

**Advertising Implementation Steering Group  
Meeting 1, 6 September 2006  
Room – Mascot A  
Stamford Plaza Sydney Airport Hotel  
MASCOT NSW 2000  
9 am – 4.30 pm**

**FINAL MINUTES**

**Attendance**

**MEMBER**

Sue Knowles  
Pio Cesarin  
Melanie Cantwell (Alternate)  
Jean Drage  
Deborah Monk  
Juliet Seifert  
Tony Lewis  
Pam Davis

Lesley Clarke  
Tony Miller  
Myles Chandler  
Brian Morton (Alternate)  
Jenny Bergin  
Raymond Khoury  
Julie Kirsop  
Lesley Brydon (Alternate)  
Lianne Richards  
Moses Kakaire (Alternate)  
Glen Wiggs  
Jeremy Irwin

**OBSERVER**

Brett Andrews

**SECRETARIAT**

Fiona Cumming  
Michael O'Connor

**APOLOGIES**

Susan Martindale  
Janne Graham  
John Gullotta  
Michael Cocks  
Alina Bain  
Joan Warner

**REPRESENTING**

Chairman  
Australian Regulator  
Australian Consumers  
New Zealand Consumers  
Australian Prescription Medicines Industry  
Australian OTC Medicines Industry  
Australian Complementary Medicines Industry  
Australian and New Zealand Medical Devices  
Industry  
New Zealand Prescription Medicines Industry  
New Zealand OTC Medicines Industry  
New Zealand Complementary Medicines Industry  
Australian and New Zealand Medical Practitioners  
Australian and New Zealand Pharmacists  
Australian Natural Healthcare Practitioners  
New Zealand Natural Healthcare Practitioners  
Australian Advertising Industry  
Australian Publication Media Industry  
Australian Radio Media Industry  
New Zealand Advertising Standards  
New Zealand Advertising Industry

Australian and New Zealand Medical Devices  
Industry

Joint Agency Establishment Group  
Joint Agency Establishment Group

New Zealand Regulator  
Australian Consumers  
Australian and New Zealand Medical Practitioners  
Australian Advertising Industry  
Australian Television Media Industry  
Australian Radio Media Industry

## **1. Welcome**

The Chair, introduced herself and warmly welcomed members to the inaugural meeting of the Advertising Implementation Steering Group (Steering Group).

The Chair set the scene by highlighting the following points:

- The Steering Group had been established by the Therapeutic Products Interim Ministerial Council (Interim Ministerial Council) to guide implementation of the operational aspects of the proposed trans Tasman advertising co-regulatory scheme.
- Most members would have been aware of or involved in the development of the proposed Australia and New Zealand advertising scheme for therapeutic products which was developed by the Interim Advertising Council (IAC) chaired by Mike Codd over the period May 2003 – October 2004.
- One of the IAC's recommendations had been that an Implementation Steering Group be established to see the approved advertising model put into place.
- The IAC had recommended a Steering Group of 12 members. However, the Interim Ministerial Council felt it important to have full stakeholder involvement around the table at the Group's meetings and thereby established the Steering Group with membership modelled on the membership of the future Advertising Council. Hence there are 22 members of the Steering Group.
- The Steering Group would not be revisiting elements of the advertising regulatory model as it has been agreed by the Interim Ministerial Council and as such is not open for re-negotiation.
- The challenge before the Steering Group is to work out how to put the proposed advertising regulatory model agreed by the Interim Ministerial Council into place so that it operates smoothly and effectively in both countries.
- The model will be subject to ongoing monitoring and evaluation once it is in operation and any changes identified as being necessary through that formal process will be considered in the future under the Australia New Zealand Therapeutic Products Authority (ANZTPA).

## **2. Membership of Steering Group: introductions and apologies**

The Chair acknowledged the recent passing of Mr Colin Harcourt, Executive Director, Australian Publishers' Bureau, and the appointment of Ms Lianne Richards as the new Australian Media representative to the Steering Group.

Dr Cumming said a few words in the memory Colin noting that he had made a significant contribution to advertising standards in Australia over the years and more recently through the IAC process and as a member of Therapeutic Goods Advertising Code Council (TGACC). The Steering Group expressed sadness that Colin would not be there to finally see the implementation of new advertising co-regulatory scheme in Australia and New Zealand.

The Chair invited all Members (or their alternates) of the Steering Group, observers and the Secretariat introduce themselves and give a brief synopsis of their position or other relevant background.

### *Apologies*

Apologies were recorded for:

- Ms Susan Martindale, New Zealand Regulator;
- Ms Janne Graham, Australian Consumer member;
- A/Prof John Gullotta, Australia and New Zealand Medical Practitioner member;
- Mr Mike Cocks, Australian Advertising Industry member;
- Ms Alina Bain, Australian Television Media member; and
- Ms Joan Warner, Australian Radio Media member

#### *Alternates*

The following persons attended as the alternates for the absent members:

- Ms Melanie Cantwell, Australian Consumers;
- Dr Brian Morton, Australia and New Zealand Medical Practitioner;
- Ms Lesley Brydon, Australian Advertising Industry; and
- Mr Moses Kakaire, Australian Radio Media Industry.

#### *Also in attendance*

- Mr Brett Andrews, who had been nominated by Medical Industry Association of Australia and Medical Industry Association of New Zealand to take over from Pam Davis as the medical device industry member, on her retirement.

### **3. Procedures and processes for Steering Group meetings**

#### **A. Conflict of Interest**

The Chair noted the importance of openness and transparency in the operation of the Steering Group, and the need to carefully manage any real, potential or perceived conflicts of interest Members may have.

To this end the Chair reminded Members that they had been asked upon joining the Steering Group to sign a “conflict of interest” declaration regarding any real or potential, direct or indirect conflicts of interest which may exist in the context of their membership of the Steering Group.

Members were also informed of the need to complete a “conflict of interest” declaration at each meeting of any potential conflicts of interest that may arise for them from the meeting’s agenda. The declaration would need to be made prior to the commencement of the meeting and provided to the Chair before the business of each meeting commences.

It was agreed that where a conflict of interest is identified for a Member regarding certain item(s) of the Steering Group’s agenda, that member would be asked to leave the room while the Steering Group decides:

- (i) whether the member may be present for the discussion;
- (ii) whether the member may be present during any decision that is necessary; and
- (iii) whether the member may participate in the decision-making.

Additionally, members supported the outcome of the meetings deliberations about the Member’s real or potential conflict of interest being recorded in the minutes.

#### **B. Confidentiality**

Members were reminded that they had been asked to sign a “Deed of confidentiality” that where information being provided to the Steering Group is identified as confidential, they will

treat that information accordingly.

While it was acknowledged that most matters considered by the Steering Group will not be confidential, should confidential information be provided as part of the meeting agenda papers at any time, that information will be marked 'confidential' and Members would be advised as to limits on communication about it.

Where a Member may table or otherwise provide confidential information, the member must take all necessary steps to ensure the meeting is aware of the confidential status of that information.

In the interests of ensuring the openness and transparency of the operations of the Steering Group, Members agreed to take all reasonable steps to treat confidential information accordingly.

### **C. Times and places for meetings**

The Chair advised that the Steering Group is scheduled to meet fact-to-face up to four times, with one of those meetings being in New Zealand.

It was proposed that the meetings of the Steering Group in Australia be held in Sydney and the New Zealand meeting be in Auckland. The Secretariat would plan to arrange the meetings in both countries at airport locations to facilitate travel to and from meetings, and maximise time available for meetings.

Members noted that the time of the Sydney meetings are planned for 9 am to 4.30 pm, while the Auckland meetings are planned for 8am to 4pm.

#### *Schedule of meetings*

It was agreed that Steering Group meetings be held on:

- 6 September 2006 - Sydney;
- 22 November 2006 - Sydney\*;
- 14 February 2007 - Auckland; and
- 30 May 2007 - Sydney

[\*Secretariat Note: The Steering Group agreed out-of-session that the 22 November meeting be moved to Canberra].

Additionally, Members understood that it may be necessary for the Steering Group to meet by teleconference on one or two occasions in order to finalise its report.

### **D. Provision of agenda papers to members**

It was agreed that the available agenda papers be provided to members electronically on CD-ROM approximately two weeks before each meeting to allow for reading any necessary research or consultation.

### **E. Decisions**

Members noted that the Steering Group is expected to operate on a basis of consensus. Where consensus is not achieved, Members would have the opportunity to seek to have their dissenting views recorded as part of the minutes.

### **F. Minutes of meetings**

The Chair advised that if possible the draft minutes of meetings should be prepared and

circulated as soon as possible after meetings, with a view to being confirmed out-of-session. with the agenda papers for the next meeting. Where this is not possible they should be circulated with the agenda papers for the next meeting, for confirmation by members at that meeting. Once confirmed, minutes will be posted on the ANZTPA project website ([www.anztpa.org](http://www.anztpa.org)).

#### **G. Report from Steering Group to Therapeutic Products Interim Ministerial Council**

Members noted that on completion of the Steering Group's work agenda, a report will be provided to the Interim Ministerial Council. It was anticipated that this report would summarise:

- the group's discussions;
- its recommendations in line with its terms of reference; and
- how its recommendations have been put into operation in implementing the trans Tasman regulatory model for advertising that the Interim Ministerial Council approved in December 2005.

#### **H. A section on the ANZTPA web-site for the Steering Group.**

The Secretariat informed members that an area on the ANZTPA project website ([www.anztpa.org](http://www.anztpa.org)) will be designated for communicating the Steering Group activities. It was anticipated that the minutes of meetings will be posted here, along with any other consultation or general information documents the Steering Group may have identified for public release.

#### **I. Other practical issues identified by members**

Members were invited to identify any other practical procedures or processes which may need to be considered towards ensuring smooth and efficient operation of the Steering Group.

One issue that was raised related to member consultation with stakeholders. It was agreed that communicating the issues being addressed through the implementation process with the organisations which nominated the member was important and that Members should consult where appropriate as necessary. More formalised consultation processes will be considered as the need arises.

### **4. Terms of reference**

The Chair highlighted that the Steering Group is charged with the responsibility of providing advice on the implementation of the trans-Tasman scheme for regulating advertising of therapeutic products agreed to by the Interim Ministerial Council in December 2005.

It was expected that the work of the Steering Group would build on the relevant considerations outlined in the IAC's report of October 2004 noting that there were some differences between the model the IAC recommended and the model agreed by the Interim Ministerial Council.

Members were given a brief overview examining the terms of reference in the full context of the key elements of the model agreed to by the Interim Ministerial Council.

The Chair considered that the Interim Ministerial Council had given the Steering Group a well-defined set of terms of reference with each component referring to a separate part of the advertising regulatory model they agreed to.

Members noted the Terms of Reference for the Steering Group as set out at Attachment A.

The importance of the Steering Group acting as a co-ordination point for liaison with Australian and New Zealand stakeholders and the TGACC on implementation as well as advising these stakeholder views to the Joint Agency Management Committee was noted.

### **Working Parties**

The Chair commented on the challenging work agenda set for the Steering Group and that the Steering Group may need to appoint working groups where it is necessary to progress the work agenda between meetings.

Members agreed that such groups may meet face-to-face or by teleconference, as determined by the Chair of the Steering Group, in consultation with the convenor of each working group.

It was noted that the terms of reference dictated that where a working group is to consider any aspects of the model that involves matters of public health and safety, membership of the working group must include appropriate representation from healthcare practitioners.

## **5. Finalising the trans Tasman advertising code and developing supporting guidelines**

The agenda papers provided to the Steering Group included a copy of the proposed Australia New Zealand Therapeutic Products Advertising Code (the Code, version 11, 17 November 2004). Members were informed that this version of the Code is based on version 10 of July 2004 which was the last version seen by the IAC. It was outlined that Version 11 incorporates the suggestions the IAC made in relation to Version 10 at its last meeting in October 2004, along with some minor editorial changes.

The Chair reminded members that Version 11 of the Code had been agreed to by Ministers as part of the overall advertising regulatory model.

Members were given a brief overview of the proposed trans Tasman legislation to be administered by the ANZTPA, including the Code.

Members were asked to consider Version 11 of the Code, with a view to agreeing to it as the final version (for the immediate future, pending ongoing regular review). The Chair considered that before the Code can be put into operation, the Steering Group needs to try to ensure that it is a workable document for stakeholders who will use it. It also needs to be a guide for advertisers, and be in a form that is legally enforceable.

More broadly, Members advice was sought on:

- whether the Code needs user-testing;
- whether the Code might need to be supported by a further set of explanatory “how to” guidelines (‘user guide for advertisers’) to support the code.

Before opening these questions up for discussion, the Steering Group was advised as to the New Zealand experience of introducing and using a code that is closely aligned to Version 11 of the trans Tasman code.

### **A. User testing**

Members were reminded that sections 2 and 3 of the IAC report (pages 17-24) outline the

discussions that had led to development of the Code as it is presented in Version 11. One of the issues raised by IAC and not pursued was whether the draft Code should be subject to some form of user-testing to ensure its format and layout are as user-friendly as possible.

#### Outcome

The Steering Group recommended that the Code should undergo user-testing before being developed as a Managing Director's Order.

It was agreed that for the next Steering Group meeting the Code be re-structured into two parts; (a) regulatory provisions and (b) guidance on interpretation of the regulatory provisions. It was proposed that the regulatory provisions become a precise and technical legislative instrument while the guidelines take into account the different target groups who will be using the Code, *viz*, advertisers, approvals officers, complaints panels and complainants. Members were of the view that professional communication advice will need to be sought on how best the guidelines might address the needs of the different target groups. The Secretariat agreed to restructure the Code accordingly for the next meeting of the Steering Group, prior to seeking such professional advice. The professional communication advice will need to take into account and be consistent with the legislative drafting requirements.

### **B. Communication Campaign**

Members considered that it will be essential for a communication campaign to be conducted in Australia and New Zealand highlighting the difference between the existing codes and the new trans-Tasman Code. This will be essential for a smooth transition to the new regulatory scheme. Members were asked to identify issues which may impact on the proposed communication campaign.

The lack of awareness of the Code by stakeholders who speak languages other than English was identified as a problem.

#### Outcome

The Steering Group recommended that some advice about the Code and how to lodge a complaint be communicated through the ethnic media as part of the education campaign associated with putting the new scheme into place.

#### *Other matters*

There was discussion as to whether pharmacy assistants in Australia should be able to receive advertising about prescription medicines (ie be classified as healthcare practitioners for advertising purposes).

#### Outcome

The Secretariat agreed to meet with the Pharmacy Guild in the first instance to progress this matter, and later with the other industry bodies, and then bring the matter back to the Steering Group for decision.

A matter identified for discussion at a subsequent meeting of the Steering Group is whether consumers may be charged a fee for lodging a complaint with any industry complaint resolution body.

### **C. Industry Codes of Practice**

Members present from the industry bodies agreed to meet prior to the next Steering Group meeting with a view to resolving any jurisdictional differences there are between their codes

and complaints handling processes. In order for industry codes to be made a condition of product licence, all codes must embody consistent principles and the trans-Tasman Code, and complaints handling processes need to be based around a set of minimum standards and deliver consistent outcomes.

Also, it was suggested that the industry codes should require that if a consumer requests information from an advertiser to substantiate a claim, then that material must be provided. This matter will be discussed at another meeting of the Steering Group

#### **D. Other matters**

It was pointed out that pages 84 and 85 of the IAC report highlight three questions relating to the Code which had not been fully resolved by the IAC. They relate to:

- the requirement for advertisements for OTC and complementary medicines to include warning statements where there are known serious adverse effects/contraindications identified for the products, and the need to develop common-sense guidelines for these declarations;
- practicalities and value to consumers of shelf-talkers and shelf-wobblers being required to contain mandatory information as per Requirement 2 of the Code; and
- definition of ‘serious risk’ in the context of advertisements directed to consumers versus those directed to healthcare practitioners.

*Requirement for advertisements for OTC and complementary medicines to include warning statements where there are known serious adverse effects/contraindications identified for the products, and the need to develop common-sense guidelines for these declarations*

The requirements in the Code for serious effects/contraindications to be included in advertising for over the counter (OTC) and complementary medicines were examined.

Members noted that:

- the IAC had recommended that advertisements for OTC and complementary medicines should include warnings where there are known serious adverse effects or contraindications; and
- that this has space (within advertisements) and cost implications for advertisers.

#### Outcome

There was support for the Secretariat to approach the operators of New Zealand’s TAPS for the guidelines they use to support this requirement and report back to the Steering Group.

*Practicalities and value to consumers of shelf-talkers and shelf-wobblers being required to contain mandatory information as per Requirement 2 of the Code.*

The mandatory information to be included in shelf talkers and wobblers was also examined. Members noted that the IAC had recommended that the Steering Group examine the practicality and value to consumers of shelf-talkers and shelf-wobblers containing mandatory information such as ‘always read the label’ as per Requirement 2 of the Code.

The advice of Members was sought as to a way forward to implement these two aspects of the Code, including feedback from New Zealand where such requirements are already in place.

#### Outcome

There was support for the Secretariat to approach the operators of New Zealand’s TAPS for the guidelines they use to support this requirement and report back to the Steering Group.

*Definition of ‘serious risk’ in the context of advertisements directed to consumers versus*

*those directed to healthcare practitioners.*

Members were informed that a further issue to be progressed from the IAC's deliberations was whether the definition of 'serious risk' may differ in the context of advertisements directed to consumers versus those directed to healthcare practitioners. It was appreciated that healthcare practitioners have appropriate levels of training and experience that allow them to be more discerning when they read or hear an advertisement that most consumers can be.

Members were provided with a short presentation describing how the term 'serious' is proposed to be used in the context of the trans Tasman legislation.

Advice was sought from the Steering Group, especially consumers and healthcare practitioners, as to whether a separate definition of 'serious risk' might be appropriate as applied to advertising directed to healthcare practitioners.

#### Outcome

The Secretariat was asked to draft a thinking piece for the next meeting on defining 'serious risk' in the context of advertising to healthcare practitioners.

#### **E. Issues related to the drafting of the Advertising Rule**

*Potential new definitions for 'advertisement' and 'advertiser'.*

Members noted that slightly amended definitions of 'advertisement' and 'advertiser' had been recommended for the purposes of making the Rules enforceable. The following definitions (as outlined in the table below) have been changed as part of the drafting of the Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule.

<b>Australia New Zealand Therapeutic Products Advertising Code</b>	<b>Draft Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule</b>
<b>Advertisement</b> means 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). (Refer A3)	<b>advertisement</b> , in relation to a therapeutic product, means any communication that promotes or discourages the use, sale or other supply of the product, whether or not the communication is in conjunction with the supply of a service or identifies the particular product or service, but does not include: (a) a product label; or (b) corrective advertising; or (c) a retraction; or (d) a communication of any of the following kinds: (i) bona fide news, a bona fide editorial or a bona fide public interest or entertainment program; or (ii) a bona fide disease awareness campaign; or (iii) bona fide educational, research or professional advice.
<b>Advertiser</b> means any person who, or entity which, communicates, or arranges for the communication of, an advertisement.	<b>advertiser</b> , in relation to an advertisement, means any person apparently responsible for the communication of the advertisement.

#### Outcome

The Steering Group provided some specific advice sought by the Secretariat to assist in drafting the Advertising Rule for the new trans-Tasman co-regulatory scheme.

## **6. Governance arrangements that need to be in place for commencement of the scheme**

The Chair highlighted that the governance arrangements proposed for the trans Tasman advertising regulatory scheme are set out in Section 8 of the IAC Report and in the model agreed to by the Interim Ministerial Council. The key aspects that need to be in place at commencement of the scheme were considered to include:

- the Advertising Council;
- the Advertising Management Subcommittee and Technical Subcommittee;
- the Central Support Unit;
- industry self-regulatory bodies;
- professional regulatory bodies; and
- a consumer consultative mechanism.

Other key issues that were raised for discussion included:

- how to establish the Central Support Unit;
- how to ensure smooth interfaces between the various governance bodies within the scheme, especially between the industry and professional regulatory bodies and the central governance groups (including the complaints resolution panels) within the scheme; and
- to consider how to establish a consumer consultative mechanism for advertising matters within the new scheme.

Additionally, the establishment of the approvals process within the Central Support Unit and the interface between the Central Complaints Panels and the Advertising Council and the Central Support Unit was identified as another area that the Steering Group needed to consider.

#### **A. The Advertising Council**

The Steering Group was briefed on the terms of reference and membership of the Advertising Council agreed to by the Interim Ministerial Council in December 2005. These arrangements allowed for the nomination of alternate members, and for the invitation of certain observers to meetings of the Advertising Council.

It was noted that the Advertising Council will be established in the Advertising Rule as an expert advisory committee to provide advice to the ANZTPA in relation to matters concerning the advertising of therapeutic products.

The TGA and Medsafe will initially be responsible for calling for nominations for members of the Advertising Council and their alternates for appointment by the Ministerial Council, and ensuring the appropriate observers and attendees are invited to the Council's first meeting. The Council's membership is to be reviewed after 12 months of operation.

The Joint Agency Establishment Group is currently drafting (generic) operating procedures and processes for expert advisory committees of the Australia New Zealand Therapeutic Products Agency (ANZTPA). There may be a need for advertising – specific *addenda* to these. If so, we will need to decide whether these specifics are first drafted by the Steering Group, or by the Advertising Council upon its establishment.

The Council is expected to meet quarterly in the first year of operation to oversee harmonisation and transition, and thereafter twice a year with one of these meetings being immediately before submission of the annual report to the Ministerial Council.

#### **B. Advertising Management Subcommittee**

The Steering Group was advised that the Interim Ministerial Council agreed to the IAC's

recommendation that there be a statutory subcommittee of the Advertising Council called the advertising Management Sub-committee, which will provide advice and report to the Advertising Council.

Members were informed that the Advertising Rule would provide for the establishment of the Advertising Management Subcommittee. Appointments to the Management Sub-committee will be made by the Advertising Council. The Interim Ministerial Council agreed that there should be a maximum of 12 members on the Sub-committee.

The IAC Report (pages 63-65) described how the IAC envisaged the Management Subcommittee would function. The IAC recommended that the Sub-committee should commence with 12 members of the Advertising Council and recommended that at the first twelve-month period of its operation, the constitution of the Sub-committee should be reviewed with the possibility of reducing the membership as the system becomes established to no more than 7 members. They subsequently agreed to a minimum membership of 8.

The Sub-committee would undertake responsibility for matters associated with the four function areas of the Central Support Unit *viz* approvals, complaints, education/training and evaluation/monitoring. To do this it would need to hold any necessary administrative decision making powers.

To ensure that the Advertising Council was kept fully apprised and able to provide input into any advertising matter under consideration by the Management Sub-committee, the Sub-committee's agenda papers will be circulated to all members of the Advertising Council before each Sub-committee meeting, as would its meeting minutes after each meeting.

### **C. Technical Sub-Committee of the Advertising Council**

The Chair advised Members that one of the functions of the Advertising Council would be making recommendations to the ANZTPA through the Managing Director on applications for the use of restricted representations for medicines and for the advertising of restricted medical devices. As this responsibility requires expert input due to its more technical nature, an appropriately constituted standing subcommittee could be appointed by the Ministerial Council (on the advice of the Advertising Council through the Managing Director) to deal with such requests.

Members noted that there would be a provision in the Advertising Rule to allow the Advertising Council to establish other subcommittees. It was expected that members of this subcommittee (who may not necessarily be members of the Advertising Council) would have expertise in:

- healthcare practice;
- consumer issues;
- the regulatory evaluation of the particular product or category of products in the application; and
- the industry sector relevant to the particular product or category of products in the application.

It was proposed that the technical sub-committee would consider applications for:

- the use of restricted representations for medicines;
- the advertising of restricted medical devices; and
- any other matters referred to it by the Advertising Council.

The subcommittee would also be able to seek other technical or professional expertise outside of its own membership as required.

#### **D. The Central Support Unit**

The Steering Group was briefed on the background to the establishment of a Central Support Unit which was recommended by the IAC to operate the administrative structure for the trans-Tasman advertising regulatory scheme.

It was noted that the Unit's broad terms of reference and estimated staffing requirements (7.5 full time equivalent staff members) are described in the IAC Report (pages 66 and 67). The administrative structure of the Central Support Unit was identified as a key establishment issue to be considered by the Steering Group.

Members were informed that the IAC considered two options in this regard (pages 67 and 68 of its report). Option 1 was that the Central Support Unit would be established as a business unit of the Australia New Zealand Therapeutics Products Agency. Option 2 was that the Management Subcommittee be established as a company limited by guarantee, which would employ all Central Support Unit staff other than the approvals officers who would be nominated and employed by the industry associations.

A short presentation summarised the pros and cons of these options for members and sought advice from the Steering Group on their preferred option, in order that work can commence to put a Central Support Unit in place.

Option 1 would be able to use the employment infrastructure of the ANZTPA for the staff of the Central Support Unit by establishing it as a business unit of the Authority. That is, the human relations frameworks, financial systems and liability and indemnity insurances etc. Members understood, however, that there was unease within the IAC arising from its consultations that industry would be likely to perceive this structure as weakening the co-regulatory nature of the existing regulatory model in Australia.

To implement option 2, members of the Management Subcommittee would have to be willing to form a company limited by guarantee and to become the employer for the Central Support Unit staff. It would incur additional costs to industry, requiring the establishment of human resources frameworks, financial systems and liability and other insurances. Possible difficulties with personal liability of company directors and conflicts of interest were also identified. However, option 2 offers a true co-regulatory approach to the administrative structure for the regulatory framework.

The IAC recommended that legally or contractually based options for establishing the Central Support Unit be explored further during the implementation period. Further investigations have not identified alternative viable options.

#### Outcome

None of the various options for employment arrangements for the Central support Unit put forward by the IAC in its report of October 2004 were fully supported. The Steering Group agreed that the most practical approach, at least in the early stages of the scheme's operation, may be for the Central Support Unit to be auspiced in ANZTPA even if contractual arrangements with the various industry bodies who would employ some of the necessary staff to fulfil the Central Support Unit's functions are in place. This would result in a virtual office environment for the Central Support Unit, and whilst having some limitations, this environment was supported as providing for flexible employment arrangements and attracting high quality staff.

## **E. Industry Self-Regulatory Bodies**

The Steering Group noted that the IAC report (pages 68 and 69) described the industry self-regulatory complaints panels which will be integrated to the co-regulatory system to:

- deal with complaints about advertisements directed to healthcare practitioners, where the matter being considered does not involve any serious public health and safety issues (whereby it would be dealt with by the relevant Central Complaints Panel);
- deal with issues related to breaches of their supportive codes of conduct which involve issues of behaviour or conduct; and
- provide details of the complaints and the outcome to the Central Support Unit handling for entry on the central data base as part of the monitoring and evaluation framework.

An issue central to these responsibilities will be that where the ANZTPA is satisfied that the relevant industry code of conduct is consistent with the Advertising Code, the ANZTPA will make compliance with a relevant industry code of conduct a condition of product licence

The Steering Group was asked to consider how to ensure that all relevant industry codes are consistent with and incorporate the trans Tasman advertising code, and that the industry codes are consistent with each other.

### Outcome

Processes for ensuring consistency between industry codes and complaints handling processes was partly discussed and reported under agenda item 5.

## **F. Professional Regulatory Bodies**

The Chair outlined that another interface within the advertising scheme will be between the central complaints handling process, and complaints handling by professional regulatory bodies of complaints about advertising done by healthcare practitioners.

Members understood that most healthcare practitioners who offer professional services are required to comply with codes of ethics or conduct which are determined by their relevant registration board or other self-regulatory body. These registration boards and self-regulatory bodies consider complaints, among other functions, which may relate to advertising of therapeutic products by healthcare professionals.

It was pointed out that of the IAC Report (pages 45 and 46) describe this more fully, and highlight the importance of close understanding and liaison between these regulatory/self-regulatory bodies and the advertising Central Complaints Panels.

The IAC recommended that:

1. Where these regulatory/self-regulatory bodies consider complaints about advertising of therapeutic products by healthcare practitioners, the body should be encouraged to provide appropriate details to the Central Complaints Panel to be recorded in the central data base for monitoring and evaluation purposes.
2. Effective awareness campaigns and information channels must be developed to ensure the professional regulatory/self-regulatory bodies refer immediately to the Central Complaints Panel any complaints they receive involving advertisements directed to consumers or others involving public health and safety.
3. The regulatory/self-regulatory bodies should be made aware that the Code applies equally to advertising by healthcare practitioners and it should be adopted by reference under their codes.
4. Where a complaint involves an advertisement for a therapeutic product by a healthcare practitioner and the advertisement is:

- directed to consumers, the complaint would be considered by the Central Complaints Panel;
- directed to healthcare practitioners and the relevant professional body has not adopted the Code, the complaint would be handled by the Central Complaints Panel;
- directed to healthcare practitioners and there is no serious risk to public health and safety, and the professional body has adopted the Code, the complaint would be handled by the professional body and the result communicated to the Central Complaints;
- directed to healthcare practitioners and there is a serious risk to public health and safety, the complaint would be dealt with by the Central Complaints Panel and the result communicated to the professional body.

The intricacies of the interface under consideration were outlined for members. It was proposed that the Steering Group needs to give consideration and advice about:

- how to achieve a smooth interface; and
- the next steps that need to be taken towards achieving it. This will include advice on which professional bodies need to be consulted and the most effective way to conduct these consultations.

### Outcome

The Steering Group identified that advertising to healthcare practitioners by healthcare practitioners is covered by:

- The Medicines Australia code and professional codes of conduct for prescription medicines in Australia, and the Advertising Standards Authority (ASA) code, RMI code and professional codes of conduct in New Zealand;
- The ASMI and NZSMI codes for OTC medicines in Australia and New Zealand respectively, and professional codes of conduct;
- The ASMI, CHC and various New Zealand industry codes for complementary medicines; and
- The MIAA and MIANZ codes for medical devices in Australia and New Zealand respectively.

As mentioned under agenda item 5, the various industry bodies will work towards consistent codes and complaints processes, the Secretariat will liaise with the relevant professional bodies about consistency of their complaints handling processes and embodying the ANZTP Code in their codes, and the Steering Group will be kept apprised of progress.

### **G. Consumer Consultation**

Members appreciated that that consumers are the target of a significant proportion of advertising about therapeutic products. The Chair highlighted that the IAC acknowledged (page 69 of its report) the need for consumers to have a genuine voice to add strength to decision-making processes for the ANZTPA in general, and specifically for advertising.

The Steering Group was informed that certain expert committees under the ANZTPA would include a person with expertise in consumer issues. The Steering Group, however, considered it important that the consumer voice is given due standing in the overall management of the trans Tasman advertising scheme.

Members noted that New Zealand has had a consumer consultative mechanism in place for some years and this process was described to the Group.

## Outcome

The Steering Group acknowledged that the New Zealand system of three meetings per year between the ASA (and Association of New Zealand Advertisers [ANZA] ) and consumers provided a good forum for sharing of information and identification of emerging issues. It was agreed that a similar scheme should be established in Australia with the introduction of the new advertising scheme.

## **7. Ensuring appropriate standards and consistency within the approvals process**

The Steering Group was informed of the background to this item. The IAC had recommended that all advertisements for medicines to be placed in mainstream media would require approval prior to broadcast or publication. This excluded advertisements on the internet which were to be exempt from this requirement for practical reasons, despite the internet being classified as mainstream media. Advertisements for medical devices which are intended to be purchased and self-administered by a consumer which include a claim that requires verification would similarly require pre-approval.

The IAC further recommended the introduction of a notification system for advertisements to be placed in non-mainstream media. The IAC's discussions leading to these recommendations, and the recommendations themselves are described in the IAC Report (pages 29-40).

The Interim Ministerial Council accepted the IAC's recommendations for the approvals processes and requirements. However, the Ministers did not accept the recommendation for a notification database. Rather, they agreed that advertisements not requiring approval should be actively monitored for compliance with the advertising Code and the level of compliance formally reviewed within 3 years after the implementation of the new regulatory model. If the review does not demonstrate an improved level of compliance then further regulatory measures to raise compliance are to be implemented.

The Steering Group noted that it is charged with putting into place appropriate processes during the implementation period to ensure appropriate standards and consistency within the approvals process.

The advertising regulatory scheme agreed by the Interim Ministerial Council describe the key elements of the approvals scheme. There are two processes of approvals envisaged:

### 1. Approvals by Central Approvals Officers

These Approvals Officers would operate within the Central Support Unit. The ANZTPA will have the power to delegate the responsibility for approving advertisements to industry associations, where the ANZTPA is satisfied that they have suitably experienced and qualified staff in their employ to act as Central Approvals Officers in Australia or New Zealand. These associations may be granted the power to approve, or refuse to approve, advertisements for all classes of therapeutic products or a designated class of therapeutic products.

### 2. Approvals by Delegated Authorities

On written application, certain delegations may also be granted by the ANZTPA to persons employed in the therapeutic products, advertising or media industries to approve or refuse to approve advertisements which are minor revisions of advertisements which

have already been approved by a Central Approvals Officer. These persons would be known as Delegated Authorities.

The Chair pointed out the importance of consistency of decision-making in interpretation of the advertising code by approvals officers. In order to help ensure appropriate standards, consistency of decision making and good communication, the Central Approvals Officers will need:

- standard operating procedures;
- an IT database to record decision-making and relevant outcomes;
- mechanisms for them to audit advertisements they have approved;
- a communication strategy to ensure close communication and sharing of information between Central Approvals Officers;
- a reporting mechanism to the Advertising Council and its Management subcommittee;
- opportunities to provide training and education to the therapeutic products industry sectors, health professionals and media/advertisers of therapeutic products; and
- assistance to co-ordinate the development of training programs for accreditation of delegated authorities and to help in the management of the accreditation scheme.

Delegated Authorities will need:

- a training and accreditation program developed
- on-going education requirements to be specified
- a communication strategy to ensure close communication with the Central Approvals Officers, and the ability to feed data on their approvals activities into the central scheme.

Members appreciated that New Zealand already has a system for delegated authorities in place and in operation. Australia does not, although some Australian companies have delegated authorities authorised to operate for advertising by that company in New Zealand. A brief description of how delegated authorities work in New Zealand was provided to members.

The Steering Group's advice was sought on how to put in place the requirements for Central Approvals Officers and Delegated Authorities in each country which would ensure that there appropriate high-standards and consistency within the approvals processes.

The statistics on approvals in Australia and New Zealand that were discussed at the August 2006 Therapeutic Goods Advertising Code Council meeting and which helped set the context for the volume of approvals currently in each country, were provided to members.

### Outcome

The Steering Group agreed that establishing the Central Support Unit (in which the approvals officers would be employed) as a virtual office would not be a barrier to ensuring consistency of standards and operation of the approvals process. This is how the New Zealand TAPS process works at present. ANZA offered to provide to the next Steering Group meeting any standard operating procedures TAPS has in place to support effectiveness of its operation in a virtual office.

The meeting agreed that while delegated authorities had been in place in New Zealand for some time, introduction of a system of delegated authorities for Australia should be delayed until the new scheme is bedded down and experience has been gained in its operation.

## **8. Development of procedural rules for the complaints resolution process**

The Steering Group noted that the Interim Ministerial Council agreed on a process for complaints resolution and review of decisions in each country as follows.

- A Central Complaints Panel is to be established for each country, 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.
- Membership of the Panels will be drawn from a common pool of experts from both countries. The Chair of each Panel will determine the appropriate membership of their Panel to hear complaints.
- In both countries the Panel is to have as a minimum the Chair and seven other expert members, as described in the model agreed by the Interim Ministerial Council. The expertise to be included in each of the two Panels is expressed a little differently, to reflect current differences in the constitution of complaints panels and in recognition that these differences “work” for each country. It is expressly stated that in appointing the pool of experts, the Ministers will give due consideration to expertise already available in New Zealand through membership of the Advertising Standards Complaints Board.
- It is envisaged that the ANZTPA will be able to delegate enforcement powers to the Central Complaints Panels in the actions they may take, including issuing ‘enforceable directions’ and arranging for the issue of infringement notices (minor fines) under certain circumstances.
- In Australia, review of decisions of the Central Complaints Panel (where requested) will be undertaken first by the ANZTPA, and subsequently through an external merits review tribunal if necessary. Finally an appeal may be made to the courts.
- In New Zealand, the first line of review will be through application to the Advertising Standards Complaints Appeal Board. Parties to a complaint may then proceed to seek review by the ANZTPA, external review to a merits review tribunal, and then the courts – if necessary.

Members were informed that the manner in which the Central Complaints Panels and subsequent review/appeals mechanisms will operate will be set out in the Advertising Rules.

The complaint resolution processes that need to be put in place for the new trans-Tasman advertising scheme were briefly summarised for Members.

To this end the Steering Group’s advice was sought on operationalising the agreed complaints resolution processes in respect of:

- how to establish a central ‘mail box’ for receipt of complaints in each country (acknowledging that New Zealand already has one in place);
- developing a standard operating procedure for ensuring complaints are referred to and handled by the correct complaints handling body and that the bodies interface effectively;
- identifying the fields necessary in a centralised data base for monitoring and evaluation the complaints resolution system (discussed under agenda item 9); and
- developing an ‘operations manual’ for the Central Complaints Panels complementary to the generic operations advice for ANZTPA expert advisory committees, as appropriate.

### **A. Establishing a central mail box for complaints.**

Members appreciated that a key element of the complaints-handling part of the scheme in each country is the establishment of a central complaints mail box, whereby all complaints regardless of their origin or destination, come through one central box. Comments were

provided on the New Zealand experience as this country already has such an arrangement in place may have.

The Steering Group was aware that the TGACC is seeking to put in place a central mail box for complaints, ahead of the trans Tasman scheme. The TGACC requested the Steering Group's collaboration in how to put this in place and make the community aware of it, to ensure anything put in place now meshes with plans for the future. It was noted that the public awareness campaign needed to ensure community awareness of the 'mail box' will be part of the overall awareness campaign which was discussed under agenda item 10.

#### **B. Standard operating procedures for complaints 'traffic'.**

The Chair commented that given the number of players in the new scheme who will be involved in the complaints handling scheme, it will be essential to have a good 'road map' of how and where complaints and their outcome should flow. Accordingly, the Steering Group's advice on the needs for this 'road map' was sought.

The Steering Group supported the development a draft road map for complaints for the Group's future consideration.

#### **C. Monitoring and evaluating the complaints handling process.**

This matter was discussed under agenda item 9 where implementation of the whole monitoring and evaluation framework will be discussed.

#### **D. Developing an operations manual for the Central Complaints Panels.**

It was noted that work is currently being undertaken by the Joint Agency Establishment Group on generic operations advice to guide all ANZTPA expert advisory committees, and that this work could be pertinent to the operation of the Complaints Panels.

#### Outcome

The meeting agreed that Australia should move as soon as possible to introduce a central mail box for complaints about advertising of therapeutic goods, so that it is well established as the New Zealand one already is, by the time the new scheme comes into effect. The TGACC was identified by the Steering Group as the body which would be best placed to 'host' the mail box. The introduction of a central mail box for Australia would need to be supported by an appropriate level of publicity, which could be achieved through media releases and communication by the bodies represented at the TGACC with their members. The Secretariat will communicate this advice to the next meeting of the TGACC (11 October 2006) and joint members of the TGACC and the Steering Group could also assist the discussion by the TGACC.

It was also recognised that complaints handling processes at the food-medicine and the cosmetics-medicine interfaces will continue to need to work seamlessly to ensure that complaints are handled through the appropriate body. The Secretariat will communicate with FSANZ and the Health Claims Watchdog, and ACCORD when the TGACC is ready to implement a central mail box to inform them of the initiative and to help ensure referrals between the jurisdictions occur as appropriate.

Members supported the development of a standard operating procedure to help ensure the swift referral of complaints from the central mail box to the appropriate complaints handling body, and reporting back to the TGACC once the complaint has been resolved for monitoring and evaluation purposes.

The meeting noted that the Joint Agency Establishment Group of TGA and Medsafe is developing an operations manual for the ANZTPA's expert committees. This manual is anticipated to be of assistance to the Central Complaints Panels, and to the Advertising Council which will itself be an expert advisory committee to the ANZTPA.

## **9. Implementing the monitoring and evaluation framework and developing an IT system to support it**

The Steering Group's advice was sought on:

- further work that needs to be undertaken to allow the IAC Monitoring and Evaluation Framework for the trans-Tasman advertising scheme to be brought into effect; and
- how to proceed with building an IT system which
  - collects all necessary data relevant to the IAC monitoring and evaluation framework;
  - allows access to all relevant stakeholders;
  - has the capacity to produce meaningful and the necessary reports; and
  - is cost effective

### **A. The Monitoring and Evaluation Framework**

Members were informed that Attachment 2 to the IAC report provides an evaluation framework for the trans-Tasman regulation of advertising of therapeutic products. Extensive work was undertaken by the IAC in developing this comprehensive framework for the new advertising scheme.

The monitoring and evaluation framework has as its centrepiece a set of key performance indicators for the new advertising regulatory scheme. Attachment A to the framework description (pages 20-24 of Attachment 2 to the IAC report) sets out for each proposed specific performance indicator, the relevant data that needs to be recorded, how often and when it should be collected, and any issues associated with the collection of the data.

Some of these data need to be collected as baseline data, before the trans-Tasman scheme commences. The framework also outlines how some key case studies could augment the quantitative data collected.

The importance of a formalised comprehensive and systematic monitoring and evaluation framework was noted particularly a system which:

- ensured all aspects of the new scheme can be adequately evaluated;
- allowed the strengths of the new scheme to be acknowledged;
- allowed the need for any changes to be identified;
- allowed the Advertising Council to make a regular clear report and appropriate recommendations about the scheme, to the Managing Director (and through/him/her to the Ministerial Council).

It was noted that there remains a lot of work to develop appropriate data-collecting methodologies and mechanisms to allow the monitoring and evaluation framework to be put into effect.

### **B. Developing the IT system**

The Steering Group considered that a comprehensive and responsive IT system that is accessible to the stakeholders who need to use it within the trans-Tasman regulatory scheme will be central to the operation of the scheme. Such an IT system would need to:

- collect all necessary data relevant to the monitoring and evaluation framework;

- allow access to all relevant stakeholders;
- has the capacity to produce meaningful and the necessary reports; and
- is cost effective.

Members appreciated that accountability of the scheme to stakeholders will be paramount, and sound reporting of monitoring and evaluation of its operation are essential to this accountability. A good IT system will deliver the capacity for the desirable level of accountability and on-going review of the scheme.

The Chair pointed out that it had been established during the IAC's lifetime that the development of an IT system to support the trans-Tasman advertising co-regulatory scheme would be the best undertaken outside of the ANZTPA's centralised IT system. An IAC IT working group had done some work towards developing the principles to guide specifications for such a system.

Members were aware that some work has already been done between the various industry bodies, the TGACC and the New Zealand Advertising Standards Association towards developing a technical specification for a relevant IT system. Mr Wiggs and Ms Seifert commented on work in this area that has been undertaken by their respective organisations.

#### Outcome

The development of an IT system capable of capturing all the necessary data to report on the operation of the new scheme against the key performance indicators in the agreed monitoring and evaluation framework, was identified as the next key step towards systematic monitoring and evaluation of the current, and then the new, schemes. The industry members agreed to meet to discuss next steps, with the TGA being an invited observer to the meeting(s). New Zealand's new database will be considered as a starting point for a trans-Tasman advertising IT system. A spokesperson from the meeting(s) will report back to the next Steering Group meeting on suggestions for progressing a trans-Tasman IT system.

## **10. Co-ordinating an education campaign tailored for specific stakeholders**

The Chair highlighted that the IAC had recognised that an education campaign would be important to the operation, recognition and credibility of the new trans-Tasman advertising regulatory scheme (as detailed in pages 81-83 of its report) through ensuring community awareness of the new advertising scheme.

The IAC believed a joint approach of a one-off government funded awareness education campaign, supported by an ongoing campaign delivered through existing communication networks and partnerships, should be undertaken.

The Steering Group noted that the possibility of a government-funded education initiative remains unlikely. The most the Government might be able to do is deliver some of the key messages as part of its existing or planned stakeholder communications associated with the launch of the joint regulatory scheme. However, the relevant pages of the IAC report give clear detail of the key messages which need to be communicated to each stakeholder group to be targeted by the campaign as the new scheme is rolled out.

To this end the Steering Group was asked to provide advice on the next steps in helping to ensure that the new scheme is recognised, understood and appropriately used by each of its

stakeholder groups. In particular advice was sought on:

- identifying possible initiatives with which there might be collaboration; and
- the next steps in having a comprehensive education campaign ready to roll out.

The option of building the key messages for each stakeholder group into existing or planned communication initiatives of other groups to be directed to the various stakeholder groups was considered.

### Outcome

The meeting acknowledged the importance of forward planning to try to ensure that, even in the absence of government funding, an effective education campaign which would reach the key stakeholders within the new scheme could be conducted. The Secretariat is to develop a paper for a later meeting which will build in (but not be limited to):

- a calendar of events likely to occur around the launch of the new scheme that could help raise awareness of and deliver information about it;
- developing a standard advertisement about the scheme and where to go for more information that publishers would run without charge;
- identifying government educational initiatives with which collaboration could be arranged;
- identifying health professional educational activities which could assist with dissemination of key messages;
- considering an on-line training option for some target groups (based on a model developed by MIAA);
- working with on-going advertising educational initiatives including those supported by the AFA, APB, ASA and TGACC;
- direct mail-outs from the regulator to product licence holders; and
- working with other publicity that will occur around the new ANZTPA scheme.

The key messages for various target groups identified in the IAC Report (October 2004) would form the basis for developing the campaign.

## **11. Refining the strategy for transition from the current Australian and New Zealand advertising regulatory schemes, to the new scheme**

The Chair advised that it was not feasible to present the Steering Group with a comprehensive transition strategy from ‘the existing’ to ‘the new’ until final operational details of ‘the new’ scheme have been agreed.

The key issue identified at this stage was to make sure that the ‘custodians’ of the existing advertising schemes in Australia and New Zealand were kept well apprised of the proposals for the new trans-Tasman scheme, and have the opportunity to provide relevant advice on it.

To this end, the regulators, TGA and Medsafe, and New Zealand’s self-regulatory bodies, the ASA and ANZA have representation on the Steering Group. So do the industry and professional bodies with self-regulatory processes or registration boards in place.

It was noted that in New Zealand, Medsafe, the ASA and ANZA might be considered to be custodians of their system, and that representatives of each of these bodies were members of the Steering Group. In Australia, the TGACC might be viewed as the overall custodian of the co-regulatory part of the system, with the Complaints Resolution Panel and Advertising

Services Managers being co-partners but none of these groups are represented on the Steering Group. The Chair of Australia's Complaints Resolution Panel and the Advertising Services Managers participate in meetings of the TGACC.

Members were aware that the IAC had recommended that the Steering Group share its agenda papers and minutes with the TGACC, and vice versa.

It was recommended that these 'custodians' of the existing schemes who have membership on the Steering Group take responsibility for reporting back to and consulting with their members/constituencies, and feed information back to the Steering Group.

It was further recommended that the Steering Group agree to share its agenda papers and minutes with the TGACC, and vice versa. It was considered that through this communication pathway, awareness of the new scheme and input of these key Australian stakeholders into the Steering Group's proceedings would be assured.

#### Outcome

It was agreed that communication from the Steering Group to all of the bodies involved in nominating the Group's members (as key stakeholders) was essential to ensure that all players in the current schemes were aware of plans for implementing the new scheme. Each Member undertook to communicate this information to their constituencies throughout the life of the Steering Group.

The Steering Group recommended that the TGACC Secretary be invited to attend meetings of the Steering Group from now on. The Secretary of the TGACC is also the Secretary for the Complaints Resolution Panel, and was the Secretary to the Interim Advertising Council. The meeting agreed the Steering Group would gain from the experience and knowledge accumulated by the TGACC Secretary through these various roles, and her participation in meetings would help deliver a close collaboration between the Steering Group and the TGACC. New Zealand's ANZA and ASA have members on the Steering Group and this arrangement for Australia would mirror New Zealand's arrangements for managing the interface between the current and the new schemes.

## **12. Other business**

Members were invited to raise any business items for discussion by the Steering Group which had not arisen under other agenda items.

The costs of the proposed arrangements as detailed in the IAC Report (pages 72-78) was raised.

#### Outcome

The Secretariat undertook to liaise within the TGA on the cost recovery model proposed for the Authority, to be assured that the advertising part of the scheme would be cost recovered. In the cost recovery model considered by the IAC an amount was expected to be cost recovered through the proposed notification scheme. This scheme is not going to be implemented, at least in the first three years of the scheme's operation, and so assurance is needed that other fees and charges associated with advertising will cover the costs of the scheme.

### **13. Close**

The Chair closed the meeting at 4.05pm and thanked all members and alternates for their contributions. Additionally the secretariat was asked to pass on a note of thanks to the Hotel.

## **TERMS OF REFERENCE FOR THE STEERING GROUP TO IMPLEMENT THE NEW TRANS-TASMAN REGULATORY MODEL FOR THE ADVERTISING OF THERAPEUTIC PRODUCTS**

The Steering Group will advise the Joint Agency Management Committee (JAMC) on the following:

- finalising the trans-Tasman Advertising Code and preparing appropriate guideline documents for release with the Code;
- developing a training and accreditation program for delegated authorities;
- co-ordinating the development of an education campaign tailored for specific stakeholders;
- the capabilities of the IT system being developed by industry to track approvals and complaints, particularly in relation to how this IT system can support the implementation of the monitoring and evaluation framework;
- any governance arrangements which need to be in place for the commencement of the new model, including canvassing legal and contractual options for the establishment of the Central Support Unit;
- whether the central approvals officers in Australia (employed by the industry associations) should be physically co-located in the Central Support Unit or whether this could be a “virtual” office;
- the development of procedural rules for dealing with complaints;
- liaising with the healthcare professional boards (or other appropriate regulatory bodies) to:
  - develop agreed processes for the adoption of the trans-Tasman Advertising Code into professional codes of conduct; and
  - clarify the role of the boards in self regulation including the handling of complaints which involve advertising by healthcare professionals; and
- refining the strategy for the transition from the current legislative requirements in Australia to the requirements of the new regulatory model for advertising.

The Steering Group is also to act as a co-ordination point to advise the JAMC on stakeholder views on implementation issues through liaising with New Zealand stakeholders and the Therapeutic Goods Advertising Code Council.

### **Working Parties**

In undertaking this work, the Steering Group may form working parties as required to facilitate the development of specific aspects of the new model. Where these working parties have been formed to consider any aspects of the model which involve matters of public health and safety, membership must include appropriate representation from healthcare practitioners.

### **Frequency**

The Steering Group is likely to meet up to six times during the implementation period, although some of these meetings may be via teleconference. At least one meeting is to be held in New Zealand.

### **Operation of Meetings**

Each meeting will have an agenda. Actions and outcomes will be distributed to members. The Steering Group is to liaise closely with the Therapeutic Goods Advertising Code Council (TGACC) with the minutes of each meeting of the Steering Group included on the agenda of the following meeting of the TGACC.