

Interim Advertising Council

Meeting 8
26 August 2004
8.00 am – 3.55 pm

The Grand Chancellor Hotel, Auckland

Minutes

1. Attendance

Mr Mike Codd (Chair)	
Dr Chris Arblaster	Australian Self-medication Industry (ASMI) (alt)
Ms Jenny Bergin	Pharmacy representative (Aust and NZ)
Mr Pio Cesarin	Therapeutic Goods Administration
Ms Lesley Clark	Researched Medicines Industry (NZ)
Mr Mike Cocks	Australian advertising industry representative
Ms Pam Davis	Medical devices industry representative (Aust and NZ)
Ms Jean Drage	Consumer representative (NZ)
Mr Colin Harcourt	Australian media industry representative
Mr James Hart	Natural healthcare professional (NZ)
Mr Jeremy Irwin	Association of New Zealand Advertisers (NZ)
Ms Val Johanson	Complementary Healthcare Council of Australia (CHC)
Ms Susan Martindale	Medsafe
Mr Tony Miller	New Zealand Self-medication Industry (SMI)
Dr Robyn Napier	Medical profession representative (Aust and NZ)
Mr Kieran Schneemann	Medicines Australia (Aust and NZ)
Mr Rob Shaw	Dietary supplements industry (NZ)
Dr Derek Weir	Consumer representative (Aust)
Mr Glen Wiggs	Advertising Standards Authority Inc. (NZ)

Ms Judith Brimer	Secretary, IAC Support Group
Ms Sharyn McGregor	IAC Support Group

Apologies

Dr Fiona Cumming	Therapeutic Goods Administration and Executive Secretary, IAC Support Group
Mr Raymond Khoury	Natural healthcare professional (Aust)
Ms Juliet Seifert	Australian Self-Medication Industry (ASMI)

2. Minutes of the meeting held 6 August 2004

The following amendments were accepted:

1. Item 4, para 3, page 2 – add “and websites directed to Australian consumers”
2. Item 5, para 2, last sentence – delete ‘small’
3. Item 5, para 5, - add ‘It was noted that the consultation did not report on the ‘end-cost’ to consumers
4. Item 6, para 9, page 9, line 7 – add, after ‘registered’, a certification of compliance from advertisers’

Moved: Pam Davis

Seconded: Rob Shaw

Acceptance of the minutes of the meeting held on 6 August 2004 in Sydney, Australia, as amended.

Carried

3. Agenda item 1 – Governance and administration of the IAC’s recommended advertising regulatory model.

At the meeting held on 6 August 2004, members had discussed various options for the governance structure of the proposed advertising regulatory model, particularly in relation to:

- the appointment of key staff in the Central Support Unit;
- management of the advertising budget;
- the holding of delegations to exercise certain powers; and
- entering into contracts with the industry associations to provide services relevant to the regulation of advertising.

As requested by members at the last IAC meeting, a paper was developed by the Support Group which clarified the proposed composition and roles of the Advertising Council and its management sub-committee, as well as presenting possible options for the employment of CSU staff, the management of the budget and delegations and the contractual arrangements.

Advertising Council

In informing members of the proposed harmonization of Australian and New Zealand competition and consumer protection regimes, the ASA representative proposed the inclusion of either one or two representatives (depending on the progress of the proposed harmonisation) from the Australian Competition and Consumer Commission / New Zealand Commerce Commission as observer(s) on the Advertising Council.

Members supported the proposal on the basis that it would be made clear in the IAC report that the membership of the Council is to be reviewed after twelve months of operation.

Otherwise, the proposed membership of the Advertising Council, as follows, was accepted.

1. an independent chair appointed by the Ministerial Council;
2. a nominee from the regulator (the Joint Agency);
3. consumer representative from Australia;
4. consumer representative from New Zealand;
5. medical practitioner – joint representative for Australian and New Zealand;

6. pharmacist - joint representative for Australian and New Zealand;
7. natural healthcare practitioner from Australia;
8. natural healthcare practitioner from New Zealand;
9. Prescription medicines New Zealand (RMINZ);
10. Prescription medicines Australia (Medicines Australia);
11. OTC medicines Australia (ASMI);
12. OTC medicines New Zealand (NZSMI);
13. Complementary medicines Australia (CHC);
14. Complementary medicines New Zealand;
15. Medical devices - joint representative for Australian and New Zealand (MIAA / MIANZ).
16. Advertising Standards Authority New Zealand;
17. Advertising industry New Zealand (ANZA);
18. Advertising industry Australia;
19. Australian media – television (Commercial Television Australia);
20. Australian media – radio (Commercial Radio Australia);
21. Australian media – publishers (Australian Publishers Bureau);

It was agreed that the central approvals officers and a representative of the central complaints handling bodies would be invited to attend Advertising Council meetings on an “as needs” basis.

Members agreed that the functions of the Advertising Council should include;

- ensuring that the trans-Tasman advertising scheme protects the public interest and uniform standards are applied;
- considering requirements for the advertising of therapeutic products and changes to the Code, consider matters raised by members, to accept submissions for this purpose and to advise the Therapeutic Products Ministerial Council and/or the Joint Agency through the Managing Director accordingly;
- providing advice to the Therapeutic Products Ministerial Council on the need for any advertising policy changes;
- reviewing regular reports on the operations of the approvals, complaints and appeals mechanisms and on education programs, in both countries;
- recommending changes to processes for handling approvals, complaints and appeals;
- report annually on the effectiveness of the advertising scheme to the Ministerial Council;
- advising the Joint Agency through the Managing Director on the composition of the Central Complaints Panel in Australia and its equivalent in New Zealand;
- developing a mechanism for regular input on the perceived effectiveness of the advertising scheme from interested consumer groups;
- making recommendations to the Managing Director on the endorsement of industry codes of practice;
- making recommendations to the Managing Director on approvals for the use of restricted representations and on requests for review of an approvals decision;
- making recommendations to the Managing Director on the suitability of applicants to hold “delegations” for approvals; and
- with the approval of the Ministerial Council, appoint standing sub-committees of its members to inquire into, and report on, any matter that is within the functions of the Advertising Council.

Members also suggested that the IAC report should clarify that the appointment of sub-committees (as working groups rather than standing sub-committees) to advise the Advertising Council should be able to be approved by the Managing Director rather than needing to be appointed by the Ministerial Council.

Management sub-committee

In considering the membership of the management sub-committee, members agreed that a media representative from Australia should be included in its constitution.

The proposed membership of the management sub-committee was agreed as follows:

1. Chair of the Advertising Council
2. Regulator
3. Consumer (Australia)
4. Consumer (New Zealand)
5. Prescription Medicines (Australia / New Zealand)
6. Complementary Medicines (Australia / New Zealand)
7. OTC Medicines (Australia / New Zealand)
8. Medical Devices (Australia / New Zealand)
9. Advertising Standards Authority (NZ)
10. Association of New Zealand Advertisers (NZ)
11. Advertising (Aust)
12. Media (Aust)

Members also confirmed the role of the sub-committee as that of a 'management sub-committee' (i.e. including considering and making recommendations on policy to the Advertising Council) rather than an 'administrative sub-committee'.

It was agreed that the role of the management sub-committee should include (amongst other activities), the:

- provision of regular reports to the Advertising Council on the operation of the approvals and complaints systems in Australia and New Zealand and on post marketing surveillance; and
- review of policy governing the system and making recommendations for policy change to the Advertising Council.

Employment of Central Support Unit (CSU) staff

Three options were put forward in the discussion paper for consideration by members, as follows:

Option 1

The CSU would be a division of the Joint Agency and its staff employed either directly by the Joint Agency or under contract. Staff would be appointed by the Joint Agency on the advice of the Advertising Council (after advice by the management sub-committee), other than the approvals officers nominated and employed by the industry associations. This option was supported by most members at the meeting held on 6 August 2004.

Option 2

The management sub-committee, established as a company limited by guarantee, would employ all CSU staff (other than approvals officers employed by industry associations). This option had not been supported by most members on 6 August 04.

Option 3

The CEO of the CSU to be established in the Australian Implementing Act as a statutory office holder appointed by the Ministerial Council on advice from the Advertising Council. This option had not been considered by members previously and was put forward by the Support Group to try and address some concerns that had been expressed about the potential loss, under option 1, of a co-regulatory basis for the system.

There was considerable opposition to both options 2 and 3 on the grounds that, in both cases, inappropriate power would be given to a body other than the Advertising Council and that this could provide an opportunity for action to be taken independently of the Council. With respect to option 3, it was suggested that such a model would rely heavily on the quality of the person appointed and would not reflect a trans-Tasman approach.

The ASMI representative expressed reservations at the inclusion of the Central Support Unit within the Joint Agency as outlined in Option 1. It was felt that this could seriously undermine the co-regulatory basis for the system of controls. Furthermore, it was considered that implementing Option 1 could potentially lead to less transparency and accountability should the internal processes of the unit not be subject to similar legal requirements as imposed on registered companies (eg in Australia registered companies are required to comply with the *Corporations Act 2001*). A request was made for the noting of this dissent in the report.

Apart from the ASMI representative, members supported option 1.

Budget for the co-regulatory part of the advertising system and delegations

Members noted that, as per option 1, the CEO, as a member of the Joint Agency staff, would hold the advertising budget and relevant delegations for approvals and complaints.

Clarification was given that delegations to carry out functions would be granted under statute. Members noted that the primary Act(s) will give the Ministerial Council power to establish committees. The constitution, function and roles of the committees would be set out in the Rules.

Complaints

It was agreed that the proposed membership of the Central Complaints Panel would be considered further later in the meeting as part of the discussion on the draft IAC report.

Members confirmed their support for the central complaint body in each country to exist as an independent statutory body, established under the Rules to deal with complaints about advertisements for therapeutic products, and reporting to the Advertising Council.

4. Agenda item 2 – A proposed system for the approval of advertisements for therapeutic products directed to consumers

At the IAC meeting held on 6 August 2004, members expressed serious concern at the poor compliance rate of advertisements that had not been approved which were directed to consumers in Australia. There was considerable support for moving towards a system requiring approval of all advertisements for therapeutic products directed to consumers.

The discussion paper prepared by the Support Group put forward a proposed scheme based on previous IAC consideration of the media-based dividing line in terms of responsibility for advertisements' compliance, i.e. the requirement for approval for all above-the-line material and notification and certification of compliance for all below-the-line material.

The paper described a two phased approach in which the first phase required all advertising material which did not need approval through the central approvals offices in Australia or New Zealand (ie as published in below-the-line media) to be notified through a central database with a certification of compliance. In the second phase industry would be given the responsibility for below the line advertising compliance, on the basis of introducing trained delegated authorities for approving all below the line material. It was expected that there would be training and education of the delegated authorities by the Central Support Unit. Random or targeted reviews of notified advertisements could be done on the basis of a percentage of the approvals on a quarterly basis.

The CHC representative requested that the Support Group confirm with the consultant the interpretation of Clause 6.2 of the Australian Therapeutic Goods Advertising Code in establishing the compliance figures.

Internet

Discussion, in the first instance, was centred on the definition of 'specified' media and the inclusion of the internet within that definition. Members were of the view that the accepted term should be 'mainstream' media ('specified' should become obsolete) and that the definition should include all electronic media.

It was agreed that website advertising would most appropriately be excluded from the requirement of pre-approval through a specific reference in the Code, rather than as an exclusion under the definition of "mainstream" media. It was noted that under this proposal notification and certification of compliance would be required for any advertisement on a website.

There was some discussion on the previously accepted view that, where an advertisement includes a reference directing consumers to obtain further information (from another source), the information in the referenced material relevant to the advertisement may be taken into account in considering the advertisement. It was suggested that, in the interest of public health and safety, it is important for the possibility for any link to be included. It was noted that the wording of the clause allows a commonsense approach to be taken when looking at referenced material.

The wording in the IAC report is to accommodate the above interpretation.

It was confirmed that the dissent of the Australian media representative to this view had been included in the draft IAC report.

Timeframes

Some members expressed concern as to the feasibility of introducing the proposed staged system of pre-approval for all below-the-line advertisements by 1 July 2006. The reasons for the concerns were that:

- the volume of material is unknown, but it is estimated that it could potentially be anywhere between 20,000 to 100,000;
- it may not be possible to acquire sufficient regulatory expertise, training and accreditation for delegated authorities by 1 July 06;
- the introduction of other regulatory requirements for some industry sectors for the first time will be a significant challenge in itself; and
- moving from no requirement for approval (e.g. alternative devices) to 100% approval within 12 months could present significant difficulties for sponsors.

Other members argued that as sponsors are required to certify compliance with advertising requirements at the time of placing products on the notification database, it should be possible for responsibility for preapproval to be accepted by the end of a twelve month period, particularly if the services of the industry associations are utilised, and that this would serve the public interest. It was suggested that by not proceeding with the previously agreed 12 month timeframe, a valuable opportunity to ensure that the public interest is met would be lost.

The representative of the medical device industry also suggested that, for medical devices, as much of the volume of advertising material is for low risk medical devices, there may not be a need from a public health and safety perspective, to move to a similar approval system for these type of advertisements.

After further discussion, members agreed that it would be worthwhile trying to influence advertisers' behaviour over a two-year period, by introducing a model in which, for below-the-line material, there would be:

- a requirement for the notification of each advertisement on a central database;
- issuing of a unique number for each advertisement on the payment of a fee; and
- the recording of certification of compliance by the advertiser.

It was proposed that the money collected from these fees could be applied to required education of sponsors, the program to be developed by the Central Support Unit (CSU) in consultation with industry associations and conducted through the industry associations or, for non-members, by the CSU.

Members generally agreed to this approach. It was felt that by the end of the first twelve-month period, sufficient evidence should be available through comprehensive post-market surveillance to assess whether or not the combination of education and self-certification was effective. If so, compliance costs would be minimised while maintaining standards necessary for public health and safety. Safeguards would be built into the model through quarterly monitoring and the complaints process. These safeguards could be further strengthened

through drafting the legislation in such a way that would require sponsors/advertisers to have all of their advertisements approved centrally where (for example) they were shown to repeatedly make false certifications or fail to lodge notifications.

If this approach was found not to be working after twelve months, the training and accreditation of delegated authorities by the Central Support Unit for the approval of below-the-line material could proceed over the following twelve months, with the introduction in the legislation of the requirement for approval from 1 July 2007.

It was suggested that this approach would dovetail well into the current pre-vetting system in New Zealand.

The AMA representative restated her concern that the suggested change to the previously proposed approvals process (ie in not committing to the phased implementation of approvals for all advertisements of therapeutic products) was not in the public interest.

The majority of members agreed that the model as outlined above should be included in the draft IAC report.

5. Agenda item 3 – An education program – audiences and key messages

At the request of members at the last meeting, a paper outlining a proposed education program for the communication of key messages to target audiences was developed by the Support Group to further the discussion.

The Chairman introduced the discussion by noting the importance of a proper advertising campaign. As an alternative to industry funding a public education campaign specifically on advertising controls on a cost recovery basis, it was suggested that a submission should be made to both Ministers for a once-off allocation of money from government for a public education campaign to inform consumers about the joint Agency, and include advertising under that campaign umbrella.

The complaints process was seen as fundamental to the success of the system and, to ensure that there is confidence in the evaluation after twelve months operation, it was considered to be important for consumers to be aware of the principles and mechanisms underpinning the system, including where to complain.

Members suggested that any rationale put forward for government funding of the initial campaign should:

- outline the potential public health and the financial benefits to government;
- note the significant input and acceptance of industry's responsibility to ongoing monitoring and education; and
- note that government is also a partner in health related advertising.

There would be a need for a proper assessment of requirements and costs for such a campaign (including advertising) within the context of the joint Agency.

Several suggestions were made by members on the proposed key messages (and their delivery) that should be directed to consumers, healthcare practitioners, media and therapeutic products industry, including:

- the addition of retailers, the food and cosmetics industries and governments agencies as audiences;
- noting where copies of the Code can be obtained;
- strengthening the wording on consumers' right to complain and the process for complaint;
- inclusion of a reference to the penalties for non-compliance;
- appropriate reference to post-market surveillance;
- the requirements for media and advertising industries should mirror those for the therapeutic products industry;
- the wording of the section on how the key messages to consumers could be delivered should include reference to New Zealand Ministry of Health programs which are similar to the Quality Use of Medicines program in the Australian Department of Health and Ageing;
- the most effective means of delivery would need to be identified and could be likely to include the development of a pamphlet.

There was some discussion on the importance of the display of approval numbers in terms of providing a guarantee for, or giving confidence to, consumers. The potential down the track for the use of a logo, not only on websites but also as a self-certification or pre-approval indication in below-the-line material, was also discussed. It was suggested that this approach could be worthy of further consideration. The inclusion of approval numbers in broadcast advertisements was seen as an advantage for consumers by some members and as adding to 'clutter' by others.

In summary, it was agreed that the report should acknowledge the need for a wider campaign, which is linked to a joint Agency campaign, that such a campaign should be funded by government rather than by cost recovery from industry, and that industry, through the usual cost recovery processes, should fund ongoing education and monitoring.

6. Agenda item 4 – Model for cost recovery

In considering the cost impact of the proposed regulatory model, Acumen Alliance had been engaged to report on the current regulatory models for advertising in Australia and New Zealand and the estimated cost of the proposed trans-Tasman regulatory model.

This report was discussed in some detail at the last IAC meeting (6 August 2004). At that meeting IAC members recommended that more work be done on refining a cost recovery model based on the Acumen Alliance report. It was agreed that these refinements should include:

- a recognition of issues of equity;
- correction of any figures which may be inaccurate due to a lack of information and/or clarity; and
- additional costing estimates for certain activities related to the transitional arrangements.

A revised model was presented to members, which factored in, as requested:

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- the potential impact of the new scheme on those industries which have previously been outside of advertising controls in Australia and New Zealand or have not been required to contribute to the cost of controls on advertising;
- the cost of self-regulatory activities relevant to advertising borne by industry associations in Australia and New Zealand;
- the need to limit any cross-subsidisation between therapeutic product sectors or between countries;
- the need for the final IAC report to take into account a preliminary cost estimate of the proposed central database for approvals and complaints, based on a user requirement document, which would need to be as close as possible to finalised by the final IAC meeting in mid October.

The paper addressed the issues raised by members at the last meeting by identifying costing elements and by proposing a multifaceted, user-pays approach to a revenue base, so as to ensure equity.

On further discussion, it was suggested that the costs section of the IAC report needs to reflect:

- the inclusion of the medical devices and NZ dietary supplements industries in the advertising scheme;
- any transitional costs, including a more realistic estimate for IT costs; and
- identification of the advertising activities in New Zealand which are expected to remain self-funding.

It was acknowledged by members that, because there are costs in Australia the equivalent of which are self-funded in New Zealand, it would be necessary to apply loadings to approval and notification fees in Australia but that the margin should be as narrow as possible. For this reason, the charge for the advertising component included in the annual product charge should remain at current levels. The difficulty of estimating the volume of “notifiable” advertisements and, therefore, the potential income stream from that source was also noted.

There was broad agreement that the cost recovery model should be based on:

- an annual product licence charge component which would remain at the current level as applied in Australia for annual product charges for registered and listed goods on the ARTG;
- a time based fee for approvals which could be marginally higher in Australia than New Zealand in recognition of the self-funded component of the New Zealand advertising scheme
- a notification fee which should be no more than A\$10 in Australia and A\$7 in New Zealand.

It was also emphasised that the administrative system for collecting notification fees must be simple and not impose unnecessary overheads on either the Joint Agency or sponsors/advertisers. The possibility of quarterly retrospective invoicing was suggested.

It was agreed that the Support Group should continue to refine the cost recovery model based on the above criteria.

7. Agenda item 5 – Transitional arrangements workprogram

The agenda paper for this item set out the key elements of the proposed transitional program which would need to be in place between the time of Ministerial approval for a new regulatory model and implementation of the approved model.

It was suggested that once the Parliamentary timetable is available, it should be possible to establish a ‘critical path’ in which the timeframe for each element is identified.

The Chairman noted the expectation that the IAC will conclude its work on 12/13 October, and that the Therapeutic Goods Advertising Code Council will continue operating until 30 June 2005, with New Zealand representatives invited to participate in TGACC meetings. He expressed the hope that the Trans Tasman Therapeutic Products Advertising Code will be introduced in both countries before 1 July 2005.

Members recommended the formation of a small steering committee to progress the work required to implement the proposed advertising regulatory model during the period October 2004 – 1 July 2005. It was suggested that the constitution of this committee could be based on that of the proposed management sub-committee to the Advertising Council.

IT Working Party

Members noted that the Therapeutic Goods Administration's Trans Tasman Group is to establish a user working party to document the user requirements for the IT systems necessary to support the proposed trans Tasman advertising arrangements. It was explained that this process would include reviewing the IT systems that currently are in place in Australia and New Zealand and, where possible, considering how best these could be integrated. This work will enable the IAC to include a reasonable estimate of IT costs associated with tracking and reporting on complaints and approvals in the costing section of the IAC report.

Self-certification and the notification scheme for below-the-line advertising

Members agreed that it was unnecessary for the notification of “below-the-line” advertisements to include details of the actual advertising text. It was agreed that requiring one notification entry for each advertisement placed in separate media would enable a rapid lodgement process and more effective IT management.

Members indicated their support for the central approvals offices in Australia and New Zealand to be delegated the power to request through a written notice that advertisements with specified notification numbers be supplied by sponsors/advertisers for review within a specified period of time. Provision should be made to impose appropriate sanctions or penalties for failing to comply with this notice, including the possibility of requiring all advertisements to be approved centrally.

Agenda item 5.1 Feedback from the Therapeutic Goods Advertising Code Council(TGACC) meeting held on Thursday 12 August 2004

Modified updated version of the Therapeutic Goods Advertising Code(TGAC)

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As a result of a call from industry for a lengthy transitional period, particularly with respect to approvals, it had been hoped to introduce the Trans Tasman Therapeutic Products Advertising Code (TPAC) before 1 July 2005. As the TGA had indicated that it would be unlikely for the existing Australian legislation to be changed before 1 July 2005, a modified TGAC was developed (incorporating as much as possible of the TPAC) for consideration of TGACC members on 12 August 04.

The introduction of the modified TGAC, thereby having a two-step introduction of the trans-Tasman Advertising Code, was seen to be confusing for advertisers by some TGACC members. Members also felt that it would be necessary for the TPAC to be approved by the Interim Ministerial Council before consideration could be given to a modified TGAC.

Should the Ministers endorse the proposed TPAC before the next TGACC meeting, it is expected that the TGACC will reconsider the possibility of changing the TGAC to more closely align with the TPAC.

It was noted that the Support Group is to prepare a summary of the major differences between the current TGAC and the new TPAC.

Sampling, giveaways and competitions

While the current TGAC prohibits the advertising of samples and giveaways of therapeutic goods, the majority of members of the TGACC and the IAC supported removing this prohibition in favour of a more principles based provision based on not encouraging inappropriate or excessive use.

It was noted that the TGACC had received correspondence on this matter from the Therapeutic Goods Administration, which confirmed the view that unless an exemption had been granted, advertising of samples and giveaways was contrary to the quality use of medicines policy. It was noted that the dissenting view of the Therapeutic Goods Administration to the proposal to change the current prohibition under clause 4.6 of the TGAC was included in the draft IAC report.

Health claims in food advertising

Members noted the following:

- The ASA representative reported the commissioning of a report proposing a trans Tasman food advertising code, including pre-approval and complaints mechanisms;
- A copy of the Initial Assessment Report, Proposal P293, Nutrition, Health and Related Claims is to be provided to TGACC members for comment;
- The section in the above report on enforcement was considered by TGACC members to be inadequate.

Agenda item 5.2 Transitional arrangements for the approval of advertisements

A paper had been prepared by the Support Group to further the discussion on transitional arrangements, especially with respect to the introduction of the TPAC and approvals timeframes.

The medical devices representative suggested that the two month lodgement period provided for in the draft IAC report for those advertisements which, while not requiring approval under the current regulatory advertising schemes, would be subject to approval as part of the proposed new approvals process and code was inadequate. Members agreed that in the absence of any certainty regarding the potential number of advertisements for medical devices which would require approval, a six month lodgement period post implementation of the new advertising model would be more appropriate. This extended period would also allow for training of medical device approvals officers and appropriate education of sponsors. It was confirmed that, during this six-month period, advertisements for medical devices would still need to comply with either the current codes in Australia or New Zealand or the TPAC (depending on when the advertisement was first published).

It was suggested that the proposed education campaign package to the therapeutic products industry which was proposed to be launched prior to the implementation of the new regulatory model, include a questionnaire in which sponsors could indicate exemptions and identify those advertisements that will require pre-approval. This would provide invaluable information on volumes and allow for timeframes to be adjusted, if necessary.

In considering the transition period and the need for a streamlined process, members had previously suggested that the current codes in Australia and New Zealand could be amended, before the commencement of the new regulatory model for advertising, to include relevant provisions of the TPAC. Noting that this suggestion would need the support of the TGACC in Australia, the Chairman indicated that at the TGACC meeting held in August 2004 there was limited support in Australia for changing the current TGAC and then introducing the TPAC in mid 2005.

Taking into account the views of the TGACC, IAC members were invited to comment on the following options which were included in the discussion paper

- It could be possible to avoid the two-step process by:
 - promoting a paper containing the differences between the current TGAC and the Advertising Code to industry before the end of 2004, on the understanding that any approvals given between 1 January 2005 and 1 July 2005 would have validity only until 1 July 2006;
 - or
 - by introducing the modified, updated TGAC as soon as possible after endorsement by Ministers of the Advertising Code, the current two year approval period in Australia for all advertisements approved before the introduction of the Advertising Code on 1 July 2005 could be retained. This would require drafting instructions for the legislation to allow those approved within that period to continue to be regulated under the Australian *Therapeutic Goods Act 1989* and associated regulations.

If either of these options were adopted, it was noted that there would need to be a transitional period during which the Central Complaints Panel would potentially need to consider advertisements for compliance with either the TGAC or the trans-Tasman code, depending on when the advertisement had been approved. It would be expected that during this transitional period, an advertisement which was approved under the TGAC would not have access to automatic approval in New Zealand.

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The ASMI and CHC representatives endorsed the retention of the two year approval timeframe.

Members noted that if the modified TGAC was introduced on 1 January 2005, there would be closer alignment with New Zealand, given the intention to introduce the TPAC there as soon as possible after its endorsement by Ministers. It was confirmed that this matter would need to be reconsidered by TGACC, following Ministerial approval for the proposed TPAC.

8. Agenda item 6 – Draft IAC report, incorporating Version 9 of the draft Australia New Zealand Therapeutic Products Advertising Code (TPAC)

Version 9, TPAC

The Chairman reminded members that there had been ‘sign-off’ on the draft Code by members, subject to written comments, two meetings previously. Outstanding issues still to be finalised were noted as:

- whether or not there is a need to include a definition of, and the requirements for, brand-only advertisements;
- whether or not endorsement by healthcare practitioners of prescription products in New Zealand should be prohibited ;
- finalising the mandatory warning statements for advertisements for medical devices;
- whether or not there is need to impose further restrictions on the advertising of the offer of a sample/giveaway and competitions; and
- the acceptance of anonymous complaints in Australia.

Members were assured that the records of dissent from members on certain aspects of the TPAC which had been sent to the IAC Support Group had been included in the draft IAC report.

Press releases

After some debate on whether or not press releases should be mentioned in the draft Code, **it was agreed that the reference to press releases included in A3.1 on page 6 of the Code should be removed.**

Brand-only advertisements

Members agreed that the issue of brand-only advertisements could be addressed by amending Requirement 2 as follows:

“An advertisement for therapeutic products must include all of the required statements in paragraphs (a) to (e), other than where:

The advertisement does not contain a therapeutic claim and displays only the brand / name / picture of the therapeutic products or the name of the sponsor and/or the price and/or point of sale;...”

Mandatory statements for medical devices advertising

Papers from the medical devices and Australian consumer representative containing differing views on the requirement for inclusion in all advertisements for therapeutic products of the mandatory statement “Always read the label” were circulated with the agenda papers.

The issue was resolved by all members agreeing to include in the Code the following words:

“Always read the label and/or, as appropriate, follow the instructions.”

Endorsement by healthcare practitioners

The RMI representative raised concerns about the TPAC permitting endorsements by healthcare practitioners of prescription medicines, whereas this practice is prohibited under the RMI Code of Practice in New Zealand.

Members noted that the TPAC is the minimum standard to be applied to the advertising of therapeutic products and that the industry associations may wish to impose additional requirements or restrictions through their codes. As it is expected that the RMI Code of Practice would be endorsed by the Advertising Council under the proposed scheme, it was not considered necessary for the TPAC and the RMI Code of Practice to necessarily adopt a harmonised approach to endorsements for prescription medicines by healthcare practitioners.

It was agreed that the wording of Requirement 6 should be retained.

The acceptance of anonymous complaints

After some discussion, it was agreed that the current suggested approach in Australia should be retained, i.e. **anonymous complaints will not be accepted but the identity of a complainant can be withheld on request.**

Other issues raised by members in relation to the Code included:

- The introduction of another step in the appeals process for New Zealand compared with the usual appeal process under the new therapeutic product legislation
- Clarification in the Code that advertising directed to healthcare practitioners will not require pre-approval;
- Clarification, by including in A4.2, page 11, first line, the words after ‘Advertisements which appear in mainstream media’, other than the internet;
- The language of the Code is to be checked by the medical devices representative to ensure that there is no inconsistency with respect to that sector;
- Members felt that it could be premature at this stage to engage a communications expert to advise on the readability of the Code and that this suggestion could be reconsidered after it has been used for some time. The majority agreed that the suggested two column format for the Code was preferable in the interim;
- To address problems with the advertising direct to healthcare practitioners of compounded products, members agreed to include in B3, page 20, after the second dot point, the words ‘must comply with the Code and’ to read:
Whenever a therapeutic claim is made for:
 - *an active ingredient that may be used in the manufacture of therapeutic products; or*
 - *a product which is exempt from product licensing;*

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it must comply with the Code and the data used by the supplier to verify the claim must be offered by the company representative.

It was suggested that submitting comments in writing to the Support Group before, or at, the September consultation meetings would be the most effective means for stakeholders to provide their input for inclusion in the final report. It was acknowledged that all stakeholders should be given the opportunity to submit written comment on the proposed regulatory model up until 23 September 2004. It is expected that these comments will be considered at the final meeting of the IAC, scheduled for mid October 2004.

The Support Group indicated that it is intended that Version 10 of the Code will be posted on the TGA and Joint Agency websites by Friday 3 September.

The pharmacy representative raised some concerns about a number of clauses of the Code. It was suggested that the Support Group meet with the pharmacy representative out-of-session to clarify some of these issues.

The Chairman asked that members provide their input on the draft report in writing to the Support Group.

The meeting closed at 3.55pm.