

**Advertising Implementation Steering Group  
Meeting 2 – 22 November 2006  
Conference Room 3 – Scarborough House  
WODEN ACT 2605  
Final Minutes**

**Item 1            Opening**

The Chair opened the meeting at 9:05 am and welcomed Members, alternates and the Secretariat.

**MEMBER**

Sue Knowles  
Brett Andrews  
Jenny Bergin  
Pio Cesarin  
Myles Chandler  
Lesley Clarke  
Mike Cocks  
Jean Drage  
Janne Graham  
Dr John Gullotta  
Jeremy Irwin  
Julie Kirsop  
Dr Tony Lewis  
Deborah Monk  
Tony Miller  
Lianne Richards  
Juliet Seifert  
Glen Wiggs

**REPRESENTING**

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

**ALTERNATES**

Marilyn Anderson  
Matthew Boylan  
James Poulos

**REPRESENTING**

New Zealand Regulator  
Australian Natural Healthcare Practitioners  
Australian Television Media

**OBSERVER**

Judith Brimer

**REPRESENTING**

Therapeutic Goods Advertising Code Council

**SECRETARIAT**

Dr Fiona Cumming  
Michael O'Connor  
David Poulton

Members received apologies from Dr Susan Martindale (New Zealand Regulator), Raymond Khoury (Australian Natural Healthcare Practitioners) and Alina Bain (Australian Television Media), and noted that there was no representative of the Australian Radio Media at the meeting.

The Chair welcomed Ms Judith Brimer, Secretary of the Therapeutic Goods Advertising Code Council (TGACC) as a permanent observer to the AISG.

The Chair commended the amount of work that had been completed out-of-session since the first meeting of AISG and thanked all those Members involved.

The Chair also thanked Members for agreeing to re-locate the second meeting to Canberra and reminded Members of the need to provide a completed conflict-of-interest statement to the Secretariat for each meeting. Kay Hick was thanked for her work with the Steering Group Secretariat and her replacement, David Poulton, was welcomed.

The Chair apologised on behalf of the Secretariat for the delay in producing the minutes from the first meeting of AISG and noted the urgency of parliamentary commitments they had at the time.

## **Item 2                    Minutes of AISG Meeting 1**

A Member recalled that during discussion of Item 3I (Member consultation with stakeholders) at AISG-1, Members had noted:

- there was no formal consultative process included in the AISG program;
- there was a broad range of work, with a correspondingly broad range of stakeholders, to be completed by the AISG during implementation of the Advertising Scheme (the Scheme); and
- the success of the Scheme was based on transparency and dependent on good information being freely available to stakeholders with ongoing debate about how the Scheme would work;

During further discussion of the Item 3I consultative issue, Members noted:

- the model for the Advertising Scheme has been agreed by Ministers and extensive stakeholder consultation already completed in relation to this model. Accordingly, there should be caution over suggesting the Implementation Group may be re-opening, or be seen to re-open, public consultation over this model;
- the role of the AISG, as expressed in the TORs, is to implement the operational aspects of the Scheme, not to facilitate or coordinate further stakeholder consultation about the intent, policy decisions, or content of any elements of the Scheme;
- the AISG, through its Members and their representative constituencies, is a key part of the broader consultative process for the Scheme. These aggregated member constituencies give the AISG enormous consultative reach out to industry, professional, consumer, and regulatory

stakeholders with an interest in the mechanics and detail of implementation;

- timely and effective consultation by Members with constituents was linked to early availability of the actions and outcomes following the meeting and allowing adequate consultative time through early availability of the agenda; and
- feedback and transparency will also be facilitated through the publication of AISG minutes and other relevant information on the ANZTPA project website.

Despite this discussion, Members agreed there was no need for amendment of Item 3I.

Members recalled from the first meeting of AISG that for the Communication Campaign (Item 5B), communication of advice about the code and lodging a complaint had been discussed in a much broader context than the specific media context referred to in the Minutes. In particular, the reference cited was used as an example based on the size of this media grouping, their strong adherence to and support for particular forms of complementary medicine and consequent strong involvement with advertising of therapeutic goods and services. Members agreed that the Secretariat re-word the outcome for this item to refer to the broader “ethnic media” as part of the education campaign.

### **Outcomes**

Members agreed to the minutes of the first meeting of the AISG subject to amendment of the outcome for item 5B – Communication Campaign, to read:

“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.”

Members agreed that the draft outcomes and actions from each meeting should be circulated within two weeks of the meeting and the draft agenda approximately one month before the next meeting.

### **ACTION**

Secretariat to amend the outcome for item 5B of the draft minutes.

Secretariat to circulate the draft outcomes and actions within two weeks following each meeting and the draft agenda approximately one month before the next meeting.

Secretariat to publish final Minutes of AISG-1 on the ANZTPA project website.

**Item 2.1 Submission Forwarded by the Australian Natural Healthcare Practitioner**

**OUTCOME**

Members noted the comments provided by Australian Natural Therapists Association Ltd regarding the matters considered at AISG-1 and agreed that these be considered during discussion of the relevant items at this meeting.

**Item 3 The Advertising Code**

Members recalled that at the first meeting of AISG (Item 5A) they agreed that the Advertising Code (the Code) would be restructured into a regulatory version and an explanatory guideline, prior to user testing. The regulatory provisions of the Code were to be re-drafted into a precise, technical, legislative instrument that would later form the basis for the Managing Director's Order. The Guideline to the Code would then provide guidance on interpretation of the regulatory provisions, taking into account the different target groups who may use the Code.

Members were advised that the existing regulatory document would require detailed re-drafting if it was to meet the necessary standards for legal precision and enforceability.

Members noted during discussion:

- The enabling legislation and the Advertising Rule will be built around the Code, which is the reverse of usual procedure. This makes the wording of the Code far more critical than it might otherwise be;
- The basic principles of the Code eg P3 – Social Responsibility, must not be changed in any way that alters the agreed intent or outcomes of the Code;
- Greater precision in the wording would act to preserve the original intent of the code, rather than opening it to re-interpretation through the courts which may lead to unintended consequences; and
- Ultimately any decision made under the Scheme can be reviewed under the legislation and must therefore be legally defensible.

**OUTCOME**

Members noted the work that has been done on developing two versions of the Advertising Code following on the advice of AISG-1 and noted that the next step in the process will be to obtain legal drafting resources for the regulatory version which will become a Managing Director's Order.

Members noted that user testing of the code and its supporting guideline should await legal scrutiny of the code.

## **ACTION**

Secretariat to seek legal assistance to allow the regulatory version of the Advertising Code to be drafted so that it is legally enforceable.

### **Item 3.1           The Code – Advertising to Pharmacy Assistants**

Members recalled that advertising to pharmacy assistants was discussed at the first meeting of AISG (Item 5B – Communication Campaign) in the context of whether pharmacy assistants should be included within the definition of healthcare professionals for the purposes of advertising. The AISG had suggested the Secretariat discuss this matter with the Pharmacy Guild of Australia.

Members were advised that the proposed meeting had not yet proceeded. In discussing the issue further, Members considered;

- The need to avoid creating artificial distinctions between media advertisements meant for registered pharmacists (healthcare professionals) and those directed to pharmacy assistants (PAs) (currently considered as “consumers”) when both types of advertisements were freely available to PAs in the workplace;
- The primary distinction was whether advertising direct to PAs required pre-approval, noting that all the other requirements relating to advertising to consumers would still apply;
- Educational material was available in the workplace in the form of the product information and consumer medicine information inserts included with the product and that in conjunction with oversight from the pharmacist, were the most accurate source of appropriate educational material for PAs;
- The specific product categories involved were either exempt therapeutic products or listed or pharmacy only medicines, as the remaining categories involved the intervention of a registered pharmacist in any recommendation and sale. Accordingly, the public-health risk associated with not obtaining pre-approval of advertisements for those OTC medicines direct to PAs appeared to be minimal, noting that they would still have to meet all the other requirements of the Code in relation to consumers;
- There was no public health justification for advertising prescription medicines direct to PAs without prior approval and similarly, restricted representations should also require prior approval before use in advertisements to PAs;
- The effectiveness of and compliance with an exemption from pre-approval would be assessed through the monitoring and evaluation framework set out by the Interim Advertising Council (IAC);

The pragmatic approach was therefore to continue to treat pharmacy assistants as consumers but to exempt advertisements for certain OTC products directly to pharmacy assistants from the requirement for pre-approval.

## **OUTCOME**

Members were of the view that a pragmatic approach should be considered and noted that this approach would be carefully monitored during the early days of the new scheme.

Members noted that advertising of prescription medicines directly to pharmacy assistants would continue to be subject to each country's legal requirement for advertising to consumers.

## **ACTION**

Secretariat to amend the Advertising Code to exempt certain OTC medicines advertisements directed solely to pharmacy assistants from requiring approval, but otherwise these advertisements continue to be subject to part B1 of the Advertising Code (that is, the Requirements for advertising to consumers), including any reference to a restricted representation needing approval.

Secretariat to extend the monitoring and evaluation framework to include monitoring the effectiveness and practicality of exempting advertisements directed solely to pharmacy assistants from requiring approval but otherwise continuing to be subject to part B1 of the Advertising Code.

### **Item 3.2 The Code – Fees Associated with Lodging a Complaint**

Members identified at the first meeting of AISG (Item 5B – Communication Campaign - Other matters) the issue of whether consumers may be charged a fee for lodging an advertising complaint with an industry complaint resolution body.

Members noted that the Interim Advertising Council (IAC) had considered this matter and acknowledged that whilst it would be open to industry and professional self-regulatory associations or regulatory boards to charge a fee for considering complaints about advertising to healthcare practitioners, it would be expected that such a fee would be waived where the complainant was a consumer.

During further discussion, Members considered:

- The potential for bogus consumer advertising complaints being organised by industry against competitors by proxy through individuals;
- The use of conflict-of-interest declarations by existing complaints resolution bodies to minimise proxy complaints and the recommendation of the IAC supporting this approach;
- The existence of a separate consumer complaints system in New Zealand that charged fees for lodgment, which may be waived where the public interest may be served. Competitors (traders and healthcare professionals) could also lodge complaints through this system where a significant consumer interest was served;
- Unanimous affirmation by Members that the healthcare professional and industry, complaint resolution bodies either do not charge, or waive, fees for lodgment of consumer complaints; and

- Likewise, Members affirmed no other fees were levied by complaints resolution bodies in relation to the processing and finalisation of consumer complaints.

## OUTCOMES

Members confirmed that each industry complaint resolution body did not charge, or always waived, fees to consumers for the lodging and resolution of an advertising complaint.

Members noted the requirement in some circumstances, that the complainant complete a “conflict of interest” declaration when lodging a complaint as a consumer to help prevent “competitor complaints” being framed as a “consumer complaint”.

Members advised that all other fees were detailed in the individual industry codes provided previously to the Secretariat.

Members noted that the cost recovery arrangements for the new Scheme were discussed under Item 10.

### **Item 3.3      The Code – Serious Effects/Contraindications in Advertisements for OTC and Complementary Medicines**

Members recalled that Part B1- Requirement 2 (Paragraph a(ii)) of the Code requires that where an advertisement for a medicine is for a product which “...when used according to the directions:

- has known serious adverse effects (in terms of severity and clinical importance); or
- is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI),

an appropriate warning of those effects must be given...”, and that interpretation and implementation of this requirement had been identified for further consideration at the first meeting of the AISG (Item 5D – Other Matters). Members noted at this time, the IAC recommendation had cost and advertising space implications for advertisers.

Members noted the information supplied on the TAPS requirements for supplementary warnings, the CIOMS definitions of “common” and “very common” in relation to the incidence of an effect, and the EU definition of “serious adverse effect”.

While there was considerable discussion around this need for additional side effect and contraindication specific warnings, supplementary to the other mandatory warnings, Members were reminded that there had been extensive discussion at IAC of this point. A Member was of the view that:

- It was important that consumers be advised in advertisements when a product was NOT appropriate for use by them or where there may be significant risks from using the product; and
- The decision point as to whether a product was suitable for a consumer should be when they read/see/hear the advertisement, not after they have selected the product from the shelf and may then subsequently read the label or CMI/PI.

During further discussion Members considered that:

- It was important to avoid conveying minor, less important or overly complex issues through a medium (advertising) that by its very nature was inherently limited in the space and/or time available. Equally, it was just as important with this medium to avoid information overload or clutter, so that the consumer impact of these supplementary warnings was not lost;
- The EU definition and the more restrictive of the CIOMS cut-offs (common, 1% incidence) may be inappropriately used in this context;
- The target audience needs to be clearly identified in the way the advertisement is framed;
- There was a need for a common sense approach to the definition of “serious adverse effect” in combination with a lower cut-off for the incidence of the adverse effect, below which a warning of the effect would not be required; and
- The TAPS principles for supplementary warnings provided an acceptable starting point for resolving this issue. Specifically these principles were identified as:
  - When the medicine was taken as directed
  - The effect was life-threatening or irreversible
  - The incidence was around or above 10% (CIOMS “very common”)

To take this forward, Members agreed that the views of relevant expert government committees in both Australia and New Zealand should be sought in relation to this approach.

## **OUTCOMES**

Members agreed that a commonsense approach be adopted in deciding when known serious side effects and contraindications for therapeutic products must be included in advertisements, that is, when the product is used in accordance with directions and:

- (a) the serious adverse effect is very common (according to the CIOMS guidelines definition); or
- (b) the adverse effect is life-threatening or irreversible; then that adverse effect should be mentioned in the advertisement, as a minimum.

Advertisements for therapeutic products should also identify specific situations where they should not be used and where precautions are needed.

## **ACTION**

Secretariat to advise the Australian Drug Evaluation Committee (ADEC), NZ Medicines Assessment Advisory Committee (MAAC), Medicines Evaluation Committee (MEC) (Aus), Therapeutic Goods Advertising Code Council (TGACC) (Aus) and the Complementary Medicines Evaluation Committee (CMEC) (Aus) of the above AISG recommendation on including warnings about specific adverse effects and precautions, in advertisements to consumers.

Secretariat to collate any comments and advice from the expert committees and bring back to the next available meeting of AISG for final consideration.

### **Item 3.4 The Code – Mandatory Information – Shelf Talkers and Wobblers**

Members recalled that the inclusion of mandatory statements (Requirement 2 of the Code) on shelf talkers and wobblers had been discussed at the first meeting of AISG (Item 5D – Other Matters).

Members considered that:

- Shelf talkers and wobblers met the definition of advertising;
- This type of advertising, which also included shelf strips, was designed to indicate product location within the retail space and as such was always co-located with the product;
- This type of advertising contained no surplus space for additional information beyond the product/brand name. The inclusion of other promotional statements was recognised as changing the nature of the advertising;
- The label was immediately available and a preferable source of information in this context; and
- Exemption from meeting Requirement 2 of the Code provided the simplest solution to this issue.

## **OUTCOME**

Members agreed that it is not necessary for shelf talkers, wobblers or strips to contain the mandatory information set out in Requirement 2 of the Advertising Code, given that they are always co-located with the therapeutic product and the product label carries all the necessary information for safe use of the product.

## **ACTION**

Secretariat to amend the Code to exclude shelf talkers, wobblers and strips from containing the mandatory information in Requirement 2.

**Item 3.5      The Code – Defining “Serious Risk” in the Context of Advertising to Healthcare Practitioners**

Members agreed at the first meeting of AISG (Item 5D – Other Matters) that a definition of “serious risk” be developed in relation to advertising to healthcare practitioners and the potential impact of this on public health.

Members were advised that the definition would be used to determine whether a complaint about an advertisement to a healthcare professional could be resolved at an industry level or needed to be considered by the Central Complaints Panel or referred to the Regulator. While this screening decision would be made primarily within the Central Support Unit as the main body receiving complaints, other complaints would still be received and screened by industry self-regulatory bodies requiring the use of a common definition for consistent decision making.

There was broad consensus amongst Members that the major public health risk with advertising to healthcare professionals lay with the advertising of a product for unapproved indications. This recognised that when a therapeutic product was used within the license conditions, the public health risks were considered during, and mitigated by the licensing process. However, it will be an offence under the new scheme to advertise unapproved indications to healthcare practitioners.

Members considered the proposal to be too broad and suggested it be refined and reconsidered at the next meeting. Members were of the view that the definition could be combined, refining the principle of advertising being not true, unbalanced or misleading, containing unsubstantiated claims or being socially irresponsible.

**OUTCOME**

Members agreed that guidelines be refined for when an advertisement directed to healthcare practitioners poses a “serious risk” to public health or safety and should then be handled by the Central Complaints Panels or the Regulator.

**ACTION**

Secretariat to refine the proposal considered at AISG-2 for when an advertisement directed to healthcare practitioners poses a “serious risk” to public health or safety and return the item to the February 2007 meeting of AISG.

**Item 4            Governance Arrangements**

**Item 4.1        Employment Options for the Central Support Unit**

Members discussed employment options for the Central Support Unit (CSU) at the first meeting of AISG (Item 6D – The Central Support Unit) but were unable to reach a consensus on the options presented at that time, other than rejecting the formation of a limited company for the CSU.

Members noted from discussion that many individual functions of the CSU had separable responsibilities, for example the Secretary of the CSU (internal) and the

secretariat for (external service) a Committee. Based on this observation there effectively appeared to be two fundamentally different employment responsibilities for the CSU.

The first was a governance responsibility embracing the integrity, accountability and impartiality of the Scheme. This included corporate management and oversight of all functional areas; legal services; provision of the Secretary for each central body e.g. the Central Complaints Panel; establishment and monitoring of operational standards; broad design, establishment and monitoring of education, training and accreditation programs; and coordination and implementation of the monitoring and evaluation of the Scheme's operation. Members felt these could be difficult to devolve to external providers, without compromising either good governance, the intent of the Scheme or the interface, goodwill and communication with stakeholders.

The second was a service responsibility, which included providing corporate services (financial, human resources, information management), secretariat support, approvals, screening and processing complaints, implementation and execution of education, training and accreditation programs, monitoring of and research into the operation of the Scheme, all of which could be readily outsourced to a greater or lesser degree.

Members noted that the extent and mix of outsourced with internal employment affected the mix of administrative overheads to direct costs. Likewise the mode of establishment for the CSU would determine the nature, applicable standards and extent of governance arrangements to be met by the CSU, again influencing the extent, mix and nature of the costs. This was noted as particularly important in regard to the nature and extent of market testing, evaluation and selection for service contracts.

Members agreed that a detailed discussion paper based on a central government core for the CSU, exploring these issues and alternatives was necessary before further progress could be made.

## **OUTCOMES**

Members agreed that there needed to be consideration of which core advertising functions of the CSU including the Secretary and secretariat, approvals and complaints, administrative, monitoring and evaluation, education and training, and accreditation functions should be fulfilled by staff employed directly by ANZTPA and which could be outsourced through contractual arrangements.

Members agreed that the approvals function should continue to be outsourced.

Members noted that outsourcing raised issues of market testing, employment transparency and accountability that needed to be explored further.

## **ACTION**

Secretariat is to develop a discussion paper on the issues and implication raised by this functional split in staffing employment including a proposed structure.

**Item 4.2 Smooth Interfaces Between the Central Complaints Panels,  
Industry Bodies and Professional Bodies**

Industry codes of practice were discussed at the first meeting of AISG (Items 5C – Industry Codes of Practice and 6E – Industry Self Regulatory Bodies) when interested members of AISG agreed to meet as a Working Group out-of-session to compare the various industry codes of practice both for consistency between the codes and with the trans-Tasman Advertising Code.

The Convener of the Working Group advised Members that considerable progress had been made, with the attention of Members drawn to the summary of the codes and the comparison between codes provided in the papers. Further, the Convener advised members that there had been substantial progress made on harmonising the codes in the Self Medication Industry sector and the Complementary Medicines Industry sector had begun addressing their differences.

The Chair conveyed the thanks of the meeting to all those involved in this Working Group, noting that in addition to the two formal meetings that had been completed, significant work had also been completed out-of-session.

The Steering Group considered the following issues during discussion:

- The risk of “forum shopping” was part of the impetus driving the move to consistency of codes within industry sectors. Members recognised that this did not necessarily imply a move to a single code for each sector but outcomes and processes should be equivalent. Members were in agreement that inter-code consistency was an essential part of promoting equity across each industry sector, whether a product licensee was a member of an industry association or not;
- The requirement for adherence to a code of practice as a condition of each product license raised cost recovery issues both for the operation of the Scheme and for individual industry associations in relation to producing, approving, implementing and maintaining their code.
- The requirement for adherence to a code applied to the entire code. This may have implications for those industry codes that make reference to matters outside the scope of the new Agency including in particular food and cosmetics; and
- Sanctions were a problematic point of divergence between codes, however the establishment of maximum fines over broader ranges of offences was being explored as a solution.

**OUTCOME**

Members noted the reports of the first two meetings of the Industry Working Group on Self Regulatory Codes (IWGSRG) and the progress made in identifying differences in the various industry self-regulatory codes which will require resolution.

## **ACTION**

The IWGSRC to report progress on:

- (i) Alignment of codes to the ANZTPA principles;
- (ii) Opinions and action on the adoption of “Promotional Monitoring Panels”;
- (iii) Harmonisation of breach classifications;
- (iv) Complaint and Appeal cost recovery; and
- (v) Alignment of sanctions

at the February 2007 AISG.

## **Item 5 Consumer Consultation Processes**

Members recalled that the first meeting of the Steering Group had acknowledged (Item 6G – Consumer Consultation) that the New Zealand system of regular meetings each year between the ASA (and ANZA) and consumers provided a good forum for sharing of information and identification of emerging issues and that a similar scheme should be established in Australia.

While certain members expressed a preference for the establishment of an overarching consumer consultative committee (IAC Report Recommendation 12), members recalled that Ministers had not endorsed this approach. Members acknowledged that a certain level of resources would be necessary to establish communications networks and foster an appropriate level of expertise in representatives if consumers were to participate effectively in the Scheme. This again raised the issue of the source and level of funding and the competing models for cost recovery.

The consumer representatives agreed to develop a more detailed paper for the next meeting of the Steering Group

## **OUTCOMES**

Members noted the consumer consultation mechanisms that exist in New Zealand in relation to the advertising of therapeutic products and agreed to consider adopting the New Zealand consumer consultation mechanisms as the model for the advertising regulatory scheme in both countries.

Members noted the importance of an appropriate funding source for effective consumer participation in the joint advertising scheme.

## **ACTION**

Consumers to develop a paper for consideration at the February 2007 meeting of AISG, on the mechanism and requirements, including the level of resources needed, to allow consumer networks to effectively participate in the joint advertising scheme.

**Item 6            Approvals**

**Item 6.1        Appropriate Standards and Consistency within the Approvals Process**

This issue was identified for further discussion at the first meeting of AISG (Item 7 – Ensuring Appropriate Standards and Consistency within the Approvals Process) at which ANZA agreed to provide the TAPS procedures for consideration by the Steering Group.

Members noted the TAPS principles and SOPs for the “virtual office”, from which a number of issues were discussed:

- The confidentiality of the industry SOPs derived from the time and money invested in them but would not carry through to the approval SOPs for the Scheme as these were to be published in the public domain;
- “Advice” to advertisers often had to be verbal, as options would be explored off-the-record. Final decisions must be written to provide a clear record and to facilitate communication between approvals officers (AOs) (via the database). Members agreed the wording of the fifth TAPS principle should be amended to clarify this issue;
- Any internal glossary of claims or indications would be rapidly outdated, but the ‘coded indications’ in the product licence database could serve this function;
- AOs should not have to evaluate claims and in particular Members were concerned that advertising approvals should not become a substitute for formal evaluation of efficacy claims elsewhere. This was discussed in the context of weight loss products and certain medical devices and the tendency for non-approval of efficacy claims in one area to establish precedents in another. The Medical Industry Association of Australia (MIAA) expressed particular interest in SOPs that deal with this issue. Members noted that a revised table of coded indications, administered outside the Scheme, would replace the need to refer to an internal glossary of permitted wording of indications. Members agreed that a note clarifying this should be added to TAPS Principle 7;
- The AOs, MIAA and the TGA Advertising Unit should be consulted during the review of existing industry and regulatory approvals SOPs and drafting of common ANZ SOPs for the approvals process in the Scheme. Members requested the non-Prescription Medicines Branch coordinate this review;
- The type and frequency of communication between AOs must be sufficient to foster consistent decision making without being onerous or inefficient. Accordingly Principle 6 should be reworded to replace proscriptive statements with more general outcomes; and
- There should be some recognition of the importance accorded by the Steering Group to face-to-face contact between AOs.

**OUTCOMES**

Members noted the principles for NZ TAPS operating within a virtual office and adopted them with modification:

- (i) A comprehensive set of tight guidelines are needed on commonly-encountered issues to ensure consistency in decision-making;
- (ii) Consultation between officers should guide any decision/advice on each unusual situation;
- (iii) Record sharing is essential;
- (iv) Have a systematic peer-review system in place;
- (v) Decisions will be given to advertisers in writing;
- (vi) Have regular appropriate communication;
- (vii) Establish a glossary of indications (noting that these would be “coded indications” in the product license database); and
- (viii) Occasional face-to-face meetings as required.

Members noted the various operating procedures being applied for approvals functions.

Members agreed that the available SOPs be reviewed and a single agreed draft SOP for the trans-Tasman approval process be developed.

## **ACTION**

Advertising Services Managers, in conjunction with the TGA Advertising Unit and the Medical Industry Association of Australia (MIAA), and in consultation with TAPS review the available Advertising Approval SOPs and draft a single SOP for consideration at the February 2007 meeting of AISG.

Secretariat is to advise Non-Prescription Medicines Branch (TGA) of the proposed review of advertising SOPs and seek their co-ordination of the review with participation by the Advertising Unit.

### **Item 6.2 Delegated Authorities**

This item was agreed without further discussion.

## **OUTCOMES**

Members recalled that at AISG-1 (Item 7 - Ensuring Appropriate Standards and Consistency within the Approvals Process) it was agreed that a delegated authorities system should not be introduced in Australia until the new advertising scheme is bedded down and experience is gained in its operation.

Accordingly, members agreed to defer developing the training and accreditation program for delegated authorities in Australia until such time as delegated authorities are to be introduced there..

*Secretariat Note:* Existing DAs for Australian Companies to issue approvals under the New Zealand Scheme are expected to carry over unchanged into the new joint Advertising Scheme.

## ACTION

Secretariat to include this matter on a future action list for consideration by the ANZTPA Advertising Council.

### **Item 7           Complaints**

Members recalled that the need for and introduction of a central complaints resolution mailbox in Australia was discussed at the first meeting of AISG (Item 8A – Establishing a Central Mailbox for Complaints). TGACC had advised that they were intending to do this ahead of the introduction of the joint Advertising Scheme and sought the collaboration of the Steering group to do this.

The Secretary of the TGACC advised members that a paper on this matter would be considered by TGACC at their next meeting. In this paper, Members of the AISG were advised that the Complaints Resolution Panel had been consulted over the establishment of the mailbox. The panel had advised the TGACC that they were the logical body to undertake this function and recommended their name be amended to reflect this change. A comprehensive education program including media releases and seminars for stakeholders was included in the paper. The paper also proposed that extensive changes to a wide range of industry and regulatory internet sites be made where there is reference to the complaints process. These proposals raised significant resource issues for the TGACC.

Members noted that:

- Complaints in respect of foods and cosmetics would be inevitably lodged with this system and procedures to deal with these seamlessly need to be developed;
- The public would become aware of complaints made in this system only after a determination on the complaint had been made; and
- This would have resource implications for tracking and reporting outcomes and the capacity to do this for consumer complaints, however these would also have to be resolved for the new Scheme.

Members requested they be kept abreast of progress in the establishment of this mailbox.

## **OUTCOMES**

Members recalled the proposal to establish a “centralised complaints mailbox” in regard to advertisements directed at consumers in Australia and noted that this matter had been referred to and was under consideration by the TGACC.

Members noted that the TGACC had consulted with the Complaints Resolution Panel which agreed that it was the most logical body to undertake this function and that their name be amended to the Therapeutic Goods Advertising Complaints Panel to reflect this role.

Members requested the Secretary of the TGACC to provide a further report on progress at the next meeting of AISG in February 07.

## **ACTION**

The Secretary of TGACC (Ms Judith Brimer) is to provide an update on progress establishing a centralised therapeutic goods advertising complaints mailbox in Australia to the February 2007 meeting of AISG.

### **Item 8            Monitoring and Evaluation**

A Working Group on Developing an Advertising IT System (WGDAITS) was established at the first meeting of the AISG (Item 9B – Developing the IT System).

The Convener of the WGDAITS advised Members that at the first meeting:

- An update had been received from the NZ consultant helping with the design and there did not appear to be any hardware or software problems with implementing the proposed system;
- The major issue remaining to be resolved is how to manage and fund the development and maintenance of the system in an efficient and equitable way; and
- The next step for the working group was to finalise how this funding was to be accomplished.

In exploring options for this funding Members of the AISG noted:

- There were three alternate ownership models:
  - (i) ANZTPA development and ownership. The high governance overheads and requirement for DSD DEFINE approved firewall mitigated strongly against this approach;
  - (ii) Establishment of a joint company. The legal and financial complexities of this approach were discussed previously by the Steering Group.
  - (iii) Outsourced with development, management and housing of the system possibly jointly by ASMI/NZSMI under contract to ANZTPA. The method and extent of funding for this approach would be a significant issue to ensure the membership of these organisations did not have to subsidise the operation of the system.
- The major concern was that this may provide another opportunity for cost shedding by those who were not members of Industry or Professional Associations. Therefore, the costs need to be recovered in an equitable manner such that all commercial users of the Scheme paid their share of the development and maintenance of the system;
- While some allowance had been made to defray these costs centrally, the amount agreed in the IAC cost recovery model was now estimated as insufficient to cover the cost of developing, implementing and maintaining the system;
- There may be opportunities to reduce the cost of implementation and maintenance. One example discussed was the security approval of the firewall used by the system. Although the information contained in the database was classified as commercial-in-confidence, a commercial firewall was considered to be acceptable rather than the corresponding Defense Signals Directorate approved firewall, with consequential savings to the system.

- The IAC monitoring and evaluation framework included a number of case studies to be completed as a benchmark for the Scheme. The research approach and resources for this would also need to be included in the revised cost recovery model.
- Research capacity in relation to the monitoring and evaluation framework could be contracted out either on an ad-hoc or ongoing basis. This needed to be considered in the cost recovery model.
- The EU had recently released an extensive benchmarking and discussion paper (Self-Regulation in the EU Advertising Sector: A report of some discussion among Interested parties: Madelin, July 2006) into the self regulation of the European Advertising market. This was considered to offer a useful starting point for local benchmarks. A member agreed to provide a copy of this report.

## **OUTCOMES**

Members noted the report from the Working Group on Developing an Advertising IT System including issues associated with establishing a centralised reporting database;

Members recalled that the evaluation framework for the Trans-Tasman Regulation of Advertising of Therapeutic Products, including key performance indicators, was at Attachment 2 of the IAC Report 2004.

## **ACTION**

Mr Glen Wiggs agreed to provide reference(s) to European benchmarking of advertising regulation, for circulation as part of the papers for this item at the February 2007 meeting of AISG.

### **Item 9            Calendar of Events for the Education Campaign**

The need for a coordinated education campaign was identified in the IAC report and discussed at the first meeting of the AISG (Item 10 – Coordinating an Education Campaign Tailored for Specific Stakeholders) which recognised the importance of forward planning.

Members noted that professional help from a public relations company could cost in the vicinity of \$250,000 for Australia. Members recalled that additional funding for this had not been approved by Ministers and that it would be important to coordinate the education campaign for the Advertising Scheme with other funded publicity for the Joint Scheme.

To this end Members considered a template for the stakeholder education calendar that would capture stakeholders, the messages and the timing.

## **OUTCOMES**

Members noted the structure for the proposed stakeholder education calendar.

## **Item 10 Transition**

Members noted that with the inclusion of the TGACC all the key players in the Scheme were now represented at the table.

Members advised that the outcomes and minutes from meetings were useful in communicating issues to their represented constituencies. Members recognised that feedback from constituents was an important input if a smooth and effective transition was to be achieved. Members agreed that wider circulation of the outcomes and minutes would facilitate stakeholder communication back through Members.

Members discussed the timing of the tabling of Bills and release of the draft Rules. They were advised that the timing of release was not clear at this stage.

### **OUTCOMES**

Members noted that all efforts are being made by key stakeholder groups to help ensure a smooth transition from the existing advertising regulatory schemes in Australia and New Zealand to the new joint scheme.

Members agreed that the outcomes and actions from AISG be forwarded to additional designated organisations and to publish agreed minutes on the ANZTPA project website to foster communications and to facilitate the smooth transition to the new advertising regulatory scheme.

Members agreed to communicate the outcomes from each meeting to relevant stakeholders within their representative group.

Members noted that the enabling legislation was still to be introduced to the parliaments and noted the delay in release of the draft Advertising Rule.

### **ACTION**

Secretariat to forward the actions and outcomes from each meeting of AISG to the TGACC.

Secretariat to publish final Minutes of the AISG meetings on the ANZTPA project website.

## **Item 10.1 Voluntary Implementation of the Price Information Code of Practice**

Members noted that the Price Information Code of Practice was being introduced by TGA on a voluntary basis in Australia on 1 February 2007. Price lists could contain information on pricing of scheduled (3, 4 and 8) medicines which was expected to drive an early but limited increase in complaints through the current Australian complaints system.

## OUTCOME

Members noted that the Price Information Code of Practice will be introduced on a voluntary basis in Australia on 1 February 2007.

### **Item 11 Cost Recovery Arrangements**

The issue of cost recovery was initially raised at the first meeting of AISG (Item 12 – Other Business) where the Secretariat undertook to liaise with TGA on the cost recovery model proposed for the Authority.

Members noted that there were key differences between the IAC proposed model and that approved by the Therapeutic Products Interim Ministerial Council (TPIMC). In particular, the TPIMC did not agree to a notification scheme for advertisements in non-mainstream media and deferred the introduction of delegated authorities in Australia. Both changes would reduce the cost recovery base for the Scheme by about \$280k in total.

There was considerable discussion of the policy framework around cost recovery for the Scheme. Members noted that while this framework was outside the TORs for the Steering Group there was value in restating the boundaries this imposed on the model. Specifically cost recovery implied:

- Users (industry) paid directly or indirectly for all the functions and services necessary to proper operation of the Advertising Scheme;
- Surpluses should not occur in the normal course of operation but in any event could not routinely be carried forward;
- Services and functions deemed to be for the public good were also included in those considered necessary for the proper operation of the Scheme and were to be cost recovered from users;
- All users of the Scheme should be charged equally and equitably for the same services;
- Cross-subsidisation between income generating functions should not occur, subject to the limitations of the cost recovery base for each function.

Members representing professional associations observed that there was a serious cost inequity apparent in the funding of the complaints system for advertising to healthcare professionals (HCP complaints system). Members of each association were expected to fund the installation and maintenance of the infrastructure for the HCP complaints system. Similarly, each association would fund the establishment and approval of their code of conduct and education programs to professionals/traders within their industry sector. Non-members however could avoid these costs yet still have access to the complaints process and derive the benefits from the industry code. This was also recognised as an obvious opportunity for cost shedding unless rectified and was a significant burden in certain sectors where less than half the participants were members of an industry association.

An alternative approach would be to fund the self-regulatory component of the scheme through an increase in the annual license fees for products. This would then be returned to Industry Complaint Resolution Bodies through contracts for the self-

regulatory components. While this would be largely cost neutral for the co-regulatory component of the Scheme, Members recognised that this approach may then cost-penalize those products not sold or promoted through advertising.

With respect to other sources of funding for the Scheme, Members noted:

- Current Government policy is for fines and other monetary sanctions applied under legislation to be returned to consolidated revenue to avoid any actual or perceived conflict of interest for the entity applying the sanctions and suggestions of “revenue-raising”. Government would not change this policy position without compelling reasons;
- Government would not change its policy position in respect of public interest functions, continuing to require these to be cost recovered; and
- Additional funding under the transitional arrangements e.g. for educational programs, was highly unlikely.

Consumer groups expressed particular concern that public interest functions were the most vulnerable under cost recovery arrangements as they could not (by definition) contribute to the cost recovery base. As such, it was important for them, that the funding model clearly showed how and to what extent, the consumer complaints, consultation, and education programs were to be funded.

Members noted that other functions including the Advertising Council were also not self-funding. In addition, certain other functions eg the IT Database had risen in cost since the IAC Cost model was last updated.

Members agreed that an iterative approach should be taken to the funding model for the Scheme and requested the Secretariat refine the existing IAC model taking into account the issues raised in this item and others at the meeting, exploring the funding alternatives discussed.

## **OUTCOME**

Members noted that some further development of the proposed cost-recovery model for the scheme was necessary to take into account how the scheme was to be implemented in each country.

## **ACTION**

Secretariat is to provide a paper to the February 2007 meeting of AISG providing options for cost-recovery arrangements taking into account full implementation of the scheme.

## **Item 12 Other Business**

Members noted there was no other business.

**Item 13      Close**

The meeting closed at 2.25pm. Members noted that the third meeting of AISG will be held in Auckland, New Zealand on 14 February 2007.