



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



Plain English Guide
to the
draft Australia New Zealand
Therapeutic Products Regulatory Scheme
(Advertising) Rule 2006

DECEMBER 2006

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1. INTRODUCTION

On 10 December 2003 the Australian and New Zealand Governments signed an agreement to establish a joint scheme for the regulation of therapeutic products in the two countries (the Treaty). The joint regulatory scheme will be administered in both countries by a single, bi-national authority, the Australia New Zealand Therapeutic Products Authority (the Authority). The Authority will replace the Therapeutic Goods Administration (TGA) in Australia and the Medicines and Medical Devices Safety Authority (Medsafe) in New Zealand and will be accountable to both the Australian and New Zealand Governments.

Article 3 of the Treaty provides for the regulation of the promotion (which is defined as including advertising) of therapeutic products, including the setting of standards.

The Therapeutic Products Ministerial Council will have the power to determine Rules which will regulate the advertising of therapeutic products and these will be given equal legislative force in Australia and New Zealand.

This document describes the proposed joint regulatory scheme for the advertising of therapeutic products. The regulatory provisions described in this document are set out in the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006.

2. DEVELOPMENT OF A NEW REGULATORY MODEL

A new co-regulatory model for the advertising of therapeutic products in Australia and New Zealand was developed by the Interim Advertising Council (IAC) and approved with a small number of modifications by the Therapeutic Products Interim Ministerial Council (TPIMC) in December 2005. Key stakeholder interest groups were directly involved in the process of developing the new regulatory model through representation on the IAC. The IAC report (October 2004) is published on the project website at <http://www.anztpa.org/advert/index.htm>.

The proposed trans-Tasman advertising scheme for therapeutic products includes:

- a definition of *advertisement* that identifies the scope of the advertising scheme;
- the requirement to comply with the Australia New Zealand Therapeutic Products Advertising Code, developed as the standard for advertising of therapeutic products in Australia and New Zealand, which will be applied for the pre-approval of certain advertisements and consideration of complaints about advertisements;
- the requirement for certain therapeutic product advertisements to be approved prior to publication;
- a range of sanctions for non-compliance with the advertising code and the Advertising Rule;
- the implementation of governance arrangements to oversee the management of the advertising scheme;
- the ability to develop and maintain processes for the pre-approval of advertisements, for the handling of complaints about advertisements and for appeals regarding advertising decisions;

- expert advisory arrangements for proposals to change the Australia New Zealand Therapeutic Products Advertising Code; and
- a monitoring and evaluation framework.

The scheme also allows for possible differences between advertising policy in Australia and New Zealand.

An Advertising Implementation Steering Group has been established to guide the implementation of the operational aspects of the new regulatory model for the advertising of therapeutic products in Australia and New Zealand. It is planned that the minutes of the Steering Group and other relevant information will be published on the project website at <http://www.anztpa.org/advert>.

3. OBJECTIVES OF THE JOINT REGULATORY MODEL

The overall objective of the proposed regulatory model is to provide an appropriate symmetry between the benefits of consumer access to accurate and balanced information and the freedom of speech, with the potential for harm from the inappropriate use of medicines and medical devices and other public health and safety issues. In keeping with the overall approach to the joint regulatory scheme, the proposed regulatory model for advertising is risk-based.

The proposed regulatory model for the advertising of therapeutic products in Australia and New Zealand has been developed to:

- effectively protect the public interest and public health and safety;
- capture and retain existing self-regulatory processes where they are working well, within a co-regulatory framework;
- improve the cost-effectiveness and timeliness of the system;
- provide stakeholders with appropriate education about the system, including a well understood avenue for the submission of complaints; and
- achieve consistency of treatment and outcomes both between Australia and New Zealand and between industry sectors and other advertisers within each country.

The proposed regulatory model covers all advertising that is permitted in each country (including advertising on the internet) directed to both consumers and healthcare practitioners of all therapeutic products [including prescription medicines, over-the-counter (OTC) medicines, complementary medicines and medical devices].

4. A COMMON, PRINCIPLES-BASED CODE FOR THE ADVERTISING OF THERAPEUTIC PRODUCTS

The *Australia New Zealand Therapeutic Products Advertising Code* (Advertising Code) includes detailed requirements on how to give practical effect to the high level Advertising Principles and the Advertising Requirements. In order to comply with the key Advertising Principles, the Advertising Requirements included in the Advertising Code must be observed.

The Advertising Code will be applicable in both countries and across all therapeutic products industry sectors and media¹. The Advertising Code will have equal legal standing in both countries as an Order of the Authority.

It should be noted that the Advertising Code remains a “living” document and details may be added as they are finalised through the Steering Group and based on experience in the future.

Coverage of the Advertising Code

Definition of an advertisement

Under the joint regulatory scheme, an advertisement in relation to a therapeutic product will be broadly defined as 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.

Bona fide news, bona fide editorial, bona fide public interest programs or bona fide entertainment programs (editorial material) will be excluded from the requirements of the Advertising Code. Any complaints made about this type of material which involves therapeutic products is to be dealt with in the first instance by the regulatory and industry codes of practice which are administered by relevant media, professional and advertising bodies.

Similarly, bona fide educational and scientific material will also be excluded from the requirements of the Advertising Code.

For the purposes of the Advertising Code, a label will not be considered to be an advertisement unless it forms part of an advertisement (i.e. a label is pictured in an advertisement). Assessment of product labels will be undertaken by the Authority as part of the pre- and post market scrutiny of material submitted in relation to a product licence. The assessment will involve considering the overall presentation of the product (taken to include matters relating to the name of the product, the labelling and packaging of the product and any advertising or other informational material associated with the product).

Interface between foods, cosmetics and therapeutic products

The therapeutic products advertising regulatory arrangements will apply to cosmetic products that are advertised with therapeutic claims (where they fit the definition of a therapeutic product). They may also apply to foods that, because they are advertised with therapeutic claims (other than nutrition or health related claims which are specifically prescribed by a relevant standard in the Food Standards Code), may then be declared to be a therapeutic product².

Some products (such as tampons and commercial/household disinfectants) are to be regulated by the Authority for Australia-only, as they are not considered to be therapeutic products for

¹ Internet advertising will be subject to all of the regulatory provisions other forms of advertising in mainstream media will be required to meet, with the exception of requiring pre-approval for advertisements.

² Taking into consideration the overall presentation of the product and whether the definition of a therapeutic product is met.

the purposes of the joint scheme. The controls on the advertising of these products (known as related goods) in Australia are currently under consideration.

5. KEY ADVERTISING PRINCIPLES AND ADVERTISING REQUIREMENTS

Key Principles

The following three Key Advertising Principles embody the spirit of the controls on the advertising of therapeutic products and have been included in the draft Advertising Rule.

PRINCIPLE 1 - Advertisements must comply with the Australia and New Zealand Therapeutic Products Act(s), 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.

Advertising Requirements

The *Advertising Requirements*, which expand and give further guidance on the Key Advertising Principles, have also been included in the draft Advertising Rule.

General requirements for all advertisements for therapeutic products

Requirement 1

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

Requirement 2

Advertisements must contain the mandatory information to encourage responsible use.

Requirement 3

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

- (a) for medicines – must be consistent with the indications included on the database of therapeutic products maintained by the Authority; and
- (b) for exempt therapeutic products – must be compliant with the Advertising Code.

Requirement 4

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

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

Requirement 5

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

Requirement 6

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

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

Requirement 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

Requirement 8

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

Requirement 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 and/or administered solely by healthcare practitioners, without approval by the Authority.

Additional requirements for advertisements directed to healthcare practitioners

Requirement 10

In the advertising of medicines, all communications made by the product licence holder (or their 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 product licence holder (or their representative).

Requirement 11

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

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

For non-therapeutic claims the sponsor must hold substantiating data to support the claims.

6. EXPERT ADVISORY COMMITTEES

Article 4 (2)(e) of the Treaty provides for the Ministerial Council to establish expert advisory committees, which will advise the Managing Director of the Authority, and to appoint and remove the members of those committees.

The General Provisions for Expert Advisory Committees are set out in Division 8.9 of the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006.

Advertising Council

The draft Advertising Rule establishes an Advertising Council at commencement of the joint scheme, as an expert advisory committee, to provide advice to the Authority in relation to matters concerning the advertising or promotion of therapeutic products.

The Advertising Council is proposed to:

- provide advice on whether the trans-Tasman advertising scheme protects the public interest and uniform standards are applied;
- monitor and make recommendations on the effectiveness of the trans-Tasman therapeutic products advertising scheme;
- recommend changes to the Advertising Code;
- provide advice on the granting of delegations to approve advertisements and the withdrawal of delegations;
- provide advice on the withdrawal of an approval for an advertisement; and
- consider any other matters referred to it by the Authority.

The Advertising Council is to have an independent chair recommended by the Authority and appointed by the Ministerial Council. The remaining members of the Advertising Council are to be appointed by the Ministerial Council, on the advice of the Authority, up to a maximum of 20 members. These committee members are to be drawn from nominations from the following parties:

- 7 experts in the therapeutic products industry, comprising 1 person nominated by each of the following bodies:

- Complementary Healthcare Council of Australia;
 - Natural Products New Zealand;
 - Australian Self-Medication Industry;
 - New Zealand Self-Medication Industry Association;
 - Medical Industry Association of Australia and Medical Industry Association of New Zealand (as a joint nomination);
 - Medicines Australia;
 - Researched Medicines Industry Association of New Zealand;
- 6 experts in the media and advertising industries, comprising 1 person nominated by each of the following bodies:
- Advertising Standards Authority (New Zealand);
 - Association of New Zealand Advertisers;
 - Advertising Federation of Australia and the Association of Australian National Advertisers (as a joint nomination);
 - Free TV Australia;
 - Commercial Radio Australia;
 - Australian Publishers Bureau;
- 2 consumer members comprising 1 person nominated by:
- Consumers' Health Forum of Australia and the Australian Consumers' Association (as a joint nomination);
 - New Zealand Ministry of Consumer Affairs and Consumers' Institute of New Zealand (as a joint nomination);
- 4 expert healthcare practitioners comprising 1 person nominated by each of the following:
- Royal Australia College of General Practitioners, the Australian Medical Association, the Australian Divisions of General Practice and the New Zealand Medical Association (as a joint nomination);
 - The Pharmacy Guild of Australia, the Pharmacy Guild of New Zealand, the Pharmaceutical Society of Australia and the Pharmaceutical Society of New Zealand (as a joint nomination);
 - The Australasian Traditional-Medicines Society, the Australian Natural Therapists Association, the Federation of Natural and Traditional Therapists Ltd and the National Herbalist Association of Australia (as a joint nomination);
 - New Zealand Association of Medical Herbalists and the New Zealand Council of Homoeopaths (as a joint nomination); and
- an expert in the regulation of advertising nominated by the Authority.

Observers

With the agreement of the Chair of the Council, the following persons may attend the meetings of the Council as observers:

- a person nominated by the Australian Consumer and Competition Commission; and
- a person nominated by the Commerce Commission of New Zealand.

It is proposed that observers will be entitled to be given the agenda and the minutes of Council meetings, suggest agenda items, attend the meeting and participate in the decision-making of any matter directly affecting the interests of the body nominating the observer.

With the agreement of the Chair of the Council, the Chair of the Central Complaints Panel in Australia and the Chair of the Central Complaints Panel in New Zealand may also attend meetings of the Council as observers. While these observers will be able to provide input into discussions, they will not have the right to participate in the decision-making of any matters before the Council.

Committee may seek advice and assistance

It is also proposed that the Chair of the Council may seek advice from other persons in performing its functions. The Chair may invite other key persons involved in the regulation of the advertising of therapeutic products (such as those people employed by the industry associations who hold the delegation to approve advertisements which need approval) on a case by case basis to a particular meeting to observe the meeting and provide expert advice. These people may also attend meetings as observers and advisers but will not have the right to participate in the decision-making of any matters before the Council.

Alternate Members

The draft Advertising Rule allows that a body mentioned in relation to the nomination of members may nominate up to two additional persons who are not members of the Council to be available as the alternate of a member nominated to the Council by that body. The Ministerial Council must appoint alternate members on the advice of the Authority. If a member is absent from a Council meeting, the member's alternate will be entitled to attend the meeting.

Annual Report

The draft Rule requires that within 3 months after the end of a financial year, the Council must give the Ministerial Council, through the Authority, a written report on the effectiveness of the regulation of the advertising of therapeutic products for that financial year, in accordance with reporting criteria agreed between the Advertising Council and the Authority.

Advertising Management Subcommittee

The Advertising Rule also establishes a subcommittee of the Advertising Council called the Advertising Management Subcommittee which is to provide advice and report to the Advertising Council.

The key functions of the Advertising Management Subcommittee are proposed to be:

- (a) receiving and reviewing regular reports on the operation of the approvals, complaints and appeals mechanisms, and the results of audits of advertisements directed to consumers in Australia and New Zealand;
- (b) monitoring the performance of contracts relevant to the provision of services for the regulation of the advertising of therapeutic products;
- (c) advising on the education of relevant stakeholder groups and monitor its implementation;

- (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 Therapeutic Products Ministerial Council;
- (f) reviewing the advertising regulatory scheme and in consultation with other stakeholders, make recommendations for any changes to the Advertising Council;
- (g) providing advice to the Council on the allocation of resources to the regulation of the advertising of therapeutic products and assisting in the preparation of the Advertising Council's annual budget; and
- (h) preparing for the Advertising Council the draft annual report to the Ministerial Council on the effectiveness of the regulation of the advertising of therapeutic products for that financial year.

The Advertising Management Subcommittee is proposed to consist of a maximum of 12 members of the Advertising Council, which must include as a minimum the following 8 members:

- The member who is the Chair of the Advertising Council;
- The member nominated by the Authority;
- One member from the consumer members nominated by the consumer groups in Australia and/or New Zealand;
- One member from the member nominated by the Complementary Healthcare Council of Australia or Natural Products New Zealand;
- One member from the member nominated by the Australian Self-Medication Industry or the New Zealand Self-Medication Industry Association;
- The member nominated by the Medical Industry Association of Australia and the Medical Industry Association of New Zealand;
- One member from the member nominated by Medicines Australia or the Researched Medicines Industry Association of New Zealand; and
- One member from the member nominated by the Advertising Standards Authority (New Zealand), The Association of New Zealand Advertisers, the Advertising Federation of Australia and the Australian Association of National Advertisers (jointly), Free TV Australia, Commercial Radio Australia, or the Australian Publishers' Bureau.

Up to four other Council members may be appointed to the Advertising Management Subcommittee by the Advertising Council.

It is anticipated that at the end of the first twelve-month period of its operation, the constitution of the management subcommittee will be reviewed with the possibility of reducing membership as the scheme becomes established.

7. ADVERTISING WHICH REQUIRES APPROVAL PRIOR TO PUBLICATION OR BROADCAST

The draft Advertising Rule provides for:

Approvals - Applications

Certain advertisements are proposed to need approval prior to publication or broadcast in the new scheme.

The draft Rule requires that an application for approval of an advertisement will have to be made in writing, in a form approved by the Authority, and signed by or on behalf of the applicant.

Approvals - exemptions

Advertisements will be exempt from pre-approval where the advertisement consists only of one or more of the following:

- the brand name of the product;
- the price of the product;
- the type or style of the product;
- a photographic or other reproduction of the product that does not contain any claim for therapeutic use in relation to the product;
- the locations or times at which the product is offered for sale;
- any other information reasonably necessary to identify the person offering the goods for sale.

Advertisements directed exclusively to healthcare practitioners in Australia are not proposed to require approval. Should New Zealand continue to require approval of advertisements directed to healthcare practitioners, such as doctors and pharmacists, it is expected that such advertisements could be submitted for approval on a voluntary basis or approved under the delegated authority system (see delegated authorities).

Approvals - medicines

Mainstream media

It is proposed that advertisements for medicines directed to consumers and printed/broadcast in mainstream media will require pre-approval, other than the internet for practical reasons (see internet advertising).

Mainstream media includes:

- newspapers and magazines;
- cinematograph films;
- displays (including posters) in shopping malls, in or on public transport or on billboards; and
- information disseminated electronically in a visible or audible form or in a combination of these forms but does not include the internet, electronic mail, narrowcast transmission, short message service (SMS) or multimedia messaging service (MMS) [ie broadcast media].

Approval of advertisements in Australia and New Zealand will apply the same criteria through the Advertising Code and similar approval processes, with approvals issued in one

country automatically recognised in the other (provided that the publication or broadcast of such advertisements is lawful in both countries). Taste and decency standards that do not relate directly to the use, sale and supply of medicines will be dealt with separately under the appropriate standards in each country. Where published in print media, these advertisements will be required to include the approval number for the approved advertisement.

Where the advertiser of a medicine seeks to include a restricted representation (a representation relating to a serious disease, disorder or condition) in an advertisement directed to consumers, approval will need to be sought from the Authority for use of that representation.

Approvals may be granted subject to certain conditions.

Approvals - Medical Devices

It is proposed that an advertisement for a medical device which is intended to be purchased and self-administered by a consumer which includes a claim that requires verification³, will be subject to the same approvals process as for advertisements for medicines in mainstream media.

Medical devices intended to be only used or administered by a healthcare practitioner will be restricted devices which require approval from the Authority before being advertised to consumers and, assuming that approval is granted, pre-approval of the advertisement as per the requirements for advertisements for medicines in mainstream media.

As is proposed for medicines, approval of advertisements in Australia and New Zealand will apply the same criteria through the Advertising Code and similar approval processes, with approvals issued in one country automatically recognised in the other (provided that the publication or broadcast of such advertisements is lawful in both countries). Taste and decency standards that do not relate directly to the use, sale and supply of medical devices will be dealt with separately under the appropriate standards in each country.

Approvals may be granted subject to certain conditions.

Central Approvals Officers

It is proposed that upon written application, the Authority will have the power to delegate the responsibility for approving advertisements to therapeutic products or advertising industry associations, where the Authority is satisfied that they have suitably experienced and qualified staff in their employ to act as Central Approval Officers in Australia or New Zealand. These associations may be granted the power to approve (or to refuse to approve) advertisements for any class of therapeutic products or a specified class of therapeutic products.

The role of these Central Approvals Officers will be to:

- exercise certain delegations for approving advertisements prior to broadcast or publication;

³ Claims that need verification include statements about facts, research results, comparisons, quotes, testimonials, and endorsements or other information about the device not covered under the Therapeutic Products legislation for the essential principles for medical devices.

- conduct regular audits of advertisements directed to consumers in all media;
- provide advice on the requirements for compliance with the Advertising Code;
- co-ordinate the development of training programs for accreditation of delegated authorities and assist in the management of the accreditation scheme;
- report regularly to the Advertising Council and its management subcommittee; and
- participate in appropriate training, accreditation and education programs for the therapeutic products industry sectors, healthcare professionals and the media/advertisers on the advertising of therapeutic products.

An approval for an advertisement will be able to be withdrawn by an approvals officer or the Authority as a result of an upheld complaint or legislative change.

Delegated Authorities

Upon written application, certain delegations may also be granted by the Authority to a person employed in the therapeutic products, advertising or media industries (known as delegated authorities) in Australia or New Zealand to approve or refuse to approve advertisements which are minor revisions of advertisements which have already been approved for publication or broadcast by a Central Approvals Officer. In deciding whether to grant these delegations the Authority is to take into consideration any recommendations made by the Advertising Council.

New Zealand has a system of delegated authorities already in place. Australia will defer introduction of delegated authorities until the overall scheme is effectively in place.

Maintaining or revoking delegations to approve advertisements

The draft Advertising Rule allows that all delegations may be subject to conditions imposed by the Authority.

The Authority may revoke a delegation where:

- the delegate has not exercised this power in accordance with the draft Advertising Rule or is no longer a fit and proper person;
- the delegate has contravened a condition to which the delegation is subject; or
- the Authority is not satisfied that the delegate has kept their skills current; or
- in the case of an industry association being delegated the power, the industry association no longer has in its employ a person or consultant who has the necessary skills, qualifications and experience to exercise this delegation or where the industry association employs such a person/ consultant but that person is not the person exercising the delegation.

In deciding whether to revoke this delegation the Managing Director may take into account any advice received from the Advertising Council. Where a delegation is revoked, the Authority must give the delegate written notice setting out the reasons for the revocation.

In deciding whether the delegate's skills are current, the Managing Director may take into account what activities the delegate has undertaken to maintain a knowledge and understanding of the regulation of the advertising of therapeutic products and relevant

processes and policy over the previous 12-month period, including the delegate's knowledge of the application of the Advertising Code.

Delegation to a Chair of the Central Complaints Panel

The Advertising rule also provides for the Managing Director to delegate to a Chair of the Central Complaints Panel the power to suspend or revoke an approval of approved advertisements.

8. ADVERTISING WHICH DOES NOT REQUIRE APPROVAL PRIOR TO PUBLICATION OR BROADCAST

Advertisements for medicines in media which is not mainstream media (other than the internet) are not proposed to require pre-approval.

The Authority may request in writing that an advertiser supply all advertising material relating to:

- an advertisement for a medicine in non-mainstream media or the internet; or
- an advertisement for a medical device which is not a restricted device and/or which contains a verifiable claim;

for the purpose of ensuring that the advertisement meets an appropriate standard (i.e. the Advertising Code), within such reasonable time as specified in the notice. Where an advertiser fails to comply with the notice within the specified period, the Authority may issue a direction that all advertisements published or broadcast by that advertiser must be pre-approved under specific conditions for a period specified, or until the notice is revoked.

Where the Authority is satisfied that the advertiser has:

- published or broadcast advertisements which have failed on more than one occasion to comply with the Advertising Code; and
- those advertisements were not advertisements for which approval is needed;

the Authority may issue a direction that all advertisements published or broadcast by that advertiser require pre-approval, for a period specified, or until the notice is revoked.

9. SECURING COMPLIANCE

A range of measures will be available to help secure compliance with the requirements of the advertising scheme. Industry bodies will continue to administer and enforce industry codes. Approval officers, the Central Complaints Panels, the Authority and the courts in each country will all have a role in securing compliance with the Advertising Code and other regulatory requirements.

The administrative, civil and criminal offence measures for securing compliance with the regulatory requirements include:

- the complaints process in general;
- withdrawal of approval of an advertisement;
- requiring an advertiser to obtain approval for advertisements that normally do not require approval;

- suspension or cancellation of a product licence;
- enforceable undertakings to take remedial action such as retractions and corrections;
- enforceable directions to take remedial action;
- non-compliance notice fines;
- court action to enforce undertakings and directions;
- court action to impose civil penalties; and
- criminal prosecution.

Complaints

Under the draft Advertising Rule, a person will be able to complain to a Central Complaints Panel in Australia or New Zealand that an advertisement for a therapeutic product breaches the Therapeutic Products Act(s), the Advertising Rule or the Advertising Code. In practice complaints would be submitted to the support unit that services the Panel. It is envisaged that in New Zealand, for example, complaints would continue to be lodged with the Advertising Standards Authority. Complaints about therapeutic product advertisements in Australia would be made to a Central Support Unit.

Central Complaints Panels

Central Complaints Panels are pivotal to the complaints process. It is proposed to establish Panels in Australia and New Zealand under the draft Advertising Rule to receive and determine complaints about therapeutic product advertisements directed to consumers in Australia or New Zealand respectively and complaints about advertisements directed to healthcare practitioners which involve concerns about serious risk to public health and safety. It is proposed that industry self-regulatory complaints panels will continue to handle complaints about advertisements directed to healthcare practitioners that do not involve matters of serious risk to public health and safety.

Membership of the Complaints Panels in Australia and New Zealand will be drawn from a common pool of experts from both countries, including people who have the necessary experience to consider the potential impact of advertisements on public health and safety.

The pool of potential panel members will be appointed by the Ministerial Council on the recommendation of the Authority. In making recommendations on membership of the expert pool, the Authority will give due consideration to the expertise already available in New Zealand through membership of the Advertising Standards Complaints Board. The Ministerial Council will designate one member of the expert pool as the Chair (Principal Member) of the Australian Central Complaints Panel and one member as the Chair of the New Zealand Central Complaints Panel.

The Chairs will be responsible for determining the appropriate composition of a Central Complaint Panel to hear a particular complaint, taking into account the required minimum composition and expertise required as described below.

New Zealand

The draft Advertising Rule provides that the Central Complaints Panel formed in New Zealand is to have as a minimum the Principal Member (being the Chairperson) and three

others being “public” members (i.e. not associated with any of the relevant industries), and four members with expertise in either the advertising and media industries.

Australia

The draft Rule allows that the Central Complaints Panel formed in Australia is to have as a minimum the Principal Member (being the Chairperson) and seven other members, each with expertise in one of the following areas:

- public health with experience in community practice in a healthcare profession;
- consumer issues;
- the regulation of advertising of therapeutic products;
- advertising sector issues;
- complementary medicines industry;
- over-the-counter (OTC) medicines industry; and
- the medical devices industry.

Where the complaint being considered involves a prescription medicine, the Chair of the Panel may nominate a person with expertise in the prescription medicines industry to attend the meeting and participate in the decision making for that particular complaint.

Attendance of Advisers/Observers

The Chairs of the Central Complaints Panels may nominate a person with expertise in a particular field to attend the meetings, if there are no members on the Panel who have this expertise. Additionally, the Chair of a Central Complaints Panel may invite a person to attend the meeting of the Panel as an observer. Any such expert advisers/observers that attend a meeting are not entitled to participate in the decision making.

Outcome of consideration by the Central Complaints Panels

The outcome of the consideration of all complaints is proposed to be made publicly available.

Action that the Central Complaint Panels may take

Where a Central Complaints Panel is satisfied a complaint is justified it would be able to ask the advertiser to provide an undertaking to take appropriate remedial action such as withdrawing the advertisement or publishing a retraction or correction. It is proposed that a Panel Chair would have delegated power to withdraw an approval to publish or broadcast an advertisement.

If an advertiser does not provide an undertaking within the time the Panel stipulates, there would be power to issue either an enforceable direction to take remedial action or a non-compliance notice (or both).

The review arrangements that apply to Complaints Panel decisions are covered below.

An advertiser who does not comply with an undertaking or direction to take remedial action or who chooses not to pay the fine under the non-compliance notice could expose themselves

to court orders or a significant fine following civil penalty proceedings or criminal prosecution.

The Therapeutic Products Bills and the Advertising Rule would provide respectively for the Authority to issue non-compliance notices and directions. It is envisaged that once the Panels gain experience in the new statutory regulated environment these powers would be delegated to Panel Chairs where appropriate.

Action that industry/ professional complaint panels may take

Most of the industry sectors and some professional groups have developed their own code of conduct which commonly includes requirements for the advertising of therapeutic products, based on the requirements included in the Advertising Code. It is proposed that where the Authority is satisfied that the relevant industry / professional code of conduct is consistent with the Advertising Code and sets up other necessary provisions, the Authority may impose as a condition on a product licence compliance with the industry code which is relevant to the type of product (eg in the same way that prescription medicines are currently required to comply with the Medicines Australia Code of Conduct as a condition of registration in Australia).

Where a complaint is being determined by an industry sector complaints panel and compliance with that industry's code of conduct is a condition of the product licence, the industry panel will be able to refer the matter to the Authority for regulatory or court action if the advertiser fails to comply with the determination of the industry panel (whether or not the parties involved are members of that industry sector association).

In New Zealand, a competitor complaint or a complaint involving an advertisement directed to a healthcare practitioner, may be dealt with centrally at the industry sector level under the relevant code of conduct and complaints process, according to the preference of the complainant.

Action that the Authority may take

As indicated elsewhere in this document, the Authority may:

- withdraw the approval of an advertisement;
- issue a direction that all advertisements published or broadcast by that advertiser require pre-approval, for a period specified, or until the notice is revoked;
- suspend or cancel a product licence;
- issue enforceable undertakings to take remedial action such as retractions and corrections;
- issue enforceable directions to take remedial action; and
- issue non-compliance notice which enable the advertiser to finalise the matter by paying a modest fine

Court action

If other action by a Complaints Panel does not secure compliance, the Authority may initiate court action:

- to enforce undertakings and directions;

- to impose civil penalties; and
- to prosecute criminal offences.

Civil penalties and criminal offences

Criminal and civil sanctions are proposed for the therapeutic product Bills in both countries to cover breaches of range of advertising requirements, including compliance with the Advertising Code. The sanctions can be broadly grouped as targeting:

- approvals: not holding a required approval or not complying with an approval condition;
- directions: not complying with a direction;
- proscribed advertisements: including publish or broadcast advertisements:
 - ◆ about unlicensed therapeutic products;
 - ◆ about unapproved indications;
 - ◆ about restricted medical devices or restricted representations for medicines;
 - ◆ that do not include required information on reasonable use with untrue testimonials;
 - ◆ with claims inconsistent with the manufacturers intended purpose, an applicable standard or essential principles;
 - ◆ with claims of government, government authority or hospital endorsement referring to the Acts, Rules Orders;
 - ◆ false, misleading deceptive advertisements;
 - ◆ failing to provide information; and
 - ◆ prescription and certain pharmacist-only medicines (Australia only).

A non-compliance notice (which brings a minor fine) may be issued for minor breaches of most criminal and civil penalty provisions, for example where an advertisement which requires approval to be published or broadcast:

- is not approved;
- differs from the advertisement which was approved (other than the price/location or times at which the products are offered for sale or information identifying the person offering the products for sale);
- does not include its approval number or is published with a false number or with an approval number that has expired; or
- is in contravention of a condition of its approval.

A person who receives a non-compliance notice may pay the fine set out in the notice, or let the matter go to court.

It is to be a defence to a prosecution of a publisher, advertising agency or media buying agency where it can be demonstrated (on balance) that the person has no control over the advertising material they publish or broadcast.

10. REVIEW OF DECISIONS

Advertising decisions of the Authority and the Central Complaints Panels will be subject to both merits and judicial review. The Therapeutic Product Bills of both countries and the Rules that set out the arrangements for the review of general regulatory decisions will apply to the review of advertising decisions.

The draft Advertising Rule provides for internal review of decisions.

External review is to be provided by a Review Tribunal in each country. The Administrative Appeals Tribunal will be the Review Tribunal in Australia. A New Zealand tribunal will be convened for New Zealand reviews.

Approvals

Applicant and the advertising approval holder will be able to seek a review from the Authority, where they are dissatisfied with a decision to not approve an advertisement or to withdraw an approval.

Where a decision is upheld by the Authority, the applicant may seek an external review by the Review Tribunal.

Judicial review will be available in Australia or New Zealand.

Complaints

Where a party to a complaint in New Zealand is dissatisfied with the determination of the Central Complaints Panel in New Zealand, there will be scope for voluntary review under the complaints arrangements for New Zealand. It is envisaged that the Advertising Standards Complaints Appeal Board (ASCAB) would conduct this review.

A party to a complaint in Australia or New Zealand may seek a review by the Authority, where they are dissatisfied with a determination by the Central Complaints Panel about a complaint or action resulting from a complaint.

Any person who is affected by a direction (e.g. to publish corrective advertising) may seek a review from the Authority.

External review would then be available from the Review Tribunal.

Where the advertiser or any party to a complaint believes that an error of law has been made, judicial review would then be available in Australia or New Zealand.

11. FEES AND CHARGES

Article 15 of the Treaty provides that fees and charges may be collected by the Authority in connection with the performance of its functions and that these fees and charges will be prescribed in Rules.

The fees and charges under the Australia New Zealand therapeutic products regulatory scheme are subject to a separate consultation.

12. TRANSITION

The overarching principles to apply to the transitional arrangements are outlined in Article 21 of the Treaty.

Transition – Advertising Code

The Advertising Code cannot be formally made as an Order by the Managing Director until the Therapeutic Products Bills are passed in both Australia and New Zealand, the Ministerial Council is established and the Ministerial Council appoints a Managing Director. Once the Managing Director makes the Advertising Code an Order, transition arrangements in each country will be important to help ensure implementation of the new advertising regulatory scheme is orderly and predictable for all stakeholder groups involved.

New Zealand

In New Zealand the self-regulatory Advertising Standards Authority Inc (ASA) is currently responsible for developing and maintaining the New Zealand Therapeutic Products Advertising Code (NZ TPAC). While Medsafe is consulted on any proposed changes to this Code, this Code is not linked to the *Medicines Act 1981*. However the requirements of this Code are broadly consistent with the requirements of the *Medicines Act 1981*.

On 1 February 2005 a new *Therapeutic Products Advertising Code* based on the provisions of the proposed *Australia New Zealand Therapeutic Products Advertising Code* came into force in New Zealand and it remains in operation now.

The New Zealand TPAC (as amended from time to time as necessary) and the advertising provisions of the *Medicines Act 1981* and Medicines Regulations 1984 will continue to apply in New Zealand to advertisements that are lawful as at the commencement date of the joint regulatory scheme until a specified date.

Under the New Zealand self-regulatory process, advertisements for therapeutic products are pre-vetted by the Therapeutic Advertising Pre-vetting Scheme (TAPS), and approvals are issued for a two year period unless changes to the advertisement are made or the New Zealand TPAC is altered. There will be advertisements in circulation at the time of implementation of the new scheme which will have complied with and been approved under the current New Zealand scheme. They may or may not comply with the new arrangements, and they will not have been granted an approval through the new scheme where it is required.

Australia

The *Australian Therapeutic Goods Advertising Code* (TGAC) and the co-regulatory arrangements that support it will remain in place until the new advertising regulatory scheme is in operation. As in New Zealand, advertisements will be in circulation in Australia (including both those which currently require approval in Australia and those which do not) at the time of the introduction of the new advertising scheme which comply with the *Australian Therapeutic Goods Act 1989*, Therapeutic Goods Regulations 1990 and the TGAC as in force at the time. However, it is possible that not all of these advertisements will comply with the new arrangements, and none of them will have been granted an approval through the new advertising scheme.

Advertisements for which an approval is required under the current and new schemes

Australia

In Australia, advertisements placed in specified media and directed to consumers must be approved ('specified media' have been re-defined as 'mainstream' media in the new advertising scheme). Consistent with other provisions for transition of product licences, it is intended that advertisements which were being legally published or broadcast in specified media prior to the commencement of the joint scheme in Australia will be able to continue to do so in Australia until the date of the approval issued under Reg 5G of the Therapeutic Goods Regulations 1990 expires (approvals are generally issued for 2 years) or if the approval is withdrawn. Once the approval date has expired (as provided for under Regulation 5J(3) of the Therapeutic Goods Regulations) it is anticipated that the advertiser must apply for approval under the provisions of the new Advertising Rule.

If the advertiser has an approval under the therapeutic goods legislation in Australia and wishes to publish or broadcast the advertisement in New Zealand once the new scheme commences and before the expiry date of the approval issued in Australia, it is proposed that the advertiser may either:

- certify that the advertisement complies with the new Advertising Code, Act and Rules, in which case a new notice of approval would be issued to be recognised as being valid in both countries until the end of the 2 year period from the date on which the approval number was originally issued; or
- apply for a single approval under the provisions of the Rules to be able to advertise in both countries.

Consideration will be given to making a Rule along these lines.

New Zealand

As part of the transitional arrangements in New Zealand, it is proposed that all advertisements for therapeutic products that have been authorised under the current New Zealand legislation will be lawful to publish after the commencement of the joint scheme until the earliest of the following dates:

- the date on which the authorised advertisement must cease to be published under any applicable Rules;
- the date on which a Scheme approval is granted for the therapeutic product that is the subject of the authorised advertisement; or
- the date on which the transitional approval for the therapeutic product that is the subject of the authorised advertisement ceases to have effect.

Consideration will also be given to making a Rule which declares when the new joint advertising scheme comes into operation.

It is also proposed that if an advertiser has an approval under the TAPS in New Zealand and wishes to publish or broadcast the advertisement (that will require approval in the new scheme) in Australia after the commencement of the new scheme and before the expiry date of the approval, the advertiser may either:

- certify that the advertisement complies with the new Advertising Code, Act and Rules, in which case a new notice of approval would be issued to be recognised as being valid in both countries until the expiry date of the original approval; or
- apply for a single approval under the provisions of the Rules to be able to advertise in both countries.

As highlighted above, consideration will be given to making a Rule along these lines.

Advertisements for which an approval is currently not legally required

Medicines

In either country there may be in circulation advertisements that were not legally required to be approved in the existing scheme (in Australia) or have not been published or broadcast within the spirit of the pre-vetting requirements within the self-regulatory scheme (in New Zealand) and which are not proposed to require approval under the new scheme. These advertisements may or may not comply with the new advertising legislation. Those that do comply with the new provisions will be able to remain in circulation provided they comply with the Advertising Code once it commences.

For advertisements which are not compliant with the new Advertising Code and other advertising provisions, it is proposed that product licence holders/advertisers who wish to continue to use the advertisement will be required to notify the Authority within a 6 month period of the date of effect of the Advertising Code of any advertisements which do not comply with the new Act, Rules or Advertising Code. These advertisers will be given written notice by the Authority that the advertisements will be able to remain in the marketplace without any action being taken for a period specified in that notice, provided that the notification is correct.

For that period, it is proposed that the Authority will not take action against a product licence holder /advertiser of such an advertisement in either country for non-compliance with the new Act, Rules or Advertising Code provided that it complies with the (previous) Australian Therapeutic Goods Advertising Code in Australia or the New Zealand Therapeutic Products Advertising Code in New Zealand.

Medical Devices

Currently there is not an approvals process in place for advertisements for medical devices in Australia, while some advertisements in New Zealand are being pre-vetted on a case-by-case basis. In the new scheme, some advertisements for medical devices will require approval, as explained earlier in this document. Those which will not require approval in the new scheme and which comply with the new legislation will be able to continue in circulation a provided they comply with the Advertising Code once it commences.

Advertisements for medical devices which will require approval (as defined in the draft Advertising Rule) are proposed to be granted a temporary exemption from requiring approval for a 6-month period following implementation of the new legislation to allow sufficient time for applications for approval to the standard of the new Advertising Code to be processed. Should an advertisement requiring approval continue to be published or broadcast after this

6-month period and not have prior approval, regulatory action may be taken or sanctions imposed on the advertiser for a breach of the Advertising Code.

Complaints

In dealing with complaints about “existing” advertisements, it is proposed that the Central Complaints Panels in Australia and New Zealand would have the discretion to take into consideration the code which was in force at the time when the advertisement was approved or (in the case of advertisements which do not need approval) when they were published or broadcast and any notification made to the Authority.

Restricted representations for medicines and restricted medical devices

The transitional arrangements for restricted representations for medicines and restricted medical devices are to be considered by the Implementation Steering Group. One option would be to provide that where an approval to refer to a restricted representation for an advertisement for a medicine directed to consumers was granted under the Therapeutic Goods Regulations - then this should also taken to be an approval under the new scheme for a period of 2 years from the date of the commencement of the new scheme. If the advertiser then wished the approval to continue after the 2 year period, approval would need to be sought under the new scheme.

As there are no current requirements for restricted medical devices, it would be reasonable for a certain period of time to elapse after the commencement date of the new legislation before the prohibition on the advertising of restricted medical devices is brought into force. During this period, it is expected that advertisers would apply, where necessary in accordance with the new legislation, for approval from the Authority to advertise a restricted medical device to consumers.

Establishment of the Implementation Steering Group

As mentioned previously, a Steering Group has been established to guide the implementation of the operational aspects of this proposed new regulatory model for advertising of therapeutic products in Australia and New Zealand. The Steering Group held its first meeting in September 2006, and another in November 2006, and is anticipated to hold up to two more meetings to assist in putting the new scheme into place.

Outcomes from this process will be published over the ensuing months on the project website at <http://www.anztpa.org/advert>.