

TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS

**Description of the
Joint Regulatory Scheme
for the
Advertising of Therapeutic Products**

DECEMBER 2005

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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 by a single, bi-national agency (the Agency), which 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 Agency will be overseen by a two-member Ministerial Council, comprising the New Zealand Minister of Health and the Australian Health Minister. This initiative will harmonise the regulation of therapeutic products in Australia and New Zealand, including the controls on the advertising of therapeutic products.

This document describes the regulatory provisions for the new advertising model, most of which will be set out in Ministerial Council Rules. Importantly, the model provides a joint approach to regulation that draws on and strengthens the existing co-regulatory model in Australia, and preserves the existing functions of the advertising and media sectors (particularly as key players in the current self-regulatory arrangements in New Zealand), while enhancing these roles through providing for these functions to be given legal underpinning.

2. DEVELOPMENT OF A NEW REGULATORY MODEL

The development of a joint regulatory scheme for the advertising of therapeutic products in Australia and New Zealand commenced in 2002 with a review of advertising therapeutic products in Australia and New Zealand (the Review) undertaken by Mr Mike Codd (the Toogoolawa Report) with a final report being publicly released in March 2003. Shortly thereafter, the Australian and New Zealand Health Ministers agreed to the establishment of an Interim Advertising Council (IAC) to further develop the Review's recommendations prior to consideration by the Australian and New Zealand governments of a proposal for a trans-Tasman therapeutic products advertising regulatory scheme.

The Interim Advertising Council was established in May 2003 by the TGA and Medsafe with members representing key stakeholders, including consumers, healthcare practitioners, the regulators and the therapeutic products, media and advertising industries (ie those who advertise, those to whom advertising is directed and the regulators). The Council met 9 times between May 2003 and October 2004 and delivered a report on its recommendations for a proposed trans-Tasman regulatory model to the TGA and Medsafe at the completion of this process, following extensive stakeholder consultation in Australia and New Zealand. In considering a new regulatory model which will be given legal effect in both countries, the Therapeutic Products Interim Ministerial Council (comprising the Australian and New Zealand Health Ministers) to a large extent accepted the key elements of the regulatory model recommended in the IAC report.

Recognising that the details of a number of operational and administrative matters need to be developed, an Implementation Steering Group is to be established to progress these

operational matters, to oversight the development of the new processes required to implement and support the approved model, and to provide advice on any other matters which required resolution before the commencement of the new scheme.

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 model for advertising is risk-based.

The proposed model for the advertising of therapeutic products 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 an 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 joint 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, OTC medicines, complementary medicines and medical devices).

4. ADVERTISING KEY PRINCIPLES AND ADVERTISING REQUIREMENTS

Key Principles

The following Advertising Key Principles embody the spirit of the controls on the advertising of therapeutic products for inclusion in the Australian and New Zealand therapeutic products implementing legislation.

PRINCIPLE 1- Advertisements must comply with the Therapeutic Products Act(s) and Rules and the Therapeutic Products Advertising Code.

PRINCIPLE 2 - Advertisements must be truthful, balanced and not misleading. Claims must be valid and have been substantiated.

PRINCIPLE 3- Advertisements must observe a high standard of social responsibility.

The Ministerial Council has the power to determine Rules which regulate the advertising of therapeutic products. These *Advertising Requirements*, which expand and give further guidance on the Key Advertising Principles, will be included in the Rules to give equal legislative force in Australia and New Zealand.

Advertising Requirements

- *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 Trans Tasman Therapeutic Products Agency; and
- (b) for exempt therapeutic products – must be compliant with the Code.

Requirement 4

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

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

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 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 Agency.

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 Agency.

- *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 Agency 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.

5. EXPERT ADVISORY COMMITTEE

Article (4e) of the Treaty provides for the Ministerial Council to establish expert advisory committees which will advise the Agency. The Ministerial Council will also appoint and remove committee members.

Advertising Council

An Advertising Council will be established in the Rules at commencement of the operation of the joint scheme, as an expert advisory committee, to provide advice to the Agency in relation to matters concerning the advertising of therapeutic products.

The Advertising Council will:

- monitor and make recommendations on the effectiveness of the overall regulatory model;
- recommend changes to the Therapeutic Products 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
- advise on general policy matters relating to advertising.

In keeping with the general principles that will apply to all expert advisory committees under the joint scheme:

- committee members will be selected from relevant experts in Australia and New Zealand and the overall balance of each committee will reflect contemporary practice in both countries;
- membership of each committee will be determined on the basis of requisite expertise, members will not be appointed to represent particular jurisdictions or interests, unless justified by a committee's terms of reference; and
- the role of each committee will be advisory - regulatory decisions will be the responsibility of the Managing Director of the Agency or his/her delegate.

As with all expert committees established under the joint scheme, members of the Advertising Council will be appointed by the Ministerial Council.

The Committee is to have an independent chair recommended by the Agency and appointed by the Ministerial Council. The remaining members of the Committee are to be appointed by the Ministerial Council, on the advice of the Agency 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:
 - The Complementary Healthcare Council of Australia;
 - Complementary medicines sector in New Zealand;
 - The Australian Self-Medication Industry;
 - The NZSMI;
 - The MIAA and MIANZ (as a joint nomination);
 - Medicines Australia;
 - Researched Medicines New Zealand;
- 6 experts in the media and advertising industries, comprising 1 person nominated by each of the following bodies:
 - The Advertising Standards Authority of New Zealand;
 - The Association of New Zealand Advertisers;
 - The Advertising Federation of Australia and Association of Australian National Advertisers (as a joint nomination);
 - Commercial Television Australia;
 - Commercial Radio Australia;

- The Australian Publishers Bureau;
- 2 consumer members comprising 1 person nominated by each of the following bodies:
 - The Australian Consumers Association and the Consumers' Health Forum (as a joint nomination);
 - NZ Consumer's Insitute;
- 4 expert healthcare practitioners comprising 1 person nominated by each of the following:
 - The 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 Australia and the Pharmacy Guild New Zealand (as a joint nomination);
 - The Australasian Traditional Medicines Society, Australian Natural Therapist Association, the Australian Federation of Natural and Traditional Therapists Ltd and the National Herbalist Association of Australia (as a joint nomination);
 - The New Zealand Charter of Healthcare practitioners and the New Zealand Association of Medical Herbalists (as a joint nomination); and
- an expert in the regulation of advertising nominated by the Agency.

Observers

The Chair of the Council may invite the following bodies to nominate a representative to attend the meetings of the Council as observers:

- the Australian Consumer and Competition Commission; and
- the New Zealand Commerce Commission.

A person nominated as an observer will be entitled until the nomination is revoked to be given the agenda and the minutes of Council meetings, suggest agenda items, attend the meeting and participate in the consideration of any matter affecting the interests of the body nominating the observer.

The Chair of the Complaint Panel in Australia and the Chair of the Complaint Panel in New Zealand may also attend meetings of the Council as observers and advisers but will not have the right to participate in the consideration of any matters before the Council.

Committee may seek advice and assistance

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 consideration of any matters before the Council.

Alternate Members

A body mentioned in relation to the nomination of members may nominate an additional person who is not a member of the Council to be available as the alternate member to the Council by that body. These alternate members must be approved by the Ministerial Council, on the advice of the Agency. If a member is absent from a Council meeting, the member's alternate will be entitled to attend the meeting.

Management sub-committee

There is to be a statutory 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 will be to:

- (a) receive and review 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) oversee the performance of contracts relevant to the provision of services for the regulation of the advertising of therapeutic products;
- (c) oversee education, accreditation and training, as well as evaluation and monitoring, programs;
- (d) monitor implementation of regulatory policy on advertising which has been approved by the Therapeutic Products Ministerial Council;
- (e) review policy governing the advertising regulatory scheme and in consultation and liaison with other stakeholders, making recommendations for any changes to the Advertising Council;
- (f) provide comments to the Council on the allocation of resources to the regulation of the advertising of therapeutic products and assist in the preparation of the annual budget bid to the Agency; and
- (g) prepare the draft annual report to the Ministerial Council on the effectiveness of the regulation of the advertising of therapeutic products for that financial year for finalising through the Advertising Council.

The Advertising Management Subcommittee is 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 Agency;
- At least one member nominated by the consumer groups in Australia and/or New Zealand;
- A member nominated by either the Complementary Healthcare Council of Australia or Natural Products New Zealand;
- A member nominated by either the Australian Self Medication Industry or the New Zealand Self Medication Industry;
- The member nominated by the Medical Industry Association of Australia and the Medical Industry Association of New Zealand (as a joint nomination);
- A member nominated by either Medicines Australia or Researched Medicines New Zealand; and
- A member nominated by either the Advertising Standards Authority (NZ), the Advertisers New Zealand Association (NZ), the Advertising Federation of Australian and Association of Australian National Advertisers (as a joint nomination), Commercial Television Australia, Commercial Radio Australia, or the Australian Publishers Bureau.

Up to four other members may be appointed to the Advertising Management Subcommittee by the Advertising Council. The general provisions for committee procedures are to apply to the Advertising Management Subcommittee.

Other subcommittees

Consistent with the general provisions for expert committees, the Advertising Council may, with the approval of the Agency, also establish other subcommittees consisting of members of the Council, as well as other relevant persons. It is anticipated that subcommittees may be established to inquire into and report either directly to the Agency or through the Council on advertising regulatory matters such as the provision of advice on requests from advertisers to refer to restricted representations for medicines or restricted medical devices in advertisements directed to consumers.

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

The Australia New Zealand Therapeutic Products Advertising Code (the 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 Code must be observed.

The Code will be applicable in both countries and across all industry sectors and media¹. The Code will have equal legal standing in both countries as a Technical Order of the Agency of the Agency.

The Code has been developed to reflect the current policy environment in each country in relation to direct-to-consumer advertising (DTCA) of prescription medicines, where DTCA of prescription medicines is permitted in New Zealand and prohibited in Australia.

Compliance with the Code will be a statutory condition of a product licence.

- **Coverage of the Code**

Definition of an advertisement

Under the joint regulatory scheme, an advertisement will be defined as *any communication which promotes or discourages the use, sale or supply of products (whether or not in conjunction with the supply of services, and whether or not the communication identifies particular products or services)*.

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 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.

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.

For the purposes of the Code, a label is not 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 Agency as part of the pre- and post market on product licences, which will consider 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 regulatory status of some small groups of products currently regulated in Australia as therapeutic products (such as antiperspirants, anti-dandruff shampoos and moisturisers containing a sunscreen) has not yet been finalised in the context of the new trans-Tasman arrangements. If it should be decided that these types of products are to be regulated by the Agency as therapeutic products, the Code will need to be reviewed to ensure that all of the requirements of the Code are appropriate for these products.

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

Some products (such as tampons and commercial/household disinfectants) are to be regulated by the Agency for Australia-only, as they are not considered to be therapeutic products for the purposes of the joint scheme. The advertising of these products (known as related goods) is described in a separate description for advertising controls in Australia and will be given legal effect through the Australian Regulations.

7. ADVERTISING WHICH REQUIRES APPROVAL PRIOR TO PUBLICATION OR BROADCAST

Approvals - exemptions

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

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

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

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

An application for approval of an advertisement will have to be made in writing, in a form approved by the Agency, and signed by or on behalf of the applicant.

Advertisements directed exclusively to healthcare practitioners in Australia will not 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

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;
- broadcast media;
- cinematograph films;
- displays in shopping malls in or on public transport;
- billboards; and
- the internet.

Approval of advertisements in Australia and New Zealand will apply the same criteria through the 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 that approval number.

Approvals may be granted subject to certain conditions.

Approvals - Medical Devices

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 Agency 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.

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.

Approval of advertisements in Australia and New Zealand will apply the same criteria through the 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.

Central Approvals Officers

The Agency will have the power to delegate the responsibility for approving advertisements to industry associations, where the Agency 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 all classes of therapeutic products or a designated 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;
- 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 Agency as a result of an upheld complaint or legislative change.

Delegated Authorities

Upon written application, certain delegations may also be granted by the Agency to a person employed in the therapeutic products, advertising or media industries (known as delegated authorities) 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 Agency is to take into consideration any recommendations made by the Advertising Council.

Maintaining or revoking delegations to approve advertisements

All delegations may be subject to conditions imposed by the Agency.

The Agency may revoke a delegation where:

- the delegate has not exercised this power in accordance with the legislation or is no longer a fit or proper person;
- the delegate has contravened a condition to which the delegation is subject; or
- the Agency 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 MD may take into account any advice received from the Advertising Council. Where a delegation is revoked, the Agency must give the delegate written notice setting out the grounds for the revocation.

In deciding whether the delegate's skills are current, the MD 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.

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) will not require pre-approval.

The Agency 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 (ie 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 Agency 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 Agency 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 Agency 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. COMPLAINTS

The Complaint Panels

Central complaints bodies (the Complaint Panels) will be established in Australia and New Zealand as statutory committees to receive and determine complaints about 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. 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.

Expert members will be appointed by the Ministerial Council on the recommendation of the Agency. In making recommendations on membership of the expert pool, the Agency must 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 of the Australian Complaint Panel and one member as the Chair of the New Zealand Complaint 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 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 complaints panel formed in Australia is to have as a minimum the Principal Member (being the Chairperson) and seven others members, each with expertise in one of the following areas:

- public health and experience in community practice in a healthcare profession;
- consumer issues;
- the regulation of advertising of therapeutic products;
- advertising sector issues;
- complementary medicines industry;
- OTC medicines industry; and
- the medical device industry.

In Australia, the Chair of the Complaints Panels may nominate a person with expertise in law or other expertise to attend the meetings, if there are no members on the Complaints Panels which have this expertise. Expert advisers are not to participate in the decision making.

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;
- a price list issued by a pharmacist which includes prescription products, the Chair may nominate a person with expertise in the practice of pharmacy to attend the meeting and participate in the decision making for that particular complaint.

Action that the Complaint Panels may take

The Complaints Panels will have powers to issue “enforceable directions” to advertisers who are found to be responsible for publishing advertisements which are in breach of the Code and/or to arrange for infringement notices (involving minor fines) to be issued to advertisers in certain situations. The Complaints panels may refer ongoing, flagrant or serious breaches of the Code to the Agency for further regulatory or court action.

The outcome of the consideration of all complaints will be made publicly available.

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 include requirements for the advertising of therapeutic products, based on the requirements included in the Advertising Code. Where the Agency is satisfied that the relevant industry / professional code of conduct is consistent with the Advertising Code, the Agency 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 Agency 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.

10. ADVERTISING OFFENCES

It will be an offence for therapeutic products to be advertised for indications or purposes of use other than those accepted in relation to the product licence (where a product licence is required to be held).

The Agency may cancel a product licence where the Agency or the Chair of the Complaints Panel gives a direction to, or makes a requirement of, a person in relation to an advertisement of that product which does not comply with the Code, Rules or Act and the person does not comply with that direction or requirement.

It will be an offence to publish or broadcast as advertisement about therapeutic products that:

- is in contravention to a notice given by the Agency to the person responsible for publishing the advertisement to prevent either a representation being made about a medicine or a reference being made to a restricted device;
- refers to therapeutic products which are exempt from the need to hold a product licence and cannot be advertised as a condition of that exemption (ie those exempted under certain conditions, imported under personal access scheme or the special access scheme – in which case strict liability applies);
- does not comply with the Advertising Requirements or the Code;

- refers to therapeutic products which do not have a product licence, unless the products are exempt from the need for a product licence; or
- contains a reference to the Act/s or the Rules, other than a statement of the product license number of the products.

An infringement notice (which may include a minor fine) may be issued 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.

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.

11. REVIEW OF DECISIONS

Decisions of the Agency will be subject to both merits and judicial review. The Treaty sets out a framework for merits and judicial review of Agency decisions in Articles 13 and 14 respectively. The Managing Director will make all regulatory decisions on behalf of the Agency. In practice delegates of the Managing Director will make most regulatory decisions.

Approvals

Product licence holders and other advertisers will be able to seek a review from the Agency's Agency, where they are dissatisfied with a decision to not approve an advertisement or to withdraw an approval.

Where a decision is upheld by the Agency, the applicant may make an external appeal to a merits review tribunal, which would be drawn from a common pool of experts in Australia and New Zealand appointed by the Therapeutic Products Ministerial Council.

Complaints

Where a party to a complaint in New Zealand is dissatisfied with the determination of the Central Complaints Panel in New Zealand, an appeal will be referred initially to the Advertising Standards Complaints Appeal Board (ASCAB)⁴.

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

An external appeal may then be made to a merits review tribunal.

⁴ In order for the determination made by the ASCAB to also apply in Australia, it may be necessary for the ASCAB to refer the matter back to the Central Complaints Panel in new Zealand for reconsideration of the initial determination.

Where the advertiser (in the case of an approval matter) or any party to a complaint believes that an error of law has been made, the matter can also be taken to the Federal Court of Australia or the courts of an Australian State or Territory.

12. FEES AND CHARGES

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

In line with the cost recovery arrangements for the Agency, regulatory activities associated with the advertising of therapeutic products (such as advertising approvals and applications for delegated authority status) will be undertaken on a cost recovery basis. The details of the model to be used for the collection of fees and charges is being developed as part of the overall cost recovery arrangements for the Agency. Stakeholder consultation on the proposed fees and charges associated with the regulation of advertising is to be undertaken as part of this broader exercise.

13. TRANSITION FOR APPROVALS (AUSTRALIA ONLY)

A number of advertisements (including both those which require approval and those which do not) will be in existence in Australia at the time of the introduction of the new scheme which comply with the Australian Therapeutic Goods Act and Regulations as in force prior to the commencement of the new scheme.

Advertisements for which an approval is currently required

It is intended that (consistent with other provisions for transition of product licences) advertisements which were being legally published or broadcast 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 TG Regulations expires. Once the approval date has expired (as provided for under Reg 5J(3) of the TG Regulations) the advertiser must apply for approval under the provisions of the Rules.

If the advertiser has an approval under the therapeutic goods legislation in Australia and wishes to publish or broadcast the advertisement in New Zealand 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 is to be issued which will 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.

Similarly, if the advertiser has an approval under the (self-regulatory) Therapeutic Goods Advertising Pre-Vetting Scheme (TAPS) in New Zealand and wishes to publish or broadcast the advertisement in Australia 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 is to be issued which will 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.

Advertisements for which an approval is currently not required

Medicines

Sponsors/advertisers will be required to notify the Agency within a 6 month period of the date of effect of the trans-Tasman Advertising Code of any advertisements which do not comply with the new Act, Rules or Advertising Code. These sponsors/advertisers will be given written notice by the Agency 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, the Agency will not prosecute any sponsor/advertiser of such an advertisement in Australia for non-compliance with the new Act, Rules or Advertising Code provided that it complies with the Therapeutic Goods Advertising Code (as defined in the Therapeutic Goods Regulations).

Medical Devices

Advertisements for medical devices which are advertisements which require approval (as defined in the Rules) are 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. If an advertisement continues to be published or broadcast after this 6-month period and does not have prior approval, the Agency may either take regulatory action or impose sanctions on the advertiser for a breach of the Advertising Code.

Complaints

In dealing with complaints about “existing” advertisements, the complaints bodies in Australia and New Zealand are to 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 Agency.

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 is also taken to be an approval under the new legislation for a period of 2 years from the date of the commencement of the new legislation. If the advertiser then wished the approval to continue after the 2 year period, approval would need to be sought under the new legislation.

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 Agency to advertise a restricted medical device to consumers.