appointment.
- (6) A person cannot be appointed as a Principal Member for more than 3 consecutive terms.
- (7) A person may resign as Principal Member by signed notice of resignation given to the Ministerial Council.

5.06 Membership of Panels

Central Complaints Panel for Australia

- (1) The Central Complaints Panel for Australia is to be constituted by the following members:
 - (a) the Principal Member for Australia (who is to be the Chair);
 - (b) not less than 7 persons from the pool of persons appointed under section 5.04, appointed in writing by the Chair.
- (2) Each member appointed under paragraph (1) (b) must have appropriate expertise or experience in at least 1 of the following fields:
 - (a) public health, with experience in community practice in a healthcare profession;
 - (b) consumer issues;
 - (c) advertising sector issues;
 - (d) the regulation of advertising of therapeutic products;
 - (e) the over-the-counter medicines industry;
 - (f) the complementary medicines industry;
 - (g) the medical devices industry.

Central Complaints Panel for New Zealand

- (3) The Central Complaints Panel for New Zealand is to be constituted by the following members:
 - (a) the Principal Member for New Zealand (who is to be the Chair);
 - (b) not less than 7 persons, from the pool of persons appointed under section 5.04, appointed in writing by the Chair.

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- (4) Of the members appointed under paragraph (3) (b):
 - (a) at least 4 members must have appropriate expertise or experience in the advertising industry or the media industry; and
 - (b) at least 3 members (not being members mentioned in paragraph (a)) must not be associated with any sector of the therapeutic products industry, the advertising industry or the media industry.

Both Panels

- (5) Subject to this Division, an appointment under this section is for the term stated in the appointment.
- (6) The term stated in the appointment must not be longer than 3 years from the date of the appointment.
- (7) A person cannot be appointed for more than 3 consecutive terms.
- (8) A person (other than the Chair) may resign as a member of a Panel by signed notice of resignation given to the Chair.
- (9) The exercise of a power or the performance of a function of a Panel is not affected by a vacancy in its membership.

5.07 Termination of appointments

- (1) The Ministerial Council may terminate a person's appointment under section 5.04 on the grounds of:
 - (a) physical or mental incapacity; or
 - (b) misbehaviour; or
 - (c) incompetence; or
 - (d) inefficiency; or
 - (e) bankruptcy; or
 - (f) failing to comply, either recklessly or intentionally, with section 5.17.
- (2) The Ministerial Council must terminate a person's appointment under section 5.04 if the person:
 - (a) is convicted of an offence punishable by imprisonment for 1 year or longer; or
 - (b) being a member (including the Principal Member) of a Panel, is absent without leave of absence from 3 consecutive meetings of the Panel.
- (3) The Chair of a Panel:
 - (a) may terminate a person's appointment under section 5.06 as a member of the Panel on any ground mentioned in subsection (1); and
 - (b) must terminate a person's appointment under section 5.06 as a member of the Panel on any ground mentioned in subsection (2).
- (4) A person's appointment:
 - (a) under section 5.05, as the Principal Member of a Panel; or

- (b) under section 5.06 as a member of a Panel;
is terminated if the person's appointment under section 5.04 is terminated.

5.08 Leave of absence

- (1) The Ministerial Council may grant leave of absence to the Chair of a Panel.
- (2) The Chair may grant leave of absence to another Panel member.

5.09 Alternate members of a Panel

- (1) The Ministerial Council may appoint in writing a person appointed under section 5.04 to be the alternate Chair of a Central Complaints Panel.
- (2) A person may be appointed under subsection (1) whether or not the person is a member of a Central Complaints Panel.
- (3) A member of a Panel (other than the Chair) may appoint in writing up to 2 persons appointed under section 5.04 who are not members of the Panel to each be available to be the alternate of the member.
- (4) If a member (including the Chair) is absent from a meeting of the Panel, the member's alternate (if any) is entitled to attend the meeting and, when so attending, is taken to be a member of the Panel.
- (5) If a person appointed as a member of a Panel under section 5.06 ceases to hold office as a member:
 - (a) the person who was the person's alternate under subsection (4) immediately before the person ceased to hold office; or
 - (b) in the absence of an alternate under paragraph (a), a person who was, under subsection (3), available to be the alternate of the person who ceased to hold office;is entitled to attend meetings of the Panel while the office is vacant and, when so attending, is taken to be a member of the Panel.
- (6) The person described in paragraph (5) (a) or (b) is taken to be the alternate of a person appointed to the vacant office until a new alternate is appointed.
- (7) If the Chair ceases to hold office:
 - (a) the person who was the Chair's alternate under subsection (4) immediately before the person ceased to hold office is entitled to attend meetings of the Panel while the office is vacant and, when so attending, is taken to be the Chair of the Panel; and
 - (b) the person is taken to be the alternate of a person appointed to the vacant office until a new alternate is appointed.
- (8) A person appointed as an alternate Chair of a Panel may resign the appointment by notice in writing to the Ministerial Council.
- (9) A person appointed by a member of a Panel as an alternate of the member may resign the appointment by notice in writing to the member.

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5.10 Participation of expert in prescription medicines (Australia only)

- (1) If:
 - (a) the subject of a complaint made to the Central Complaints Panel for Australia is an advertisement about a prescription medicine; and
 - (b) there is no member of the Panel with expertise or experience in the prescription medicines industry;
the Chair of the Panel may nominate a person appointed under section 5.04 to attend a meeting of the Panel convened to consider the complaint and to participate in consideration of the complaint.
- (2) A person nominated under subsection (1) is taken to be a member of the Panel for the purposes of a meeting of the Panel mentioned in that subsection.

5.11 Attendance of advisers and giving of expert advice

- (1) Subject to subsection (2), the Chair of a Central Complaints Panel may invite a person with expertise in a particular field mentioned in subsection 5.04 (2) who is not a member of the Panel to attend a meeting of the Panel in relation to a complaint and give expert advice in relation to the complaint.
- (2) The Chair may invite a person under subsection (1) only if there is no member of the Panel with expertise in the particular field.
- (3) The Chair cannot invite a person under subsection (1) who is not a person appointed under section 5.04 to attend more than 1 meeting in relation to the complaint.

5.12 Attendance of observers

- (1) The Chair of a Central Complaints Panel may invite a person to attend meetings of the Panel as an observer.
- (2) Unless the invitation is revoked, an observer:
 - (a) is entitled to attend meetings of the Panel; and
 - (b) may take part in the discussion of matters arising at the meetings; as the terms of the invitation provide.

5.13 Meetings

- (1) Meetings of a Central Complaints Panel are to be held at the times and places that the Chair of the Panel directs.
- (2) The Chair is to preside at meetings of the Panel at which he or she is present.

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- (3) If the Chair or Chair's alternate is absent from a meeting, a member nominated by the Chair or, if no member is nominated, a member chosen by the members of the Panel present at the meeting, is to preside.

5.14 Quorum

- (1) Subject to this section, at a meeting of a Central Complaints Panel a quorum exists if the Chair and 4 other members of the Panel are present.
- (2) At a meeting of the Central Complaints Panel for Australia to consider a complaint, the quorum must include a member with expertise or experience in the sector of the therapeutic products industry that is relevant to the therapeutic product concerned.

Note If an expert member has disclosed an interest in, or prejudicial relationship affecting, the complaint and cannot participate in consideration of the complaint (see section 5.17), the member's alternate with requisite expertise may be included in the quorum (see section 5.09).

- (3) Subsection (2) does not apply if:
 - (a) for any reason (including the disclosure of an interest or prejudicial relationship under section 5.17), neither the member nor an alternate of the member with expertise or experience in the relevant sector is able to participate in the consideration of the complaint; and
 - (b) the member (or alternate, as the case may be) expressly agrees to the complaint being considered in his or her absence.
- (4) If:
 - (a) a meeting of the Central Complaints Panel for Australia is convened to consider a complaint of a kind mentioned in section 5.10; and
 - (b) a person is nominated under that section to attend the meeting for that purpose;the quorum must include that person.
- (5) A quorum for a meeting convened to consider a complaint does not include a member of the Panel if the complaint was made by the member or by a body represented by the member.

5.15 Decision by majority

Central Complaints Panel for Australia

- (1) On a matter arising at a meeting of the Central Complaints Panel for Australia, the decision of the majority of the members of the Panel present at the meeting and entitled to participate in consideration of the matter is the decision of the Panel.
- (2) For subsection (1), not more than 1 member with expertise or experience in the therapeutic products industry (the *participating industry member*) is entitled to participate in the consideration of a particular matter.

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- (3) Subject to subsection (4), the participating industry member must have expertise or experience in the sector of the therapeutic products industry that is relevant to the therapeutic product concerned.

Example

If the product is an over-the-counter medicine, the participating industry member must have expertise or experience in the over-the-counter medicines industry.

- (4) If an accepted industry sector code of conduct applies to the advertising of the therapeutic product concerned, the participating industry member must have expertise or experience in the sector of the therapeutic products industry that is responsible for maintaining the code.

Central Complaints Panel for New Zealand

- (5) On a matter arising at a meeting of the Central Complaints Panel for New Zealand, the decision of the majority of the members of the Panel present at the meeting and entitled to participate in consideration of the matter is the decision of the Panel.

Both Panels

- (6) If a Central Complaints Panel cannot reach a majority decision on a matter, the decision of the Chair is the decision of the Panel.
- (7) However, it is intended as far as reasonably practicable that the Chair take into account the views of the other members who are entitled to participate in consideration of the matter.

5.16 Effect of vacancy

The exercise of a power or performance of a function of a Central Complaints Panel is not affected by any vacancy in the membership of the Panel.

5.17 Disclosure of interests and prejudicial relationships

- (1) The purpose of this section is to place on a member of the Panel the onus of disclosing interests or prejudicial relationships relating to a matter so that the Panel has the opportunity to decide whether it is appropriate for the member to take part in deliberations or decisions about the matter.
- (2) A member of a Central Complaints Panel (including a person taken to be a member under section 5.09 or 5.10) who is aware that he or she has an interest in, or a prejudicial relationship affecting, a matter being considered or about to be considered at a meeting of the Panel must, without delay, disclose the nature of the interest or the relationship at, or before, the meeting of the Panel.

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- (3) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Panel otherwise determines:
 - (a) be present during any deliberation of the Panel about the matter; or
 - (b) take part in any decision of the Panel about that matter.
- (4) When the Panel is making a determination under subsection (3) about a member who has made a disclosure, the member, and any other member who has an interest in, or a prejudicial relationship affecting, the matter to which the disclosure relates, must not:
 - (a) be present during any deliberation of the Panel; or
 - (b) take part in making the determination.
- (5) A member is not to be taken as having an interest in, or a prejudicial relationship affecting, a matter solely because:
 - (a) the Authority is the complainant in relation to the matter; and
 - (b) the member is employed, or engaged as a consultant, by the Authority.

- (6) In this section:

affected person, in relation to a member considering or about to consider a matter at a meeting of the Panel, means a person known to the member to have an interest in the matter.

interest means a pecuniary interest, direct or indirect.

prejudicial relationship, in relation to a member considering or about to consider a matter at a meeting of the Panel, means a relationship between the member and an affected person of such a kind that a reasonable person with knowledge of the relationship would perceive the likelihood of bias in the member's consideration of the matter.

Note A prejudicial relationship might exist where the spouse or other close associate of a member has a pecuniary interest in the matter to be considered by the Council or a subcommittee. A prejudicial relationship might also exist where the member:

- (a) has a contractual relationship or understanding with a business involved in the therapeutic products industry, the advertising industry or the media industry (this might include a retainer to provide advice to the business from time to time); or
- (b) in the absence of such a relationship or understanding nevertheless receives significant benefits from a business of that kind (such as free travel or accommodation).

5.18 Procedure generally

- (1) Subject to subsection (2), so far as this Rule does not provide for the procedure of a Central Complaints Panel, the Panel may determine its own procedure.
- (2) A determination under this section is of no effect unless the procedure concerned has been:
 - (a) submitted to the Authority for the Authority's consideration; and
 - (b) approved by the Authority.

Section 5.19

5.19 Reports to Advertising Council

- (1) A Central Complaints Panel must give to the Advertising Council periodic written reports on the operation of the Panel during a reporting period.
- (2) Each reporting period must be for a consecutive period of not more than 12 months.
- (3) The Panel must determine the reporting period for the Panel, and the parameters on which reports are to be based, in consultation with the Advertising Council.

5.20 Validity of acts of members etc

Anything done by a person purporting to be or act as a member (including the Chair) of a Central Complaints Panel is not invalid merely because:

- (a) the occasion for the person's appointment had not arisen; or
- (b) there is a defect or irregularity in connection with the person's appointment; or
- (c) the appointment had ceased to have effect.

Division 5.3 Procedure on complaints

5.21 Definitions for this Division

In this Division:

advertiser, in relation to a complaint about an advertisement, means the person who, based on the complaint and the assessment of a Central Complaints Panel, appears to be responsible for requesting the publication or broadcast of the advertisement.

5.22 Complaints about advertisements

- (1) Subject to this section, a person may complain to a Central Complaints Panel that an advertisement about a therapeutic product that is published or broadcast contravenes:
 - (a) the relevant Act; or
 - (b) this Rule; or
 - (c) the Advertising Code.
- (2) A complaint about an advertisement cannot be made:
 - (a) to the Central Complaints Panel for Australia if the same complaint has been made to the Central Complaints Panel for New Zealand; or
 - (b) to the Central Complaints Panel for New Zealand if the same complaint has been made to the Central Complaints Panel for Australia.

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- (3) Paragraph (2) (a) does not apply if the complaint has been transferred to the Central Complaints Panel for Australia by the Central Complaints Panel for New Zealand under section 5.29.
- (4) Paragraph (2) (b) does not apply if the complaint has been transferred to the Central Complaints Panel for New Zealand by the Central Complaints Panel for Australia under section 5.29.
- (5) A complaint must:
 - (a) be in writing, unless the Panel is satisfied that the complainant is unable, because of physical incapacity, to make a written complaint; and
 - (b) include sufficient information to enable the identity of the complainant to be confirmed; and
 - (c) indicate whether subsection (2), (3) or (4) applies in relation to the complaint.
- (6) The Panel is not required to accept a complaint that does not comply with subsection (5).
- (7) The Panel must not accept a complaint about an advertisement that is directed solely to healthcare practitioners unless the Authority is satisfied that a claim, representation or other information contained in the advertisement constitutes a serious risk to public health and safety.
- (8) If the Panel does not accept a complaint, the Panel must give written notice to the complainant of its decision and the reasons for the decision.

5.23 Procedure on acceptance of a complaint

- (1) If a Central Complaints Panel accepts a complaint, the Panel:
 - (a) must give to the complainant and the advertiser written notice that the complaint has been accepted; and
 - (b) may make initial inquiries so that the details and background of the complaint are available to the Panel when it considers the complaint.
- (2) The notice must:
 - (a) give details of the complaint; and
 - (b) invite the complainant and the advertiser to send written submissions to the Panel, together with any supporting documents.
- (3) If a complaint is accepted by the Central Complaints Panel for Australia, the Panel may disclose the identity of the complainant to the advertiser if:
 - (a) the complainant is a commercial entity in the therapeutics industry, the media industry or the advertising industry; or
 - (b) in any other case — the complainant does not indicate at the time of making the complaint that the disclosure is not to be made.
- (4) In paragraph (3) (a), *commercial entity* does not include a healthcare practitioner.

Section 5.24

5.24 Dealing with complaint

- (1) Subject to this Division, a Central Complaints Panel that accepts a complaint must consider the complaint and decide whether it is justified.
- (2) In considering the complaint, the Panel must have regard to:
 - (a) any written submissions and documents given to the Panel; and
 - (b) the results of its inquiries (if any); and
 - (c) information obtained about the complaint; and
 - (d) any advice provided by the Advertising Council or another expert advisory committee.
- (3) A Central Complaints Panel may inform itself on any matter, and consult such persons, as it thinks fit.
- (4) The Panel may require the advertiser to produce evidence in support of a claim made in an advertisement that is the subject of a complaint.
- (5) The Panel must give written notice to the complainant and the advertiser of the Panel's decision and the reasons for the decision.

Note For action that the Panel may take if the Panel decides that a complaint is justified, see sections 5.31 and 5.32.

5.25 Withdrawal of complaint

- (1) The complainant may withdraw a complaint at any time.
- (2) The Chair of a Central Complaints Panel may treat a complaint to the Panel as withdrawn if, before dealing with the complaint under section 5.24, the Chair is satisfied that:
 - (a) the complaint is trivial, vexatious, misconceived or lacking in substance; or
 - (b) the subject matter of the complaint has been dealt with by the Panel or by another authority; or
 - (c) the subject matter of the complaint can more effectively or conveniently be dealt with by another authority; or
 - (d) both:
 - (i) the complainant does not intend to proceed with the complaint; and
 - (ii) on the basis of the complaint, there does not appear to have been any contravention of the relevant Act, this Rule or the Advertising Code.
- (3) If the complaint is withdrawn under subsection (1), the Chair must inform the advertiser of the fact.
- (4) If the Chair treats a complaint as withdrawn under subsection (2), the Chair must give written notice to the complainant and the advertiser of the Chair's decision and the reasons for the decision.

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- (5) If the Chair treats a complaint as withdrawn under paragraph (2) (c), the Chair may, in writing, refer the matter, and any material relating to the matter, to the authority concerned.

Note As to termination of a complaint on transfer of proceedings, see section 5.29.

5.26 Dealing with subject matter despite withdrawal of complaint

- (1) A Central Complaints Panel may deal with the subject matter of a complaint accepted by the Panel despite the withdrawal of the complaint if it appears to the Panel that there may have been a contravention of the relevant Act, this Rule or the Advertising Code.
- (2) If the Panel decides to deal with the subject matter of a complaint under subsection (1), the Panel must give written notice of its decision and the reasons for the decision to the advertiser.

5.27 Panel may refer complaint to another authority

- (1) If a Central Complaints Panel is satisfied that:
 - (a) the subject matter of a complaint, or the advertisement to which a complaint relates, involves a matter that could more effectively or conveniently be dealt with by another authority; and
 - (b) a complaint relating to the matter could have been made by the complainant to the authority;the Panel may, in writing, refer the matter, and any material before the Panel relating to the matter, to the authority.
- (2) If the Panel refers a matter to another authority, the Panel must give written notice of its decision to the complainant and the advertiser.
- (3) The referral of a matter under subsection (1) does not prevent the Panel from dealing with other matters to which the complaint relates in accordance with this Division.
- (4) This section applies despite the withdrawal of the complaint.

5.28 Dealing with matters not specified in complaint

- (1) A Central Complaints Panel may deal with a matter that is not mentioned in a complaint if it is satisfied that the advertisement to which the complaint relates may contravene the relevant Act, this Rule or the Advertising Code in some other way.
- (2) If the Panel decides to deal with a matter under subsection (1), the Panel must give written notice of its decision to the advertiser.
- (3) The notice must:
 - (a) give details of the matter not mentioned in the complaint and the possible contravention of the relevant Act, this Rule or the Advertising Code that are to be dealt with by the Panel; and

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- (b) invite the advertiser to send written submissions to the Panel, together with any supporting documents.
- (4) This section applies despite the withdrawal of the complaint.

5.29 Transfer of complaint between Panels

- (1) Subject to this section, if a complaint is made to the Central Complaints Panel for Australia, the Central Complaints Panel for Australia may decide to transfer the complaint to the Central Complaints Panel for New Zealand to be dealt with by that Panel.
- (2) Subject to this section, if a complaint is made to the Central Complaints Panel for New Zealand, the Central Complaints Panel for New Zealand may decide to transfer the complaint to the Central Complaints Panel for Australia to be dealt with by that Panel.
- (3) A decision under subsection (1) or (2) may be made:
 - (a) on the application of the complainant or the advertiser; or
 - (b) on the initiative of the Panel.
- (4) A Panel must not make a decision under subsection (1) or (2) about a complaint if the Panel has already made a decision:
 - (a) under section 5.24, as to whether the complaint is justified; or
 - (b) under section 5.27, that the subject matter of the complaint, or the advertisement concerned, be referred to another authority.
- (5) A Panel must not make a decision under subsection (1) or (2) unless it is satisfied that it is appropriate, having regard to all the circumstances of the complaint, to do so.
- (6) Before a decision is made under subsection (1) or (2) on the initiative of a Panel, the Panel must give to the complainant and the advertiser a reasonable opportunity to make submissions on the proposed transfer of the complaint.
- (7) If a Panel (the *transferring Panel*) decides under subsection (1) or (2) to transfer a complaint, the transferring Panel must:
 - (a) notify the complainant and the advertiser of its decision; and
 - (b) transfer to the receiving Panel all submissions, documents, material or other information relating to the complaint in the possession of the transferring Panel.
- (8) If a Panel decides under subsection (1) or (2) to transfer a complaint, consideration of the complaint by that Panel is terminated.
- (9) A Panel to which a complaint is transferred under this section must deal with the complaint as far as possible as if the complaint had been made to that Panel.

Section 5.31

5.30 Sharing of information

- (1) The Central Complaints Panel for Australia may share information about, or contained in, a complaint made to the Panel with the Central Complaints Panel for New Zealand.
- (2) The Central Complaints Panel for New Zealand may share information about, or contained in, a complaint made to the Panel with the Central Complaints Panel for Australia.

5.31 Request by Panel to take action

- (1) If, under section 5.24, a Central Complaints Panel decides that a complaint about an advertisement is justified, the Panel may request in writing a person to do one or more of the following within a reasonable period specified in the request:
 - (a) withdraw the advertisement;
 - (b) suspend the publication or broadcast of the advertisement for a period, or until a date, specified in the request;
 - (c) publish or broadcast a retraction;
 - (d) publish or broadcast a correction;
 - (e) recover any advertisement concerned that is still in circulation;
 - (f) destroy the advertisement;
 - (g) withdraw a particular claim or representation made by the advertisement, and give the Panel a written undertaking in accordance with subsection (2).
- (2) For paragraph (1) (g), the written undertaking must state that the person will not use the claim or representation concerned in any other advertisement unless:
 - (a) the Authority has approved the use of the claim or representation; or
 - (b) the advertiser satisfies the Panel that the use of the claim or representation would not result in a contravention of the relevant Act, this Rule or the Advertising Code.
- (3) In deciding whether to request a person to take any action mentioned in subsection (1), the Panel must have regard to:
 - (a) the need to safeguard public health and safety; and
 - (b) protecting the public interest; and
 - (c) if the advertisement does not comply with a requirement of the Advertising Code — the manner in which it differs from that requirement.
- (4) A request by a Central Complaints Panel under this section may specify that the action be taken by the person in:
 - (a) Australia; or
 - (b) New Zealand; or

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- (c) both Australia and New Zealand.
- (5) The Panel, in making a request to a person, must set out its reasons for the request.
- (6) The Panel must also give written notice of the making of the request to the complainant, setting out its reasons for the request.
- (7) The requirements of subsections (5) and (6) are in addition to the requirements of subsection 5.24 (5) for giving notice of the Panel's decision on the complaint.

5.32 Request for undertaking to take urgent action in serious cases

- (1) Despite section 5.31, if a Central Complaints Panel is satisfied, in relation to a complaint mentioned in subsection 5.31 (1), that the advertisement concerned constitutes a serious risk to public health and safety, the Panel may request in writing a person to give a written undertaking in accordance with subsection (2) within 48 hours after the request is made.
- (2) For subsection (1), the undertaking must state that that the person will take such action in respect of the advertisement (being 1 or more of the actions specified in subsection 5.31 (1)) as is specified in the request within a reasonable period specified in the request.
- (3) The Panel, in making a request to a person, must set out its reasons for the request.
- (4) The Panel must also give written notice of the making of the request to the complainant, setting out its reasons for the request.
- (5) The requirements of subsections (3) and (4) are in addition to the requirements of subsection 5.24 (5) for giving notice of the Panel's decision on the complaint.

5.33 Referral of requests etc to the Authority

- (1) If a person:
 - (a) fails to comply with a request made by a Central Complaints Panel under section 5.31 or 5.32; or
 - (b) breaches an undertaking of a kind mentioned in paragraph 5.31 (1) (g) or subsection 5.32 (2) given to the Panel;the Panel:
 - (c) must refer the complaint and the request or breach of undertaking immediately to the Authority; and
 - (d) may make a recommendation to the Authority about the action to be taken in relation to the advertisement to which the complaint relates.

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- (2) Without limiting paragraph (1) (d), the Panel may recommend that the Authority do one or more of the following:
 - (a) if the advertisement is an approved advertisement — suspend or revoke the approval of the advertisement;
 - (b) accept a written undertaking given by a person in relation to the advertisement under section [362] of the Australian Act or section [349S] of the New Zealand Act;
 - (c) if the therapeutic product concerned is a licensed therapeutic product — suspend or cancel the product licence;
 - (d) give a direction of a specified kind under section 5.34.

Note for paragraphs (2) (a) and (d) The Authority's power to suspend or revoke the approval of advertisements or to give a direction may be delegated to the Chair of a Central Complaints Panel. See section 3.17 or subsection 5.34 (6) respectively.

- (3) The Panel must give written notice of a recommendation made under subsection (1) to the person, and to the complainant, setting out its reasons.
- (4) A notice under subsection (3) must include a statement that the Authority (or the Chair of the Panel, as the case may be) may give a direction under section 5.34 in relation to the advertisement concerned.
- (5) However, a failure to comply with subsection (4) does not affect the validity of any direction given.

5.34 Directions by the Authority

- (1) If a Central Complaints Panel makes a recommendation to the Authority under section 5.33 about action to be taken in relation to an advertisement, the Authority, by written notice, may direct that a person do one or more of the following within a reasonable period specified in the direction:
 - (a) withdraw the advertisement;
 - (b) suspend the publication or broadcast of the advertisement for a period, or until a date, specified in the request;
 - (c) publish or broadcast a retraction;
 - (d) publish or broadcast a correction;
 - (e) recover any advertisement concerned that is still in circulation;
 - (f) destroy the advertisement;
 - (g) withdraw a particular claim or representation made by the advertisement, and not use that claim or representation in any other advertisement unless the person satisfies the Authority, or the Panel, that the use of the claim or representation would not result in a contravention of the relevant Act, this Rule or the Advertising Code.
- (2) Nothing in subsection (1):
 - (a) prevents the Authority from giving a direction under this section of a kind other than a kind recommended by the Panel, if the Authority is satisfied that it is appropriate in the circumstances to do so; or

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- (b) affects the power of the Authority to take any other action mentioned in subsection 5.33 (2).
- (3) The Authority must not give a direction under this section unless the Authority is satisfied that the direction is necessary in the interests of public health and safety, or in the public interest generally.
- (4) A direction under this section may specify that the action be taken by the person in:
 - (a) Australia; or
 - (b) New Zealand; or
 - (c) both Australia and New Zealand.
- (5) A direction under this section may be subject to conditions imposed by the Authority.
- (6) The Authority may delegate all or any of the Authority's powers to give a direction under this section in relation to advertisements that are the subject of recommendations made by a Central Complaints Panel to the Chair of the Panel.

Note 1 Failure to comply with a direction given under this section may give rise to a criminal or civil penalty, or to the imposition of a penalty by notice as an alternative to criminal or civil proceedings. See:

- (a) for Australia — [sections 326CP and 327CP and Division 3 of Part 3] of the Australian Act; and
- (b) for New Zealand — [sections [] and []] of the New Zealand Act.

Note 2 Failure to comply with a direction given under this section may lead to revocation of a product licence. See section [] of the Medicines Rule and section [] of the Medical Devices Rule.

Note 3 For internal review of decisions relating to the giving of directions, see Part 7.

5.35 Panel not to deal with complaint if court proceedings begun

- (1) A Central Complaints Panel cannot deal with a complaint if a proceeding has begun in a court in Australia or New Zealand about the subject matter of the complaint and the proceeding has not been finally disposed of.
- (2) If, after a complaint has been made to a Central Complaints Panel, a proceeding begins in a court in Australia or New Zealand about the subject matter of the complaint, the Panel cannot deal with the complaint until the proceeding is finally disposed of.

5.36 Register of complaints

- (1) A Central Complaints Panel may cause to be published on the Authority's website or, with the written permission of the Authority, on another website maintained wholly or partly for the purpose, a register of complaints and related information.

- (2) The register may include copies of, and information about, the following:
- (a) complaints received and accepted by the Panel under this Part;
 - (b) decisions made by the Panel under this Part in relation to complaints;
 - (c) action taken or recommended by the Panel in relation to complaints;
 - (d) statements of reasons given for decisions or action mentioned in paragraph (b) or (c);
 - (e) directions given under section 5.34;
 - (f) any other information that the Panel considers appropriate.

Part 6 Advertising Council

Division 6.1 Interpretation

6.01 Definitions

In this Part:

Chair means Chair of the Council.

Council means the Advertising Council.

member means a member of the Council.

subcommittee means a subcommittee under Division 6.4.

trans-Tasman advertising scheme means this Rule, the *Therapeutic Products Act 2006* of Australia, the *Therapeutic Products Act 2006* of New Zealand and the Advertising Code.

Division 6.2 Establishment, purpose, functions and constitution of Council

6.02 Establishment

- (1) There is established a Council to be known as the Advertising Council.
- (2) The Council is an expert advisory committee.

6.03 Purpose and functions of Council

- (1) The purpose of the Council is to ensure that the trans-Tasman advertising scheme protects the public interest and, in particular, to ensure that uniform standards are applied.
- (2) Accordingly, the Council has the functions of giving advice, and making recommendations, to the Authority as provided in this Rule.
- (3) The Council may provide advice in relation to:
 - (a) the advertising of therapeutic products; and
 - (b) the trans-Tasman advertising scheme including:
 - (i) the effectiveness of the scheme; and
 - (ii) the need for any changes to the Advertising Code; and
 - (c) the granting of delegations to approve advertisements; and
 - (d) any other matters referred to the Council by the Authority.
- (4) The Council may make recommendations in relation to:
 - (a) the revocation of a delegation to approve advertisements; and
 - (b) the revocation of an approval for an advertisement.

Section 6.04

6.04 Constitution

- (1) The Council consists of a Chair appointed under section 6.06 and not more than 20 other members appointed under section 6.05 from within the categories mentioned in the table to subsection (2).
- (2) A nominating body mentioned in column 4 in an item in the table to this subsection, or 2 or more bodies indicated in the item as acting jointly, may nominate a person to be a member of the category mentioned in column 2 in that item.

Item	Category of member	No. of members	Nominating body or joint nominating bodies
1	Expert in the therapeutic products industry	7	Complementary Healthcare Council of Australia Natural Products New Zealand Australian Self-Medication Industry Inc New Zealand Self-Medication Industry Association Inc Medical Industry Association of Australia Inc and the Medical Industry Association of New Zealand, jointly Medicines Australia Researched Medicines Industry Association of New Zealand Inc
2	Expert in the media and advertising industry	6	Advertising Standards Authority Inc The Association of New Zealand Advertisers Inc Advertising Federation of Australia Ltd and the Australian Association of National Advertisers, jointly Free TV Australia Ltd Commercial Radio Australia Ltd Australian Publishers' Bureau
3	Consumer	2	Australian Consumers' Association and the Consumers' Health Forum, jointly Consumers' Institute of New Zealand Inc and the New Zealand Ministry of Consumer Affairs, jointly

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Item	Category of member	No. of members	Nominating body or joint nominating bodies
4	Healthcare practitioner	4	Royal Australian College of General Practitioners, the Australian Medical Association, the Australian Divisions of General Practice Ltd and the New Zealand Medical Association, jointly The Pharmacy Guild of Australia, The Pharmacy Guild of New Zealand Inc, the Pharmaceutical Society of Australia and the Pharmaceutical Society of New Zealand Inc, jointly Australian Traditional-Medicines Society, the Australian Natural Therapists Association Ltd, the Federation of Natural and Traditional Therapists Ltd and the National Herbalist Association of Australia, jointly New Zealand Association of Medical Herbalists and the New Zealand Council of Homeopaths, jointly
5	Expert in the regulation of advertising	1	Australia New Zealand Therapeutic Products Authority

- (3) If a person is nominated, the Authority in its discretion may recommend the person's appointment under subsection 6.05 (1).

6.05 Appointment of members

- (1) Members are to be appointed in writing by the Ministerial Council on the recommendation of the Authority.
- (2) The Ministerial Council is entitled to appoint to be a member whoever it believes in its discretion to be appropriately qualified, but it is intended that members should be appointed on the basis of expertise rather than to represent a particular jurisdiction or interest unless required by this Part for the office.
- (3) A member is appointed for the term stated in the member's appointment.
- (4) The term stated in the appointment must not be longer than 3 years.
- (5) However, a member may be reappointed for further terms of up to 3 years each, but may not serve more than 3 consecutive terms.

6.06 Appointment of Chair

- (1) The Ministerial Council must appoint to be Chair of the Council a person recommended for that office by the Authority.
- (2) A person appointed under subsection (1) must not be associated with any sector of the therapeutic products industry, the advertising industry or the media industry.
- (3) The Chair holds that office for the term stated in the appointment.
- (4) The term stated in the appointment must not be longer than 3 years.
- (5) However, the Chair may be reappointed for further terms of up to 3 years each, but may not serve more than 3 consecutive terms.
- (6) An appointment under this section must be in writing.

6.07 Resignation or vacancy

- (1) A member may resign as a member by signed notice of resignation given to the Ministerial Council.
- (2) The Chair may resign from that office by signed notice of resignation given to the Ministerial Council.
- (3) If the Chair ceases to be a member, his or her office as Chair is taken also to be vacant.

6.08 Termination of appointment

- (1) The Ministerial Council may terminate a member's appointment on the grounds of:
 - (a) physical or mental incapacity; or
 - (b) misbehaviour; or
 - (c) incompetence; or
 - (d) inefficiency; or
 - (e) bankruptcy; or
 - (f) failing to comply, either recklessly or intentionally, with section 6.33.
- (2) The Ministerial Council must terminate the member's appointment if the member:
 - (a) is convicted of an offence punishable by imprisonment for 1 year or longer; or
 - (b) is absent without leave of absence from 3 consecutive meetings of the Council.

6.09 Leave of absence

- (1) The Ministerial Council may grant leave of absence to the Chair.

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- (2) The Chair may grant leave of absence to another Council member.

6.10 Alternate members

- (1) A nominating body may nominate up to 2 persons who are not members of the Council to be the alternate of a member (the *relevant member*) nominated to the Council by that body.
- (2) The Council, on the advice of the Authority, may appoint a nominated person to be available to be the alternate of the relevant member.
- (3) If a member is absent from a meeting of the Council and has an alternate, the alternate may attend the meeting.
- (4) If a person had an alternate immediately before he or she ceased to hold office as a member, the alternate may attend meetings of the Council while the office is vacant.
- (5) A person entitled to attend meetings under subsection (4) is taken to be the alternate of the person (the *new member*) appointed to the vacant office until an appointment is made under subsection (1) in relation to the new member.
- (6) An alternate who attends a meeting under this section is taken to be a member of the Council.
- (7) A person nominated by a nominating body to be an alternate may resign the appointment by notice in writing to the body.
- (8) In this section:

alternate, in relation to a member, means a person appointed under subsection (2) to be the alternate of the member or, if 2 persons have been appointed (whether or not at the same time), either of them.

nominating body means:

- (a) except where paragraph (b) applies—a nominating body mentioned in subsection 6.04 (2); and
- (b) if 2 or more nominating bodies are indicated in subsection 6.04 (2) as acting jointly to nominate a person to be a member—both or all of those bodies acting jointly.

Division 6.3 Council Procedures

6.11 Council procedures generally

- (1) In performing its functions, the Council:
- (a) must act according to this Division; and
- (b) must act with as little formality and as quickly as the requirements of this Division, and a proper consideration of the issues before the Council, allow; and

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- (c) is not bound by rules of evidence; and
 - (d) may, in any way it considers appropriate, obtain information necessary to allow it to perform its functions; and
 - (e) may receive information or submissions orally or in writing.
- (2) In addition, the Council must comply with any directions given, in writing, to the Council by the Ministerial Council or the Authority about the Council's performance of its functions.

6.12 Meetings

- (1) The Chair may, by written notice to the Council, direct the Council to hold meetings at the times and places, and to deal with matters in the manner, stated in the notice.

Note Section 2.24 of Schedule 1 to the *Administration and Interpretation Rule* enables the Council, if it so desires, to permit its members to participate in a meeting, or all meetings, although physically absent from the place of meeting.

- (2) Subject to this Division, the procedure of a meeting is as decided by the Council.

6.13 Observers to Council

- (1) With the agreement of the Chair, the following may attend meetings of the Council as an observer:
- (a) a person nominated by the Australian Competition and Consumer Commission;
 - (b) a person nominated by the Commerce Commission of New Zealand;
 - (c) the Chair of the Central Complaints Panel for Australia (who is taken to be nominated by that Panel);
 - (d) the Chair of the Central Complaints Panel for New Zealand (who is taken to be nominated by that Panel).
- (2) An observer under subsection (1) is entitled:
- (a) to be given the agenda and minutes of Council meetings, as if the person were a member of the Council; and
 - (b) by notice in writing to the Chair, to suggest agenda items to be considered by the Council.
- (3) The Chair may invite a person involved in the regulation of the advertising of therapeutic products to attend a meeting of the Council as an observer and provide expert advice.
- (4) An observer may take part in a discussion at a meeting of the Council, but an observer nominated by a body may only discuss an issue directly affecting the interests of the body.
- (5) The Chair is to decide whether an issue directly affects the interests of the body nominating an observer.

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6.14 Presiding member

- (1) The Chair must:
 - (a) preside at a Council meeting; or
 - (b) nominate a member of the Council to preside at the meeting.
- (2) If the Chair is temporarily absent from a meeting without having nominated a member to preside, the member chosen by the members present must preside.
- (3) A member chosen to preside may exercise the powers and functions of the Chair.

6.15 Quorum

At a Council meeting, a quorum consists of:

- (a) if the Council has an even number of members—half of that number; or
- (b) if the Council has an odd number of members—the number of members constituting a majority of the Council's membership.

6.16 Decision by majority

- (1) On a matter arising at a meeting of the Council, the decision of the majority of the members of the Council present at the meeting is the decision of the Council.
- (2) For deciding a matter arising at a meeting of the Council that directly affects the interests of a body that nominated a person under paragraph 6.13 (1) (a) or (b), the person so nominated is taken to be a member of the Council under subsection (1).
- (3) The Chair is to decide whether a matter directly affects the interests of the body that nominated a person.
- (4) If the Council cannot reach a majority decision on a matter, the decision of the Chair is the decision of the Council.
- (5) However, it is intended as far as reasonably practicable that the Chair take into account the views of other members.

Division 6.4 Subcommittees

Subdivision 6.4.1 Advertising Management Subcommittee

6.17 Definition

In this Subdivision:

Subcommittee means the Advertising Management Subcommittee.

6.18 Establishment

There is established a subcommittee of the Council to be known as the Advertising Management Subcommittee.

6.19 Functions

Subject to any terms of reference issued from time to time by the Council, the functions of the Subcommittee are as follows:

- (a) receiving and reviewing regular reports on the following:
 - (i) the operation of the approvals, complaints and appeals mechanisms;
 - (ii) the results of audits of advertisements directed to consumers in Australia and New Zealand;
 - (iii) the results of audits of advertisements directed to healthcare practitioners in Australia and New Zealand;
- (b) monitoring the performance of contracts relating to the provision of services for the regulation of the advertising of therapeutic products;
- (c) monitoring and advising on the education of relevant stakeholder groups;
- (d) advising on the training and accreditation of approvals officers and delegated authorities;
- (e) monitoring aspects of the trans-Tasman advertising scheme approved by the Ministerial Council;
- (f) reviewing the trans-Tasman advertising scheme and, in consultation with other stakeholders, making recommendations to the Council for changes;
- (g) providing advice to the Council on the allocation of resources for the regulation of the advertising of therapeutic products, and assisting in the preparation of the Council's annual budget;
- (h) preparing for the Council for each financial year a draft of the annual report to the Ministerial Council on the effectiveness of the regulation of the advertising of therapeutic products.

6.20 Constitution

- (1) There must be at least 8, and not more than 12, members of the Subcommittee.
- (2) The Subcommittee must include the following members of the Council:
 - (a) the Chair;
 - (b) the member nominated by the Authority;
 - (c) the member nominated under subsection 6.04 (2) by the Medical Industry Association Inc of Australia and the Medical Industry Association of New Zealand.

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- (3) The Subcommittee must include the following members appointed by the Council from among those nominated under subsection 6.04 (2):
 - (a) 1 member from the members within the consumer category;
 - (b) 1 member from the following:
 - (i) the member nominated by the Complementary Healthcare Council of Australia;
 - (ii) the member nominated by Natural Products New Zealand;
 - (c) 1 member from the following:
 - (i) the member nominated by the Australian Self-Medication Industry Inc;
 - (ii) the member nominated by the New Zealand Self-Medication Industry Association Inc;
 - (d) 1 member from the following:
 - (i) the member nominated by Medicines Australia;
 - (ii) the member nominated by Researched Medicines Industry Association of New Zealand;
 - (e) 1 member from the members within the category expert in the media and advertising industry.
- (4) The Council may appoint up to 4 other members of the Council to be members of the Subcommittee.

6.21 Chair

The Chair of the Council is also the Chair of the Subcommittee.

6.22 Resignation or vacancy

- (1) A member of the Subcommittee may resign as a member of the Subcommittee by signed notice of resignation given to the Council.
- (2) If a member of the Subcommittee ceases to be a member of the Council, he or she ceases to be a member of the Subcommittee at the same time.

6.23 Leave of absence

- (1) The Ministerial Council may grant leave of absence to the Chair.
- (2) The Chair may grant leave of absence to another Subcommittee member.

6.24 Alternate members

An appointment of an alternate under section 6.10 in relation to a member of the Council is also taken:

- (a) if the member is a member of the Subcommittee — to be an appointment of the alternate in accordance with that section in relation

to the member in his or her capacity as a member of the Subcommittee;
or

- (b) if the member later becomes a member of the Subcommittee — to become an appointment of the alternate in accordance with that section in relation to the member in his or her capacity as a member of the Subcommittee.

Subdivision 6.4.2 Other subcommittees

6.25 Definition

In this Subdivision:

Chair, in relation to a subcommittee, means the Chair of the subcommittee.

6.26 Council may establish other subcommittees

- (1) The Council, with the approval of the Authority, may establish a subcommittee by instrument in writing.
- (2) Subject to subsection (3):
 - (a) a subcommittee consists of members and other persons as provided by instrument; and
 - (b) the function of a subcommittee is to inquire into or consider, and report to the Council on, any specified matter as provided by instrument that is within the functions of the Council.
- (3) An instrument may provide generally for matters that are necessary or convenient to be provided for in relation to a subcommittee.
- (4) In this section:

instrument, in relation to a subcommittee, means the instrument establishing the subcommittee or a separate instrument relating to the subcommittee made by the Council with the approval of the Authority.

subcommittee means subcommittee established under this section.

Subdivision 6.4.3 Subcommittee procedures

6.27 Subcommittee procedures generally

- (1) In performing its functions, a subcommittee:
 - (a) must act according to this Division; and
 - (b) must act with as little formality and as quickly as the requirements of this Division, and a proper consideration of the issues before the subcommittee, allow; and
 - (c) is not bound by rules of evidence; and
 - (d) may, in any way it considers appropriate, obtain information necessary to allow it to perform its functions; and

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- (e) may receive information or submissions orally or in writing.
- (2) In addition, a subcommittee must comply with any directions given, in writing, to the subcommittee by the Council or the Authority about the performance of the subcommittee's functions.

6.28 Meetings

- (1) The Chair may, by written notice to a subcommittee, direct the subcommittee to hold meetings at the times and places, and to deal with matters in the manner, stated in the notice.

Note Section 2.24 of Schedule 1 to the *Administration and Interpretation Rule* enables a subcommittee, if it so desires, to permit its members to participate in a meeting, or all meetings, although physically absent from the place of meeting.

- (2) Subject to this Division, the procedure of a meeting is as decided by the subcommittee.

6.29 Presiding member

- (1) The Chair must:
 - (a) preside at a subcommittee meeting; or
 - (b) nominate a member of the subcommittee to preside at the meeting.
- (2) If the Chair is temporarily absent from a meeting without having nominated a member to preside, the member chosen by the members present must preside.
- (3) A member chosen to preside may exercise the powers and functions of the Chair.

6.30 Quorum

At a subcommittee meeting, a quorum consists of:

- (a) if the subcommittee has an even number of members—half of that number; or
- (b) if the subcommittee has an odd number of members—the number of members constituting a majority of the subcommittee's membership.

6.31 Decision by majority

- (1) The decision of the majority of the members of a subcommittee is the decision of the subcommittee.
- (2) If the subcommittee cannot reach a majority decision on a matter, the decision of the Chair is the decision of the subcommittee.
- (3) However, it is intended as far as reasonably practicable that the Chair take into account the views of other members.

Division 6.5 Miscellaneous

6.32 Annual report on the effectiveness of advertising regulation

- (1) Within 3 months after the end of a financial year, the Council must prepare a written report for the Ministerial Council.
- (2) The report must deal with the effectiveness, for the year, of the regulation of advertising for therapeutic products.
- (3) The report must be prepared in accordance with reporting criteria agreed between the Council and the Authority.
- (4) The Council must give the report to the Authority for forwarding to the Ministerial Council.

6.33 Disclosure of interests and prejudicial relationships

- (1) The purpose of this section is to place on a member of the Council or a subcommittee the onus of disclosing interests or prejudicial relationships relating to a matter so that the Council or subcommittee has the opportunity to decide whether it is appropriate for the member to take part in deliberations or decisions about the matter.
- (2) A member who is aware that he or she has an interest in a matter, or a prejudicial relationship affecting a matter, being considered or about to be considered at a meeting of the Council or a subcommittee must, without delay, disclose the nature of the interest or the relationship at, or before, the meeting of the Council or the subcommittee, as the case may be.
- (3) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Council or subcommittee otherwise determines:
 - (a) be present during any deliberation of the Council or subcommittee about the matter; or
 - (b) take part in any decision of the Council or subcommittee about that matter.
- (4) When the Council or a subcommittee is making a determination under subsection (3) about a member who has made a disclosure, the member, and any other member who has an interest or prejudicial relationship in the matter to which the disclosure relates, must not:
 - (a) be present during any deliberation of the Council or subcommittee; or
 - (b) take part in making the determination.
- (5) A member is not to be taken as having an interest in, or a prejudicial relationship affecting, a matter solely because the member is employed, or engaged as a consultant, by the Authority.
- (6) In this section:

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affected person, in relation to a member considering or about to consider a matter at a meeting of the Council or a subcommittee, means a person known to the member to have an interest in the matter.

interest means a pecuniary interest, direct or indirect.

prejudicial relationship, in relation to a member considering or about to consider a matter at a meeting of the Council or a subcommittee, means a relationship between the member and an affected person of such a kind that a reasonable person with knowledge of the relationship would perceive the likelihood of bias in the member's consideration of the matter.

Note A prejudicial relationship might exist where the spouse or other close associate of a member has a pecuniary interest in the matter to be considered by the Council or a subcommittee. A prejudicial relationship might also exist where the member:

- (a) has a contractual relationship or understanding with a business involved in the therapeutic products industry, the advertising industry or the media industry (this might include a retainer to provide advice to the business from time to time); or
- (b) in the absence of such a relationship or understanding nevertheless receives significant benefits from a business of that kind (such as free travel or accommodation).

6.34 Authority may seek further advice

Advice given by the Council to the Authority may be passed to another person or body (including an expert advisory committee) for the advice of that person or body.

6.35 Chair may seek advice and assistance

The Chair, on behalf of the Council, may seek advice from other persons about the performance of the Council's functions under this Division.

6.36 Validity of acts of members etc

- (1) Anything done by a person purporting to be or act as a member is not invalid merely because:
 - (a) the occasion for the person's appointment had not arisen; or
 - (b) there is a defect or irregularity in connection with the person's appointment; or
 - (c) the appointment had ceased to have effect.

- (2) In this section:

member includes Chair, and a member and chair of a subcommittee.

6.37 Records and reports

- (1) The Council must keep a record of its proceedings.
- (2) The Council must prepare any other report about its activities that is requested by the Ministerial Council or the Authority.

Part 7 Internal review of decisions

7.01 What is an initial regulatory decision?

- (1) For this Part, an *initial regulatory decision* is a decision by the Authority of a kind mentioned in subsection (2), other than a decision made on review under section 7.03.
- (2) For subsection (1), the kinds of decisions are:
 - (a) a decision under section 2.03 in relation to an application for acceptance of an industry sector code of conduct;
 - (b) a decision under section 3.05 in relation to an application for approval of an advertisement;
 - (c) a decision under section 3.08 in relation to the variation of a condition of an approval mentioned in paragraph (b);
 - (d) a decision under section 3.09 in relation to the suspension of an approval mentioned in paragraph (b);
 - (e) a decision under section 3.10 in relation to the revocation of an approval mentioned in paragraph (b);
 - (f) a decision under section 4.05 in relation to an application for approval of the use of a restricted representation;
 - (g) a decision under section 4.07 in relation to the variation of a condition of an approval mentioned in paragraph (f);
 - (h) a decision under section 4.08 in relation to the suspension of an approval mentioned in paragraph (f);
 - (i) a decision under section 4.09 in relation to the revocation of an approval mentioned in paragraph (f);
 - (j) a decision under section 4.14 in relation to an application for approval of a reference to a restricted medical device;
 - (k) a decision under section 4.16 in relation to the variation of a condition of an approval mentioned in paragraph (j);
 - (l) a decision under section 4.17 in relation to the suspension of an approval mentioned in paragraph (j);
 - (m) a decision under section 4.18 in relation to the revocation of an approval mentioned in paragraph (j);
 - (n) a decision under section 5.34 in relation to giving a direction.

7.02 Application to review initial regulatory decision

- (1) Subject to subsection (2):
 - (a) an applicant or approval holder who is dissatisfied with an initial regulatory decision mentioned in paragraph 7.01 (2) (a) to (m) inclusive; or

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- (b) a person whose interests are affected by an initial regulatory decision mentioned in paragraph 7.01 (2) (n);
may apply in writing to the Authority for a review of the decision.
- (2) Subsection (1) does not apply to an initial regulatory decision made personally by the Managing Director.
- Note* Initial regulatory decisions made by the Managing Director personally may be reviewed by a Review Tribunal, see:
- (a) for Australia — section [^412] of the Australian Act;
(b) for New Zealand — section [] of the New Zealand Act.
- (3) An application must be made within 30 days after notice of the decision is given to the applicant or approval holder.
- (4) If the application concerns an initial regulatory decision of a kind mentioned in paragraph 7.01 (2) (b), (c), (d), (e) or (n), the Authority may send a copy of the application to the following:
- (a) the Advertising Council;
(b) either or both of the Central Complaints Panels.
- (5) In this section:
- applicant*** means an applicant for:
- (a) acceptance of an industry sector code of conduct under section 2.03; or
(b) an approval under section 3.05, 4.05 or 4.14, as the case requires.
- approval holder*** means the holder of an approval under section 3.05, 4.05 or 4.14, as the case requires.

7.03 Review of initial regulatory decision

- (1) Subject to this section, on receipt by the Authority of an application under section 7.02, the Managing Director must:
- (a) personally review the initial regulatory decision; or
(b) cause the decision to be reviewed by a delegate of the Managing Director who:
- (i) was not involved in the initial regulatory decision; and
(ii) if the delegate is a member of the staff of the Authority — holds a more senior office than the delegate who made the initial regulatory decision.
- (2) A review under subsection (1) must take place as soon as practicable after the application is received, having regard to the need (if any) to obtain advice from the Advertising Council or another expert advisory committee.
- (3) On a review, the Managing Director or delegate may:
- (a) confirm the initial regulatory decision; or
(b) revoke the initial regulatory decision, or revoke that decision and make a decision (including a decision to impose conditions) in substitution for the revoked decision.

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- (4) In making a decision under subsection (3), the Managing Director or delegate must take into account any recommendation on the matter made by the Advertising Council or a Central Complaints Panel, as the case requires.
- (5) If, within 60 days after an application is made under section 7.02, the applicant does not receive notice of the decision of the Authority on review of the initial regulatory decision, the Authority is to be taken to have confirmed the initial regulatory decision.
- (6) Until a decision is made on review, the making of an application does not affect the operation of the initial regulatory decision.
- (7) The person reviewing the initial regulatory decision must give the applicant a notice in writing stating the result of the review.
- (8) A notice under subsection (7) must include a statement to the effect that, subject to the applicable legislation of Australia or New Zealand (as the case requires), the applicant may:
 - (a) apply to the Authority for a statement setting out the reasons for the decision on review; and
 - (b) apply to a Review Tribunal for a review of that decision.
- (9) If the person reviewing the initial regulatory decision does not accept a recommendation of the Advertising Council, the person must notify the applicant of that fact.
- (10) If the decision of the person reviewing the initial regulatory decision is to grant an approval subject to conditions, the conditions must be set out in the notice.
- (11) A failure to comply with the requirements of subsection (7), (8), (9) or (10) does not affect the validity of the decision on review.

7.04 Notice of initial regulatory decision to include statement about review

- (1) If the Authority gives written notice of the making of an initial regulatory decision (other than a decision made personally by the Managing Director) to a person who is entitled under this Part to apply for a review of the decision, the notice must include a statement to the effect that the person may:
 - (a) under this Part, apply for a review of the decision; and
 - (b) if the person is dissatisfied with the decision on review, and subject to the applicable legislation of Australia or New Zealand (as the case requires), apply to a Review Tribunal for a review of that decision.

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- (2) If the Authority gives written notice of the making, by the Managing Director personally, of an initial regulatory decision to a person who is entitled under this Part to apply for a review of the decision, the notice must include a statement to the effect that the person may, subject to the applicable legislation of Australia or New Zealand (as the case requires), apply to a Review Tribunal for a review of that decision.
- (3) A failure to comply with the requirements of subsection (1) or (2) does not affect the validity of the initial regulatory decision.

Note For review of decisions by a Review Tribunal generally see:

- (a) for Australia — [Part 4, Division 1] of the Act;
- (b) for New Zealand — [Part] of the Act.

7.05 Internal review declared to be a regulatory function

For paragraph (b) of the definition of *regulatory function* in Article 1 of the Agreement, the function of the Authority in reviewing decisions by the Authority, as provided under this Part, is declared to be a regulatory function.

Schedule 1 Advertising requirements

(Subsection 2.01 (3))

General requirements for all advertisements for therapeutic products, whether directed to consumers or healthcare practitioners

1. Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.
2. Advertisements must contain mandatory information to encourage responsible use.
3. To assist consumer to make informed choices, advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated.
4. Advertisements must not directly or indirectly nor by implication, omission, ambiguity, exaggerated claim or comparison:
 - mislead or deceive, or be likely to mislead or deceive; or
 - abuse trust, or exploit lack of knowledge; or
 - where directed to consumers, exploit the superstitious or, without justifiable reason, play on fear or cause distress.
5. Advertisements must not unduly glamorise products and where directed to consumers must not prey on the vulnerability of particular audiences.
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 accepted industry sector codes of conduct, 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.

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

Additional requirements for advertisements directed to consumers

8. Advertisements for medicines must not refer directly or by implication to serious diseases, conditions, ailments or defects, without approval from the Authority.
9. Advertisements for medical devices must not refer directly or by implication to medical devices, or procedures involving medical devices, that are intended to be used or administered solely by healthcare practitioners, without approval by the Authority.

Additional requirements for advertisements directed to healthcare practitioners

10. In the advertising of medicines, all communications made by company representatives must comply with the Advertising 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 applicant 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.

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

When requested, the licence applicant (or their representative) must be able to supply a copy of the 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 applicant must hold substantiating data to support the claims.