

Interim Advertising Council

Meeting 5
8 December 2003
8.00 am – 4.00 pm

The Hotel Grand Chancellor
Auckland

Ratified Minutes

1. Attendance

Present

Mr Mike Codd (Chair)	
Ms Marilyn Anderson	Medsafe
Ms Jenny Bergin	Pharmacy representative (Aust and NZ)
Mr Pio Cesarin	Therapeutic Goods Administration
Mr Mike Cocks	Australian media/advertising industry representative
Ms Jean Drage	Consumer representative (NZ)
Mr James Hart	Natural healthcare profession (Aust and NZ)
Mr Jeremy Irwin	Association of New Zealand Advertisers (NZ)
Ms Val Johanson	Complementary Healthcare Council of Australia (CHC)
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)
Ms Juliet Seifert	Australian Self-medication Industry (ASMI)
Dr Derek Weir	Consumer representative (Aust)
Mr Glen Wiggs	Advertising Standards Authority Inc. (NZ)

Dr Fiona Cumming	Therapeutic Goods Administration and Executive Secretary, IAC Support Group
Ms Judith Brimer	Secretary, IAC Support Group

Apology

Ms Susan Martindale	Medsafe
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2. Welcome

The Chairman welcomed Ms Marilyn Anderson, Medsafe alternate, to the meeting and informed members that Ms Faye Sumner, New Zealand medical devices representative, as agreed at the last meeting, would be in attendance for the discussion on item 7 of the agenda.

3. Minutes

The following amendments were requested:

1. page 6, item 7, delete the last two sentences.
2. page 7, item 7, add to the last paragraph, “should the New Zealand government decide to accept that these goods are to be regulated by the joint Agency”.
3. page 8, item 9c, replace ‘serious’ with ‘substantial’
4. page 9, item 9 point 2, delete ‘including pre-approval, and complaints handling through the co-regulatory processes;’
5. page 11, para. 4. Replace ‘It was accepted’ with ‘There was majority acceptance’.
6. page 11, para 7, second sentence, add ‘about advertisements directed to consumers’ after ‘complaints’
7. page 14, delete k) and insert ‘including trade practices advice, after ‘expert advice’
8. page 14, insert new paragraph ‘The pharmacy representative expressed the view that it is important to have a balance of industry and healthcare practitioners in the constitution of the Central Complaints Panel.’ after the first paragraph on the discussion on the membership of the panel.
9. page 15, para. 2, replace ‘serious’ with ‘significant’
10. page 17, para 4, first line, insert after ‘argued’ the words ‘at least in the short to medium term’ and after ‘line’ the words ‘until there is evidence to support its removal’ and in the second last line, after ‘would act’ insert ‘as’
11. page 18, para. 3, second line, after ‘to order’ add ‘the advertiser to remove’ and delete ‘removal’
12. page 18, para 4, replace ‘advertisements’ with ‘approvals, not only for specified media but also for below-the-line advertisements.’
13. page 18, para 5, replace ‘would be passed’ with ‘could be introduced’ and insert after ‘Australia,’ the words ‘or soon thereafter’
14. page 18, delete the last paragraph

The minutes were accepted as amended.

4. Agenda item 1, Mechanisms for consumer consultation

The New Zealand and Australia consumer representatives had prepared submissions on possible models for consumer consultation and involvement in the proposed advertising arrangements.

In introducing the discussion, the New Zealand consumer representative suggested that a consumer advisory committee for advertising matters established in the legislation would give consumers a genuine voice and add strength to decision making processes.

The Australian consumer representative suggested that a community advisory committee for which there are excellent precedents, rather than a purely consumer advisory committee, could provide a valuable mechanism for regulatory/community relationships, enable focus on priority concerns and provide a common point of access.

In further discussion, the need to establish another consumer statutory body with its associated costs was questioned. It was suggested that the broader need for such a body for the joint agency, rather than one specifically for advertising, could be supported. The New Zealand representatives commented on the value of the existing, informal Code Consultative Committee comprising consumers, advertisers, government and TAPS adjudicators, which meets three times per year. The purpose of the committee is for briefings on current advertising issues and to make recommendations about the New Zealand Therapeutics Advertising Code.

It was noted that part of the role of the Advertising Board will be to consult with relevant stakeholders where appropriate and that consumers are a special group that needs to be drawn effectively into the consultation process.

It was suggested that the final IAC report should note that the majority of IAC members recommend that:

- the Joint Agency consider establishing a consumer advisory committee, established in the legislation, to advise the agency on all therapeutic products regulatory matters, including advertising.
- an informal, regular consultation process be established in Australia, along the lines of the existing New Zealand consultative process (which should be maintained, to address issues relating specifically to advertising arrangements; and
- those elements of the new system that involve specific consumer consultation or education be funded directly by government rather than by industry.

The Chairman thanked the consumer representatives for their work and contributions.

5. Agenda item 2

Agenda item 2.4 Advertising to healthcare practitioners – section B3 draft from the working party

The working party established to devise section B3, Advertising to healthcare practitioners, of the Advertising Code, had provided a draft which was circulated with the agenda papers.

The Chairman drew members' attention to Appendix 1 in which proposed exclusions were listed, and to the proposed additional rule (7), and invited comment on the paper.

In noting the concern of some natural healthcare practitioners in Australia at the application of the Advertising Code to healthcare practitioners, the CHC representative was of the view that there had been only limited consultation on this issue. It was suggested that this would be a major change from the current Therapeutic Goods Advertising Code which specifically excludes healthcare practitioners.

In subsequent discussion, the CHC representative indicated that the parts of the complementary industry sector, including some healthcare practitioners, were concerned about restricting claims in material directed to healthcare practitioners to the indications entered on the database. However, this concern would be addressed if it was accepted that such material is for educational rather than promotional purposes

It was explained that, as generic information that is either educational or bona fide research is exempt from the Advertising Code, factual new information can be provided even where the indications are not entered on the database. It was noted that, under section 22(5) of the *Therapeutic Goods Act 1989*, it is an offence to advertise therapeutic goods in Australia for an indication other than those included in the Australian Register of Therapeutic Goods. It is expected that this requirement would continue into the new system.

When further doubt was expressed as to the reason for including a section on advertising to healthcare practitioners in the Advertising Code, the ASMI representative explained that industry associations were extremely keen to see their own codes maintained and endorsed by the new Advertising Board. She said that in order to achieve that, and to retain the value of the industry codes, industry associations must demonstrate the application of a minimum benchmark standard in relation to principles that should apply to advertising to healthcare professionals and inclusion of advertising to Healthcare Professionals in the Advertising Code set such a benchmark. It was noted that currently some of the industry codes have authorization from the Australian Competition and Consumer Commission (ACCC). Given that ACCC authorisation in Australia would no longer be applicable when working in two jurisdictions, endorsement instead by the Advertising Board would be necessary.

Members' attention was drawn to the current legal underpinning of the Medicines Australia Code of Practice, with compliance with that code a condition of registration for prescription medicines, and to the previous IAC recommendation that compliance with any industry code authorised by the Advertising Boards become a condition of issuing a product licence. The ASMI representative supported this recommendation, as it was seen to provide the broadest coverage possible for the industry code and a level playing across the whole sector, rather than for just the membership of any one organization within that sector.

The Chairman confirmed that reference to the industry codes in the Advertising Code and endorsement by the Advertising Board, on the basis of their consistency with baseline principles, would enable compliance with the relevant industry code to be a condition of a product licence. Both non-members and members of the industry associations, therefore, would be bound by the relevant industry code.

When it was suggested that a reference in the Code to a requirement for such advertisements to comply with industry codes could suffice, it was explained that, as the codes differ, a minimum common baseline standard must be established to ensure consistency of standards across all codes. It was noted that the principles in proposed section B3 are written in such a way as to enable all sectors to meet the basic requirements, regardless of those differences.

The application of the additional requirement (7) to all sectors was then queried by the CHC representative?.

Requirement 7

7. All communications, including verbal statements, made by company representatives must comply with the Code. Wherever a therapeutic claim is made, a company representative must offer the approved Product Information or other substantiation of efficacy provided by the sponsor to the Trans Tasman Therapeutic Products Agency.

It was explained that this clause had been framed to require the application of whatever provision relating to evidence supporting claims is required in the relevant jurisdiction and to take account of likely recommendations from the Australian Expert Committee on Complementary Medicines in the Health System.

There was some discussion on the inclusion of the words 'including verbal statements' in Requirement 7. Members were of the view that because communications by company representatives involving verbal statements could be considered a conduct issue, it would be appropriate for industry associations to manage this conduct. However, there remained the expectation by most members that promotion of products by company representatives should stay within the limits of legitimate information held on the joint agency data base in terms of indications and claims.

It was agreed that the words ‘including verbal statements’ be deleted from Requirement 7. A reference to the industry codes of practice dealing with verbal statements and other issues of conduct relating to communication by company representatives is to be added under Requirement 7.

Discussion on Appendix 1, section B3.

The medical practitioner representative informed members of the New Zealand Medical Association’s position that, for the protection of the community, Requirement 6 should be retained.

It was agreed that because of the knowledge and experience of healthcare professionals, retention of the second part of the Requirement would not be appropriate but that the first part, i.e. ‘Advertisements must not unduly glamorize products or services’ should be included as Requirement 6.

Requirement 5

Clarification was sought on exclusions for clinical trials and research from this requirement. It was suggested that there should be transparency where funding has been provided by a product licence holder and that a reference to coverage of this issue by industry codes should be included as a note to Requirement 9, along the lines of “Industry codes address ways of ensuring transparency in appropriate cases for sponsor funding of research.”

PHARMAC is to be added to exclusion from this requirement of any statement about listing on the PBS.

The majority of members agreed that the paper prepared by the working party on advertising to healthcare practitioners should be incorporated into the Advertising Code as part B3.

Agenda item 2.3, written submissions from stakeholders - submission from the Australian Traditional Medicines Society (ATMS)

Following the stakeholder consultation in Sydney on 27 November, an ATMS representative made a submission on various aspects of the proposed Advertising Code.

Members considered the points raised in the submission as follows:

Item B - definition of ‘healthcare practitioner’

It was noted that the requirements for recognition as a healthcare practitioner (professional) differ between Australia and New Zealand. In Australia, there is a list of healthcare professionals that have been recognised by the TGA, on the basis of number of

members and professional standards, as able to receive advertising directed to healthcare professionals. In New Zealand, under the Health Practitioners Competence Assurance Act 2003 a healthcare professional is a person who is, or is deemed to be, registered with an authority as a practitioner of a particular health profession. As there is no requirement to register under the Act, there are many practising healthcare practitioners that are not registered.

It was suggested that a definition appropriate for both countries could be developed on a principles-based approach, with requirements that any recognised body would normally have in place a code of ethics, a code of practice and accreditation, continuing education, complaints and appeals mechanisms.

It was noted that this is a ‘work in progress’ with clarification required before 1 July 2005.

Item C - Education, research and professional advice

It was suggested that clarification be provided to the ATMS representative that, in fact, the Advertising Code will have the force of the law.

Item D – Advertising of therapeutic goods to healthcare practitioners

It was noted that the issues raised in the submission had been raised by the CHC representative earlier in the meeting.

There was some further discussion on the difference between material which was promoting a product and purely educational material. It was agreed that in providing educational material, no promotional material should be included.

The CHC representative again expressed the view that information about ingredients that are not on the register should be able to be provided to healthcare practitioners and not regulated as an advertisement.

The Chairman clarified that the current requirements for such material are no different from those proposed in the trans Tasman Advertising Code.

Item E Complaints process

The comments were noted.

The paper from Health World Limited was noted.

The paper from Peter Ochsenham was discussed

There appeared to be a misunderstanding in the paper about the requirements for the advertising of raw materials to healthcare professionals. There was clarification given

that advertising to healthcare professionals about finished product would be required to comply with the Advertising Code.

Agenda item 2.1 Feedback from stakeholder consultation meetings - revised Advertising Code

A revised Advertising Code (Version 6a) was tabled, in which suggested rewording by the Support Group based on the IAC meeting held on 20-21 November and feedback from the stakeholder consultation meetings held in Australia on the 27 November and New Zealand on 28 November 2003 were colour coded.

The minutes of the consultation meetings were noted.

Agenda item 2.2 Matters arising from stakeholder consultations

A paper on particular policy issues raised at the stakeholder consultation meetings was tabled by the IAC Support Group. Members took into account the approaches put forward, and the recommendations made in the paper, with respect to disclosure of active ingredients, inclusion of serious adverse effects and the status of disease state campaigns when reconsidering the Advertising Code. It was noted that the issues related to advertisements directed to healthcare practitioners had been dealt with earlier in the meeting. The item on 'other' therapeutic products was noted.

Version 7 of the Advertising Code, including colour coded changes and comments as a result of members' consideration of Version 6a, is to be found at Attachment A.

An outline of the amendments and reasons for the changes are provided at Attachment B.

It was noted that part B4, General processes had been rewritten by the Support Group.

In noting that stakeholders at both consultation meetings had called for further broad consultation, **the Chairman proposed one additional consultation meeting in Australia and in New Zealand, to be held on 3 February 2004 in New Zealand (after the proposed meeting with complementary industry) and on 4 February 2004 in Australia.**

Agenda item 2.5 Authorization of industry codes

A paper on clarification of the relationship between the Advertising Code and industry and professional codes of practice had been circulated with the agenda papers.

There was some discussion on the possible lack of authority for the industry associations to impose fines on non-members. It was suggested that if, as a condition of product licence compliance were to be required with authorised industry codes, there may be doubt as to whether this would give sufficient legal authority for industry associations to apply to fines to non-members. In that event, the fines may have to apply centrally. The

Medicines Australia representative said that currently in Australia fines are imposed on both members and non-members.

Further work is to be done on the legal means for the application of fines to non-members of associations for non-compliance with the relevant industry code.

The paper was noted.

Agenda item 2.6 ACCC feedback

A report on the recommendations of the Australian Competition and Consumer Commission (ACCC) on the potential overlap of advertising controls between trade practices legislation in Australia and the proposed trans-Tasman products legislation had been circulated with the agenda.

The paper was noted.

6. Agenda item 3 - Workplan

As there were a number of important questions to be answered and discussed about transition and cost issues raised in the paper prepared for agenda item 5, for which there would be insufficient time to address at this meeting, it was agreed that another IAC meeting should be scheduled for 2 February 2004.

It was noted that the agenda for the meeting to be held on 20 February 2004, would contain two items, being, firstly, the consideration of the paper on medical devices and the proposed arrangements and, secondly, consideration of the draft report.

The workplan is to be amended to accommodate the additional IAC and consultation meetings to be held on 2, 3 and 4 February 2004.

The workplan was noted.

7. Agenda item 4 – Advertising Board membership

The Chairman advised it was expected that the existing template for membership of the IAC would carry forward to the Advertising Board and noted the wish of the Australian media, the medical devices industry (both countries) and New Zealand complementary medicines industries for direct representation on the Board. Should this be accepted, the number of members on the Board would expand from fifteen to eighteen.

While accepting the suitability of this constitution for the transition phase under the governance of the IAC, the ASA and ANZA representatives proposed consideration of another option for the constitution of the final Advertising Board. This proposal suggested a membership of 9, with an independent chair and 8 others drawn from consumers and those responsible for advertising and managing the system. That is, there would be 4 members from each country comprising one consumer representative (in New

Zealand's case nominated by health consumer organisations) and one each from the manufacturing, advertising and media industries.

In the discussion, the following comments were made:

1. As the system would be relying on the media for effective compliance, there is a strong case for separate media representation on the Board;
2. If the Board is to meet 6 times per year, the smaller it is the more effective it is likely to be.
3. If the membership of the Board was restricted to eight plus the Chair, it would be inevitable that, in Australia, a body such as the existing Therapeutic Goods Advertising Code Council would be required to draw in regulators and professional expertise, so a two-tiered management structure would result.
4. There is a need to take the representation of the New Zealand complementary products industry sector into account.
5. The possibility of scaling back the size of the Board, once the new system is operating, should be flagged.

A revised paper on the proposed structure of the Advertising Board is to be prepared for the IAC meeting to be held on 2 February 2004.

8. Agenda item 7 – Advertising of medical devices, New Zealand

At the last IAC meeting, it was suggested that a representative of the New Zealand devices sector be invited to attend this meeting, thus providing an opportunity for New Zealand focussed issues to be raised.

The Chairman welcomed Ms Faye Sumner, as the Chief Executive Officer of the Medical Industry Association of New Zealand, to the meeting.

Ms Sumner thanked the Chairman for the opportunity provided to her for this discussion and said that the industry sector is very conscious of the lack of representation on the IAC despite the introduction of regulation of the sector. She noted the close working relationship of the Medical Industry Association of New Zealand with the MDARG.

The following matters were canvassed in the discussion:

- a) the need to consider the implementation of the advertising requirements in relation to the regulatory timeframes for devices;
- b) the speed with which the introduction of advertising processes, such as approvals and complaints, are to be introduced when there is no industry experience in these areas;
- c) the need to clarify the distinction between the advertising of product and the advertising of services;
- d) the development of industry code coverage of advertising issues;

- e) the willingness of the industry to find a joint Australia/New Zealand representative for the IAC, should the opportunity be provided;

The Chairman noted the importance of the transition period and that, for medicines, early implementation was a possibility and, for devices, the transition period will provide an opportunity for refining the model.

9. Agenda item 5 – transition/roll out and cost recovery

In the meantime, the Chairman summarised the possible transition arrangements as follows, inviting comments by IAC members to be forwarded to the Support Group as soon as possible to facilitate the development of further papers. The transition arrangements will apply principally to Australia, as many elements of the proposed new model are already in operation in New Zealand.

The present proposition reflects that once the Joint Agency Act has been passed through the Australian parliament, it may be possible to call into effect certain parts of the proposed arrangements in Australia, such as the Advertising Code (excluding devices) and the complaints mechanisms. This would happen before 1 July 2005. It has been suggested by the IAC at this stage at least, that the current pre-approval arrangements in Australia should stay the same over that period. With the development and roll out of the new elements, it is proposed that the TGACC would cease operation, possibly from 1 July 2004 or soon thereafter, and there would be governance by the IAC (possibly expanded to 18) until July 2005.

Further work on volumes and costs would be effected, under IAC guidance, including further research enabling a view to be formed as to what dividing line for pre-approval of advertisements should apply from 1 July 2005.

To prepare for that, some months notice will be needed. To be effective in measuring volumes, and to assess the operation of the complaints processes, resources need to be allocated for, among other things, an education program to inform consumers about their rights. The information gained from the response, and the volumes of complaints, would help inform the cost assessment for the new system.

If there is a model where approvals for first time are delegated firstly to industry associations, so that the primary role of the adjudicator would be developing education and quality control processes, there would be a need to work on a fee structure with parity between Australia and New Zealand. An assessment of the volumes of approvals and complaints, and revenues, would establish whether or not there is viability for the associations or there is a need to find other mechanisms to fund their activities.

There are some elements of the new system, i.e consumer participation elements such as consumer education and internet logos, for which the final report is anticipated to reflect the view that this should be funded by government. If the response from government is that, nevertheless, cost recovery must proceed, there would be a need to work with the

regulator to acquire up-front funding of education, the repayment of could possibly be spread over some years.

Strong views were expressed by the ASMI representative, and others, that better information on costs and a more developed paper on transition was needed and that an IAC meeting should be scheduled specifically for consideration of those matters. It was agreed that this should take place on 2nd (?) February 2004 in New Zealand.

The draft report of 20 February will contain more detail of the proposed transition arrangements and anticipated costs. If the Ministerial Council agrees with recommendations, there will be a need to act quickly to get the proposals under way.

In the ensuing discussion, it was suggested that the education program should be prepared in advance of the transition period. If that were to be so, professional advice would need to be sought on the sort of program, and its timing, that would effectively bring the new model and access to it to the attention of consumers.

10.Interface food/cosmetics

A paper from the Support Group on the interface of the proposed model with the advertising of foods and cosmetics had been circulated with the agenda.

The Executive Secretary sought the view of members on the proposal that when a cosmetic or food advertisement is carrying a therapeutic claim, i.e treat, prevent, manage, cure, alleviate, the same controls as for the advertising of therapeutic products should apply.

There was general agreement with the proposal.

The meeting closed at 4.30pm.