

**Therapeutic Goods Advertising
Code Council**

Annual Report 2004

Introduction

The Therapeutic Goods Advertising Code Council (TGACC) is established by Regulation 42A to the *Therapeutic Goods Act 1989* and its functions include the following –

- to consider the requirements for the advertising of therapeutic goods and changes to the Therapeutic Goods Advertising Code, to accept submissions for this purpose and to advise the Minister accordingly;
- to make recommendations to the Minister for achieving greater uniformity in approval processes and standards for advertising therapeutic goods in mainstream print and broadcast media; and
- to make recommendations to the Minister about requests for review of an ‘advertising approval’ decision made by the Secretary (or delegate) to the Department of Health and Ageing.

The TGACC membership is outlined at [Appendix 1](#).

Significant issues considered by the Council in 2004

Sampling, giveaways and competitions

A long-standing recommendation from the TGACC, for amendment to the TGAC for removal of clause 4.6, reliance on strengthened clauses 4.1.2(f) and 4.1.2(c) and the introduction of the additional appendix to the Code containing factors that would be taken into account when considering issues around advertisements for samples, giveaways and competitions, was referred by the TGA to the National Coordinating Committee on Therapeutic Goods (NCCTG) for its views.

Some TGACC members expressed concern that the view taken by NCCTG was to accept the offsetting, strengthening recommendations but not the deletion of clause 4.6. No rationale for treating the package in this way was offered in the NCCTG minutes.

While the view of NCCTG was noted, some TGACC members expressed the view that, as per its co-regulatory responsibility for the advertising of therapeutic goods as described in regulation 42B, its recommendations should be put forward directly to the Minister. The importance of considering the package as a whole and not as separate components was stressed, as was the importance of this package being judged in an advertising context, rather than in the context of the distribution responsibilities of the States and Territories. It also was noted that the recommendation would not have any impact on the role that the States and Territories legislation provides with respect to the distribution of samples.

Some Members suggested that as TGA representatives on the Code Council were party to the recommendation through their participation in the Working Group process, and in the Code Council meetings where decisions were taken, it would be appropriate for the Council to be advised of the reasons for the TGA Executive taking a different view on this matter – assuming it has done so. Correspondence between the Council and the National Manager of the TGA did not resolve the issue and TGACC indicated its wish for the matter to be put directly to the Minister.

It was suggested that the most effective way to conclude the matter is via the Interim Advertising Council (IAC) processes and the proposed version of the new Trans Tasman Advertising Code. A summary of the IAC's work program is at [Appendix 2](#).

Members noted that the IAC is of the same view as this Council in relation to this issue, and that the proposed draft Therapeutic Products Advertising Code (TPAC) reflects this view.

It was agreed that, in the eventuality that clause 4.6 is to be retained, the wording of the clause should be reconsidered in the light of concerns raised by members that an 'offer of a sample' is not confined to the provision of therapeutic goods.

As at 31 December 2004, the matter remains subject to consideration by the Parliamentary Secretary to the Minister for Health and Ageing.

Restricted representations

Several issues arose during the course of the year relating to restricted representations.

Clarification was given by the TGA that based on its indications, a listed product would be ineligible for approval to use a restricted representation. However, there could be circumstances whereby a listed product could be approved for the use of a restricted representation by the Secretary without changing the status of the product from listed to registered, such as suitability, compatibility or "medicine interaction" statements. It was also pointed out that the mere mention of a disease listed in Part 1 of Appendix 6 would not necessarily, on its own, constitute a prohibited representation, unless it was a representation in relation to the treatment, cure or prevention of those diseases.

There was in-principle support for the removal of Table 1 Part 2, Appendix 6 of the Code, which is a list of diseases, conditions, ailments and defects for which the advertising of serious forms is restricted, with support for the following proposed definition of 'restricted representation'.

"representations relating to those diseases, conditions, ailments and defects (or symptoms of the aforementioned) which are generally accepted by the body of medical opinion as being not suitable for self diagnosis, treatment or management by consumers".

Health claims in food advertising

Over several years, TGACC members have become increasingly concerned at the number advertisements for food products making health / therapeutic claims, in breach of current food legislation, particularly with respect to the level of therapeutic claims made.

The proposed trans Tasman harmonisation of regulatory controls for the advertising of therapeutic products has provided the opportunity for in-depth discussion of the making of therapeutic, health and related claims in food advertising, the interface between food and therapeutic products and how best a level playing field can be achieved.

A persistent call was made on both sides of the Tasman, during the consultation undertaken as part of the Toogoolawa Report on a proposed trans Tasman system of advertising regulatory controls for therapeutic products during 2002, for consistency and equity in the regulation and enforcement of therapeutic claims made for foods, cosmetics and therapeutic products. The Toogoolawa Report concluded that the way to ensure equity and consistency of the regulation of claims for foods and therapeutic products would be to remove the prohibition on the making of therapeutic claims on food products, while providing that any therapeutic claim made in respect of food product be governed by the Therapeutic Products Advertising Code and subject to the same pre-approval and complaints handling processes in the trans Tasman agency arrangements.

It is currently not lawful for therapeutic claims to be made in the advertising of foods in either Australia or New Zealand. However, there is an on-going problem because the advertising of some such products include illegally made therapeutic claims and there is minimal, if any, enforcement action taken against them.

The Toogoolawa Report suggested that a consistent approach could be achieved if the food and cosmetic regulators were to adopt the Code, or at least the complaints resolution powers, into their legislation.

The Interim Advertising Council was particularly concerned about the Australian and New Zealand Food Regulation Ministerial Council decision to allow nutrition and health related claims on food. It has been noted that the policy guideline endorsed by the Australia New Zealand Food Regulations Ministerial Council in December 2003 has provided a framework for developing standards and regulatory enforcement and that Food Standards Australia New Zealand (FSANZ) has developed requirements for biomarker claims on foods, including a new Standard for nutrition, health and related claims. This policy could have serious implications for a level playing field for complaints handling, enforcement and sanctions between products regulated as foods, and those regulated as medicines.

It has been decided by Ministers that all "serious" food health claims (including biomarker maintenance claims) will require prior regulatory approval. However, unless these claims are permitted only in the context of a level playing field for complaints handling, enforcement and sanctions between products regulated as foods and those regulated as medicines, the medicines industry clearly will be put at a disadvantage when promoting certain medicinal products with similar therapeutic claims.

The IAC has strongly advocated the need for the pre-approval for any food health claims which could be considered to be therapeutic claims and for appropriate processes to be set in place to monitor, enforce and apply penalties and sanctions, with a view to ensuring a level playing field between foods and medicines.

The Therapeutic Goods Advertising Code Council noted that therapeutic claims in food advertisements always have been prohibited under the Food Standards Code.

At the TGACC meetings held in June and August 2004, concerns were expressed as to:

- the necessity for consistency of definitions and nomenclature between therapeutic goods and foods arenas, for example 'serious disease', 'health claims', 'therapeutic claims';
- the suggestion that the regulatory distinction between therapeutic products and foods might need to be clarified;
- the omission of obesity from the National Health Priorities Areas list;
- the fact that there is no international standard and, therefore, there must be compliance with Australian requirements;
- level playing field issues between foods and therapeutic products, such as the standards of manufacture, licensing and annual costs, in the context of competing interests and similar claims;
- the handling of advertisements for foods in which therapeutic claims are made. Concern was expressed as to the effectiveness of multiple jurisdictions dealing with day to day advertising breaches. It was suggested that a simple amendment to the Therapeutic Goods Act to remove the current exemption for food could be the most effective approach to achieve a level playing field. It was considered unlikely that this approach would be taken;
- to avoid the possibility of confusion, such as FSANZ approving the use of a high level claim and then the TGA declaring the product to be a therapeutic good, there would need to be a referral mechanism between the two agencies;
- the addition of complementary medicinal substances to food and the implied health claims that may be conveyed, regardless of label claim; and
- equitable quality platforms, i.e. stability data.

The major issue of concern identified was that of effective enforcement, which is outside the purview of the central body FSANZ. TGACC members have noted that complaints about advertisements, after a central logging process, will be dealt with by States and Territories and New Zealand. Historically, dealing with problems in food advertising by States and Territories in Australia has been found difficult in terms of priority, resources, consistency and timeliness. As well, although it is possible to do so, reliance on declaring a product to be a therapeutic good under the Therapeutic Goods Act 1989 can be cumbersome and not always appropriate.

In October 2004, a submission was put forward from the Council to FSANZ on the initial assessment report "Proposal 293 Nutrition, Health and Related Claims".

Mandatory statements in medical devices advertising

The application of the requirements in Clause 6.2 of the TGAC to advertisements for medical devices was raised, in the first instance, during the consideration of a complaint by the Complaints Resolution Panel. A view was reached by Panel members that the statement “always read the label” should be mandatory for all advertisements for therapeutic goods that are directed to consumers and that all advertisements for therapeutic goods that have ingredients, for direct marketing or internet advertising, should contain a full list of active ingredients.

At the CRP’s request, a paper prepared by the CHF representative was prepared for the consideration of TGACC members. In the paper, it was noted that the content of labels is controlled by Therapeutic Goods Orders and that the purpose of the label for any therapeutic good is to carry key information for consumers. The view was put that all advertisements for therapeutic goods should carry the statement ‘always read the label’.

The MIAA representative’s understanding of clause 6.2 was that the wording ‘where applicable’ had been included so as to exclude medical devices advertising from the requirement of the clause and it was felt strongly the statement “always read the label” would not be appropriate in many circumstances.

Clarification was given that the wording ‘where applicable’ had been included in clause 6.2, at the time of the last review of the TGAC, with respect to the inclusion of lists of ingredients so as to provide an alternative to the inclusion of a long list of active ingredients.

The CRP Chairman confirmed that the Panel view was reflected in the paper and said that the current wording of the clause failed to carry through the intent for all advertisements for therapeutic goods to carry the statement ‘always read the label’.

The suggested approach was fed into the IAC process.

Approval numbers and qualifying statements within advertisements

The inclusion of a requirement for approval numbers to be prominently displayed, stand-alone and always located in the bottom right-hand corner of all print advertisements was supported.

TGACC members agreed, too, that a more robust mechanism is needed to ensure consistency; ACCC findings and approaches taken with respect to ‘fine print’ are relevant, altering meaning by the use of qualifications in fine print is of concern and that the practice of the Advertising Services Managers approving advertisements before artwork/film is finalized can be problematic.

The ASMs attention was drawn to this view formally by way of a letter.

The interpretation of references to websites in advertisements

Following the advice of the TGA Legal Unit to the Interim Advertising Council and discussion by the TGACC, members recommended the inclusion of the following wording in the TPAC.

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

Proposed hybrid Therapeutic Goods Advertising Code

In August, members considered an updated version of the Therapeutic Goods Advertising Code (TGAC) which incorporated, as far as possible within existing Australian legislation, the key provisions for advertising directed to consumers included in the draft Trans Tasman Therapeutic Products Advertising Code.

Industry representatives had requested, as part of transitional arrangements, the development of a new version of the Therapeutic Goods Advertising Code for application during the period up to 1 July 2005. The reason for this was to ensure the application of the same standards as those of the Trans Tasman Therapeutic Products Advertising Code as early as possible, thus smoothing the way for advertisers, particularly in relation to approvals.

Some members expressed disquiet at the introduction of the draft proposed modified TGAC on the basis that the introduction of a hybrid code could be confusing for advertisers, that there are some significant changes and that the trans Tasman code has not been finalised. Members were assured that amendments would be made to ensure the modified TGAC's alignment with the trans Tasman code after approval has been given by the Interim Ministerial Council.

Because there were differing opinions as to whether there should be a one or two-step transition from the current code to the new, two options were put forward for the consideration of members and consultation.

1. Further consideration of an updated, modified TGAC, which will reflect what will be approved by the two Ministers. (If this version of the TGAC were accepted by the TGACC, this could involve retaining the current two year approval period in Australia for all advertisements approved before the introduction of the Advertising Code on 1 July 2005. This would require drafting instructions for the legislation to allow those approved within that period to continue to be regulated under the Australian *Therapeutic Goods Act 1989* and associated regulations); and
2. Preparation of a summary of the major differences between the current and the draft trans Tasman codes and of a proposed timeframe for the validity of approvals whereby any approval between 1 January and 1 July would be valid only until 1 July 2006.

The summary of the differences was prepared, has been updated regularly and used in the educational seminars presented by the TGACC.

Issues raised by the Complaints Resolution Panel at TGACC meetings

Mr Alan Limbury was appointed unanimously by the TGACC for a fourth term of office as Chairman of the Complaints Resolution Panel.

Apprehended bias and the Complaints Resolution Panel

A policy statement made by an industry association about an issue which shortly afterwards became the subject of a complaint gave rise to a possible perception of bias where a nominee of the association is a member of the Panel. To preclude the possibility of any apprehended bias, it was suggested that it would be sufficient that the Panel Executive Officer inform the nominee of the situation as soon as the suggestion of apprehended bias is made.

Referral of complaints to other bodies

The Complaints Resolution Panel refers to other bodies matters where the Panel had formed the view under regulation 42ZCAF(2)(c) that the matter would more appropriately be dealt with by another body. Under regulation 42ZCAF(2)(c), the CRP may treat a complaint as withdrawn if the subject matter of the complaint can more effectively or conveniently be dealt with by another authority, for example, the ACCC, but there is no express provision in the Regulations which permits the Panel to forward the relevant documents to that other authority.

The TGACC agreed that the Regulations should be amended to give the Panel explicit authority to do the above, wherever appropriate.

Declaration of conflict of interest

TGACC members noted that CRP members had agreed that a declaration of conflict of interest should be a standing item on the CRP agenda for the following reasons:

- There is possibility of a perception of bias where a panel member is either employed by or acts as a consultant for a competitor of a party to a complaint;
- the current regulations do not mention the perception of bias but there would be a likelihood of justified industry concern were a competitor's employee to sit on the Panel for the consideration of a complaint.

A guiding principle was formulated and included in the procedures of the Panel.

ASMs/TGA meetings

The Advertising Services Managers and members of the TGA Advertising and Export Section met four times during the year to discuss issues arising from the approvals process, TGACC considerations and the determinations of the Complaints Resolution Panel, so as to ensure a consistent approach to decision-making by all parties.

Summary of recommendations for amendment to the Therapeutic Goods Advertising Code and the Therapeutic Goods Regulations 1990

The legislative program for ordinary business was suspended because of the development of the proposed Trans Tasman system for the introduction of the Joint Agency. As a result, none of the recommendations made by the TGACC for amendment to the TGAC or the regulations since July 2003 were implemented.

Several members expressed their disquiet at the extended hold-up and suggested that some form of transition process should be put in place, given the possibility of significant delays to the full implementation of the Trans Tasman scheme, to enable a way to be found to amend existing legislation for those recommendations with commercial implications.

Therapeutic Goods Advertising Code

- **4.5 Testimonials**

*Testimonials must not breach the Code. They must be documented, genuine, not misleading and **illustrate typical cases only.***

- **Approval numbers**

In addition to the Code requirement that approval numbers be prominently displayed, they must also be stand-alone and always located in the bottom right-hand corner of print media advertisements.

- **Samples, giveaways and competitions**

1. **Delete**

Clause 4.6 Samples

An advertisement for therapeutic goods (other than therapeutic devices and sun screening preparations) must not contain an offer of a sample.

2. **Clause 4.1.2**

ADD as a preamble to Clause 4.1.2

Factors to be taken into account when considering whether or not an advertisement complies with 4.1.2(f), in cases such as sampling, giveaways and competitions, include those found in Appendix X.

Replace

4.1.2 An advertisement for therapeutic goods *must not*:

(c) Mislead directly or by implication or through emphasis, comparisons, contrasts or omissions;

with

4.1.2 An advertisement for therapeutic goods *must not*:

(c) mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions;

and

Replace

4.1.2 An advertisement for therapeutic goods *must not*:

(f) encourage inappropriate or excessive consumption

with

4.1.2 An advertisement for therapeutic goods *must not*:

(f) encourage, or be likely to encourage, inappropriate or excessive consumption
use

3. ADD a new Appendix to the TGAC

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

- The nature of the advertisement
- The nature, quantity and risk of therapeutic goods offered as samples, giveaways or prizes or required to be purchased as a condition of entry to a competition
- The risk of the therapeutic goods advertised
- The design of any competition

Therapeutic Goods Regulations

- **CRP referral to other bodies**

That the Regulations be amended to give the Complaints Resolution Panel explicit authority to refer matters to other bodies, wherever appropriate.

- **Request for an undertaking to comply**

That an amendment to the Regulations be made to enable the Complaints Resolution Panel to request an undertaking from an advertiser that a particular representation will not be made again.

- **An amendment to the regulations be made to:**

1. enable alternates to be appointed for a particular meeting; and
2. either provide for the Panel to have no power to deal with a complaint, or provide for the Panel to have the ability to treat a complaint as withdrawn, where court proceedings about the subject matter of the complaint have been discontinued.

Education and Communication

Seminars

Five seminars were held during the year, two in Sydney and one each in Melbourne, Brisbane and Adelaide. More than 300 stakeholders who attended these comprehensive seminars on the current requirements, also were updated on the proposed new arrangements, including the Therapeutic Products Advertising Code and the differences between the TPAC and the TGAC.

The seminars were presented by:

- Advertising Services Managers from the Australian Self-Medication Industry and Complementary Healthcare Council of Australia;
- A representative from the Medical Industries Association of Australia;
- Head of Advertising and Export Section, TGA; and
- Executive Officer to the TGACC and CRP.

In addition, the team was invited to provide a full-day seminar and workshop to members of the Direct Selling Association of Australia.

TGA legal training day

A legal training day presented by the TGA's Legal Services Group on 1 April 2004 was attended by the ASMs, the CRP Executive Officer, the Executive Directors of the ASMI and the CHC and TGA officers. Issues covered on the day included:

- The power of the ASMs to withdraw the approval of advertisements;
- The release of approved scripts to broadcasters is acceptable with sponsors' knowledge. The provision of approval material to the self-regulatory system is not legal;
- Sole traders – there is no Commonwealth constitutional power to regulate non-corporate individuals. They may be subject to corresponding State legislation, e.g. NSW and Tasmania;
- Legal liability for ASMs is covered under insurance requirements of the contracts relating to the delegations. As the Complaints Resolution Panel Chairman receives remuneration at commercial rates, there is no entitlement to assistance from government with legal costs;
- Product certification under s.26A(2)(j) of the *Therapeutic Goods Act 1989* is the responsibility of the sponsor;
- Where there is a link through an advertisement to therapeutic goods, the advertisement must comply with the TGAC and, if in specified media, requires approval before publication;
- Where an advertisement includes a reference to obtain further information, such as a phone number, website, mailing address or book, and the referenced material is relevant to what is being advertised in the advertisement, that material forms part of the advertisement; and
- The current approach of the ASMs to require a statutory declaration for a testimonial should be retained.

Website

The website continues to be an invaluable resource for interested parties in Australia and internationally.

Applications for the use of a restricted representation (s.42DE of the *Therapeutic Goods Act 1989* refers)

During 2004, the TGACC considered a number of applications from sponsors, seeking permission to use “restricted representations” in advertisements for therapeutic goods directed to consumers.

Prior to making a decision, the Act requires the Secretary to the Department of Health and Ageing (or Delegate) to consider any recommendation made by the TGACC about the applications received. After consideration in terms of the public interest criteria in the TGAC, the following recommendations, to permit the use of “restricted representations” were made by the TGACC –

GlaxoSmithKine Australia Pty Ltd - Panadol

“suitable for pain and fever relief for asthmatics who are sensitive to aspirin and non-steroidal anti-inflammatory drugs (NSAIDS) (or words to that effect)”;

Boots Healthcare Australia Pty Ltd – Nurofen

The proposed representations accepted as meeting the public interest criteria were: “If you are pregnant, as with all medicines, we advise you not to take *Nurofen* (ibuprofen) without advice from your doctor and not to use *Nurofen* in the last 3 months of pregnancy”; and

“As advised on the pack, *Nurofen* should not be taken if you have an existing stomach ulcer or other stomach disorders, if you have kidney or heart problems or are allergic to ibuprofen or other anti-inflammatory medicines.”

Pfizer Pty Ltd – Diflucan One (fluconazole 150 mg single dose) - for advertising in relation to vaginal candidiasis (vaginal thrush). The TGACC believed the arguments put forward to support the use of a restricted representation met the public interest criteria, any restricted representation should be approved on the basis that it is in line with the label claim approved by the Medicines Evaluation Committee. However, members noted that the use of the word ‘simple’ in the context of the label claim is misleading, for the reasons described above, and should not be included in advertising. Any substitute wording should be considered to ensure that it is not similarly misleading and, as recommended by the TGACC pharmacy representative, any approval only should come into effect six months after an education program has been implemented for pharmacy.

Johnson & Johnson Pacific Pty Ltd – 4 Monistat products

To allow a reference to diabetes in advertising as thrush may be a consequence of undiagnosed diabetes.

The TGACC recommended that approval be given for the use of restricted representations for the four Monistat products, with the wording of the first of the proposed claims amended to reflect that repeated thrush infections may suggest unrecognised diabetes and, for both claims, that there should be a requirement to include a statement that women experiencing such episodes should seek medical advice.

The Delegate subsequently granted permission in relation to the above applications and following notification in the Government Notices Gazette, the final approvals (along with any conditions imposed) were posted, and remain publicly available on the 'advertising' pages of the TGA website (www.tga.gov.au)

The TGACC also considered three (3) other applications for the use of "restricted representations", but was unable to recommend that permission be granted to use the representations in consumer advertising.

Review of a decision of the Secretary's delegate to refuse to approve an advertisement

Where the Secretary's delegate (appointed by either the Australian Self Medication Industry or the Complementary Healthcare Council of Australia) refuses to approve an advertisement under Regulation 5G, the sponsor is able to seek a review of this decision by the Minister (or Minister's delegate) under Regulation 5M.

The Minister for Health and Ageing received three (3) such appeals during 2004.

The TGACC considered these appeals and provided advice to the Minister (or delegate) in relation to the various subject matters. The TGACC recommended that the decisions of the Secretary's delegate be upheld in two (2) of the cases and overturned in one (1) case.

Prior to making a decision in relation to the appeals, the Minister's delegate considered these recommendations made by the TGACC, in line with the requirements of the Regulations.

Conclusion:

The normal responsibilities of the TGACC under the current system were executed properly and its work was enhanced by the considerations of the Interim Advertising Council.

The period between 1 January 2005 and implementation of the proposed Trans Tasman advertising arrangements provides the opportunity to introduce the new elements developed over the past four years and to test the viability of much of the proposed system.

Pio Cesarin
Chair (since February 2005)

Judith Brimer
Executive Officer

TGACC Representatives

Chairman Mike Codd (till December 2004)

Members

Manufacturer/Supplier Representatives	
Australian Self-Medication Industry	Juliet Seifert
Complementary Healthcare Council	Val Johanson
Australian Direct Marketing Association	Jason Korke
Direct Sellers Association of Australia	Les Dell
Advertising Industry Representatives	
Australian Association of National Advertisers	Clare Martin
Advertising Federation of Australia	Michael Cocks
Consumer Representatives	
Australian Consumers' Association	Robin Andrew/Martyn Goddard
Consumers' Health Forum	Alan Barclay
Healthcare Professional Representatives	
Australian Traditional Medicines Society	Raymond Khoury
Pharmacy Guild of Australia and Pharmaceutical Society of Australia	Jenny Bergin
Royal Australian College of General Practitioners	Ass. Prof. Andrea Mant
Government Representative	
Therapeutic Goods Administration	Craig Davies

Observers

Australian Competition and Consumer Commission	Ziv Gavrilovich
Australian Pharmaceutical Manufacturers' Association	Fiona Woodard/Deborah Monk
Complaints Resolution Panel Chair	Alan Limbury
Cosmetics, Toiletries and Fragrances Association of Australia	John Woods
Media – Broadcast	Alina Lieurance/Moses Kakaire
Media – Print	Colin Harcourt
Medical Industry Association of Australia	Pam Davis
Medsafe New Zealand	

Experts

Advertising Services Manager, ASMI	Catherine Brunskill
Advertising Services Manager, CHC	Tricia Campbell/Montse Pena
Advertising Standards Authority NZ	Glen Wiggs (August)
Association of New Zealand Advertisers	Jeremy Irwin (August)

Trans Tasman Advertising Review and Interim Advertising Council

The work of the Interim Advertising Council (IAC), the body responsible for further developing the recommendations from the Toogoolawa Report on the proposed model for Trans Tasman advertising arrangements, proceeded in tandem with the work of the Therapeutic Goods Advertising Code Council (TGACC) in relation to the current system. This integrated approach was facilitated by having in common the Chairman, the IAC Secretary/TGACC Executive Officer and several members, with the Chairman reporting on the IAC processes at each TGACC meeting.

Trans Tasman Advertising Review

The work agenda of the IAC on the development and/or consideration of the following continued until the final IAC meeting on 12 and 13 October 2004:

- High level principles
- Single Advertising Code
- Legislation framework
- Processes for approvals, complaints, sanctions, appeals
- Pre-approval dividing line
- Internet advertising
- Interface issues
- Transition, roll out and costs
- Role, composition, powers of the final Advertising Council

Key outcomes included the following:

Three key Advertising Principles to be included in high level legislation in Australia and New Zealand:

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.

Advertising Requirements (which elaborate on the Principles), as described in the proposed Australia New Zealand Therapeutic Products Advertising Code, to be included in the Joint Rules.

The Australia New Zealand Therapeutic Products Advertising Code (TPAC) is to provide the standard to be applied in each country. During the development of the TPAC, recommendations were made for amendment to the Therapeutic Goods Advertising Code based on consideration by members of issues that had been debated by the members of the Interim Advertising Council.

Each industry sector is to adopt the TPAC within its own code of practice. Where this is the case, industry may request that the Joint Agency, through the Managing Director, formally recognise an industry code of practice and impose compliance with that code as a standard condition of a product licence for relevant products.

The agreement that all existing arrangements in terms of industry contracts with TGA for the operation of Code Council and CRP and the delegations for approvals will not change until the agency is established, remained in place.

Work was undertaken by consultants engaged by the Therapeutic Goods Administration on the likely cost of the new system, a comparison of the level of compliance between 'above the line' and 'below the line' material, and on the potential volume of advertising material in the market place.

A media-based dividing line for the requirement for approval of medicines advertisements directed to consumers has been proposed. Advertisements for devices which contain a verifiable claim, or promote a restricted device, also would require approval. A Central Approvals Office in Australia and the Therapeutic Advertisement Pre-Vetting System (TAPS) in New Zealand would be responsible for operation of the approvals system.

Because the level of compliance of below the line material was clearly shown to be unacceptable (Schoombie Report), a 'notification' system has been proposed. Details of advertisements (which may be published in a range of media) directed to consumers but not requiring approval would need to be included on a central approvals database as a notification. As part of this notification process, the sponsor/advertiser would be required to certify that the advertisement complies with the Code. An identifier for the advertiser and a unique notification number for each advertisement would automatically be allocated. The sponsor/advertiser should also be able to seek further advice from the Central Approvals Office in Australia or the TAPS in New Zealand on whether a particular advertisement complies with the Code.

It is proposed that all complaints about advertisements for therapeutic products in Australia and New Zealand be entered into a central database. All complaints about advertisement that are directed to consumers would be considered by the central complaints body in each country. Industry complaints bodies would deal with complaints about advertisements directed to healthcare practitioners. Appeals processes have been outlined.

A proposed monitoring and evaluation framework is based on a set of key performance indicators, such as compliance with, and awareness of, the code, the number and nature of complaints, their details, measures of simplicity, cost-effectiveness and timeliness, and measures of consistency and transparency and accountability for approvals and complaints processes.

The proposed central database is key to the effective and efficient operation of the whole system and work on it needs to start as soon as possible to make sure that it's fully operational by the time the Joint Agency commences. A proposal put forward by the New Zealanders, modeled on their own custom designed, simple, cost effective web-based complaints database (including the IP involved) was thought by the IAC to be a good offer.

The decision that needs to be made relates to which side of the firewall for the Joint Agency should the advertising database be located. If it is introduced on the regulator's side, it would need to be fully compatible with the Joint Agency arrangements, there could be complexity and considerable cost, and having to fit in with the overall IT development program would take time. If located outside Joint Agency it could be possible to take advantage of the NZ developed database, introducing it at an early date and at a significantly reduced cost.

It is expected that after consideration of the final report on the work of the Interim Advertising Council by the Interim Ministerial Council, work will continue on any outstanding matters, including the legislative framework, governance, interface issues and transitional arrangements.