

Therapeutic Goods Advertising  
Code Council

Annual Report 2000

# Council Representatives

## Members of Council

Manufacturer/Supplier Representatives	
Australian Self-Medication Industry	Juliet Seifert (Chair from March)
Complementary Healthcare Council	Philip Daffy (Chair January – March) Heidi Schuett (from March)
Australian Direct Marketing Association	Kathy Gard (January – March) Dawn Grassick (from March)
Direct Sellers Association of Australia	Les Dell
Advertising Industry Representatives	
Australian Association of National Advertisers	Clare Martin
Advertising Federation of Australia	Stephen Robson (January – March) Michael Cocks
Consumer Representatives	
Australian Consumers' Association	Sarah Fogg
Consumers' Health Forum	Derek Weir
Healthcare Professional Representatives	
Australian Traditional Medicines Society	Raymond Khoury
Pharmacy Guild of Australia and Pharmaceutical Society of Australia	John Bell
Royal Australian College of General Practitioners	Andrea Mant (January – March) Sue Whicker (from March)
Government Representative	
Therapeutic Goods Administration	Graham Peachey

## Observers to Council

Australian Pharmaceutical Manufacturers' Association	Fiona Woodard
Complaints Resolution Panel Chair	Alan Limbury
Cosmetics, Toiletries and Fragrances Association of Australia	John Woods
Medical Industry Association of Australia	Pam Davis

## Experts

Advertising Services Manager, ASMI	Deon Schoombie
Advertising Services Manager, CHC	Sue Cheetham
Chair, Complementary Medicines Evaluation Committee	David Roberts
Chair, Medicines Evaluation Committee	Richard Whiting
Immediate Past Chair	Philip Daffy

# Highlights of 2000

Where 1999 could be termed ‘the year of the Review’, 2000 was ‘the year of implementation’ for all of the new advertising arrangements for therapeutic goods.

The first part of the year was taken up with refining the proposed amendments to the regulations, the launch of the Therapeutic Goods Advertising Code, the implementation of the education program and addressing outstanding issues from the Review.

## 1. Finalising the new arrangements

At the end of 1998 Senator Tambling initiated a reform program for the regulation of complementary medicines in Australia. In particular, attention was given to the review of the Therapeutic Goods Advertising Code and its related provisions.

The TGACC was the key body responsible for overseeing the review of all advertising arrangements during the course of 1999. Outstanding issues from the review, addressed in 2000, included:

- practicalities of the new levels of evidence, including consultation with industry on the levels of evidence for traditional medicines
- necessary steps to ensure the orderly transition from the old to the new, including a transitional period for existing advertising claims
- the distinction between educational and promotional material
- sanctions that are timely and have teeth
- legislative amendments to ensure that the package of reforms was effectively underpinned in law

## **Advisory Group**

The implementation process began with the establishment of the Advisory Group and a six-month trial period during which time sponsors could test the system based on the new Code and the *Guidelines for Levels and Kinds of Evidence Required to Support Therapeutic Claims*.

Consultation with industry on levels of evidence requirements for traditional medicines took place and there was a forum held by the TGA on 3 February 2000.

An industry/TGA roundtable meeting was held on 16 February to fully brief industry representatives and refine the role and activities of the Advisory Group.

A four-year transition period was instituted, to enable compliance by existing products in the market place with minimum disruption.

The TGA representative on Code Council provided a report on the operation of the Advisory Group at each TGACC meeting.

## 2. The launch of the Therapeutic Goods Advertising Code (TGAC)

One hundred representatives from industry, advertising agencies, expert committees, government and consumer organizations attended the launch at Curzon Hall in Marsfield, Sydney, on 7 April.

A media session was held immediately before the lunch. The interest from television, radio and print journalists resulted in excellent media coverage of the event and the new code.

The National Manager of the Therapeutic Goods Administration, Mr Terry Slater, introduced the speakers, Mr Philip Daffy (TGACC Chair 1999), Ms Juliet Seifert (TGACC Chair 2000) the keynote speaker, The Hon. Senator Grant Tambling.

In launching the new advertising arrangements and the new Therapeutic Goods Advertising Code, The Hon. Senator Grant Tambling noted the need to move the advertising of therapeutic goods into the twenty first century, that there had been widespread agreement that advertisements should be truthful, valid and not misleading and that there was strong support for a system able to deal with transgressor with 'timeliness and teeth'. Senator Tambling acknowledged the work done during the course of the review and congratulated TGACC and Task Force members on their perseverance and determination in seeing the review through. He referred to the work of CMEC, in conjunction with the TGA and other expert committees, in developing the guidelines for levels of evidence to support indications listed or registered on the ARTG. In conclusion, Senator Tambling said, "It is the wider consuming public that will feel the impact of the new Code the most, and the community should benefit from the new approach the Code foreshadows. There should be a new clarity, greater opportunities in the market place and, in the end, an informed and confident consuming public".



**The Hon. Senator Grant Tambling (left) with the National Manager of the Therapeutic Goods Administration, Mr. Terry Slater at the launch of the Code.**

### 3. Education and Communication Program

To ensure a smooth, trouble-free transition to the new system, the Code Council Communications Team devised a multi-faceted education/communication program directed to sponsors, consumers, healthcare professionals and media. This specialist committee was chaired by the AFA representative and included the Advertising Services Managers, a TGA representative, ADMA and PSA/PGA representatives and the TGACC Executive Officer. The Executive Director of the Australian Publishers' Bureau was co-opted to the Team who, as well as enhancing the work of the Communications Team, took every opportunity to talk to publishers all around Australia about the new system.

#### **Roadshows**

A Roadshow Team, including the Advertising Services Managers from PMAA (now ASMI) and CHC, a TGA representative and the TGACC/CRP Executive Officer, travelled to major capital cities, where exceptionally well-attended public information sessions for sponsors and consumers and media representatives were held over a period of two weeks following the launch of the Code. Sponsors, consumers and media representatives eagerly grasped the opportunities for questions about the new arrangements. The resultant lively discussions on issues of concern kept the presenters on their toes!

#### **Website**

A comprehensive, user-friendly and logical website was constructed to address the needs of consumers and advertisers. The website outlines the requirements and processes involved in the advertising of therapeutic goods to the public. The visitor can take a journey through the website to be well-informed on advertising matters or can quickly locate and reference information required for a particular reason.

Advertising approvals processes are explained and a Glossary of Permissible Representations provides an invaluable tool for industry.

The section on the Complaints Resolution Panel and complaints mechanisms gives ready access to the process of making a complaint, the procedures followed by the Panel and a register of complaints. The full text of each determination is available on the register.

The website clearly demonstrates a commitment to transparency in the operations of the TGACC and the CRP.

#### **Leaflet**

Through the good offices of the major distributors Fauldings and Sigma, and the Australian Consumers Association, 250,000 copies of a leaflet directed to consumers and entitled "How do I know I can rely on healthcare advertising?" were disseminated to pharmacies Australia-wide and directly to consumers by inclusion in Choice magazine.

## **Print advertisements**

The Australian Publishers' Bureau demonstrated support for the new system by arranging placement of 'filler advertisements' promoting the new Code in mainstream print publications.

## **Poster**

A poster version of the website was developed and provides a useful tool for conferences and seminars.

4. Significant issues considered in 2000 by the Council

## **Separation of advertising claims from market entry requirements**

The *Guidelines for Levels and Kinds of Evidence Required to Support Therapeutic Claims* relate to market entry requirements, not to advertising claims. TGACC's role is to decide what is appropriate to be advertised to the public. Advertising claims, however, must be consistent with the purpose statements on the Australian Register of Therapeutic Goods.

Labels are included in the definition of 'advertisement'. Reference to labels is made in Clause 6, Minimum Requirements of the TGAC. However, product labels are covered by guidelines and standards that apply during the Listing and Registration processes. A subcommittee was formed which met on 24 July. The following recommendations were put forward to the TGA.

- Exclude labels from the definition of 'advertisement' in the Therapeutic Goods Act;
- Amend all references in the Regulations that draw together advertising and labelling to make the advertising and regulatory requirements separate;
- Add to the section on approval and any other relevant section in the Regulations, the requirement for any representation of a label in an advertisement to comply with the Code.
- Amend the Code to include the requirement for any representation of a label in an advertisement to comply with the Code.
- The principles of the Code should be applied by the TGA when assessing labels at market entry.

Subsequently, the TGA advised that use of the review of labelling could be the vehicle used to facilitate discussion and as a more effective way of achieving separation of advertising from market entry requirements than a change to the definitions of advertisement.

## **Generic information and advertising**

It was agreed that there should be one definition of 'advertisement' (that in the Therapeutic Goods Act) and published or broadcast material is either information or an advertisement.

A new category, “Generic information”, was created in the Regulations, with requirements for compliance with principles based on public interest criteria and consistent with the principles outlined in Clause 4 of the Therapeutic Goods Advertising Code.

### **Analgesics warning statements**

Concern was expressed by industry about inclusion in the new Code of the word “harmful” in analgesics warning statements. It was suggested that the use of the word “harmful” is unnecessary and serves to undermine consumer confidence in product. The ASMI Analgesics Working Party was expanded to include TGACC members, considered proposals at two meetings and made recommendations to Code Council.

### **The regulation of internet advertising of therapeutic goods**

Internet advertising was flagged as a major issue for discussion in February. Notice was given to members in May for discussion at the June meeting. A recommendation for inclusion of the internet in the definition of specified media was agreed at two subsequent meetings. However, after a submission from the CHC Executive Director, the issue as to whether internet controls should fall under self regulatory or co-regulatory mechanisms was opened again for discussion at the meeting held on 11 October. TGACC invited representatives from the ACCC to attend the meeting. After a lengthy debate there was lack of unanimity among members on the issue and the Chair undertook to convey members’ views to Senator Tambling.

### **Devices**

A meeting was held on 22 February 2000 with representatives from the medical devices sector to discuss the implications of the changes as a result of the review, to achieve the outcome of a level playing field across the full range of therapeutic goods and to consider any concerns that there may be.

There was unanimous support for the application of the Therapeutic Goods Advertising Code to all advertising for devices. There was unanimous agreement for the incorporation of devices advertising into the complaints mechanism in the proposed regulatory amendments. It was agreed that advertisements for therapeutic devices should not be subject to the approval process.

### **Health claims in food advertising**

In August, Ms Sonia Bradley, ANZFA representative, was invited to present to TGACC members an overview of the regulatory controls for the advertising of food. A subcommittee was then formed to consider matters of consistency between the management of health claims in food and therapeutic claims.

At the meeting of the subcommittee held on 4 October, Ms Bradley presented and answered questions on the Review of Health and Related Claims Proposal 153.

A TGACC response to the Proposal was submitted.

In conclusion:

With the end of the review and the implementation of the new system, Code Council's overall responsibility for all advertising arrangements has been acquitted. The Council has resumed its role of providing advice to the Minister to ensure that the Code remains relevant, reflecting community values and standards, and that there is a level playing field for all advertisers.

We now have a system in which there has been significant deregulation without compromising public health and safety or public interest, there is a greater range of permissible representations in advertising and a clear regulatory framework for market entry and advertising decisions, including a requirement that all claims be verified and backed by appropriate evidence to support those claims.

Juliet Seifert  
Chair

Judith Brimer  
Executive Officer