

Interim Advertising Council

Consultation Meeting

27 November 2003

9 am – 5.00 pm

**The Masonic Centre
Castlereigh Street, Sydney**

Meeting Notes

Attendance

1. A list of participants is at Attachment A.

Welcome

2. In welcoming everyone to the meeting, Dr Cumming, Head of the Interim Advertising Council (IAC) Support Group, noted the importance for all to work to providing the right information to the IAC so that diverse interests can be taken into account in its considerations.

Background

3. Dr Cumming reminded everyone that, while being the ‘first cab off the rank’, the advertising review is part of the bigger picture trans Tasman project. In referring to the Pearce Report of 2000, followed by the Toogoolawa Report of 2002, it was noted that while the latter provided a broad outline for a scheme of advertising controls, many issues remained unresolved and were being progressed by the Interim Advertising Council which was established in May 2003 under the Chairmanship of Mike Codd, the consultant for the 2002 review.

Four meetings of the six scheduled meetings of the IAC have been held to date.

In answer to questions, the following points were made:

4. The full trans Tasman scheme is to commence on 1 July 2005. In moving from the current system to implementation, there will be an orderly, systematic transition period in which benefits will be delivered before 2005.
5. A transition arrangement would be developed for New Zealand products newly listed on the joint agency register of therapeutic products, to enable application of the advertising arrangements.

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6. Arrangements for advertisements with a two year approval will have to be thought through.

NOTE: A copy of Dr Cumming's presentation is at Attachment B.

Agenda

7. Several papers had been circulated before the meeting, including the draft Advertising Code (version 5) and papers on approvals, complaints, sanctions and compliance, governance and on an evaluation framework. A copy of Version 6 of the Advertising Code and a summary of changes to the Code from the IAC meeting held on 20-21 November 2003 were tabled.

The order of the agenda was agreed as follows:

The Advertising Code
Complaints and approvals process
Sanctions
Governance arrangement
General discussion
Next steps

The Advertising Code

PART A

Preface

8. The words in the first line, 'supplied to consumers', were queried, on the basis that there is an understanding that intent was for the application of the Code to be more broadly based. It was explained that the opening sentence referred to market entry requirements and is there to provide a context for the advertising of products.

Object

9. The Object was accepted without comment.

Interpretation

10. The Interpretation was accepted without comment.

Definitions

'advertisement'

means any communication which promotes or discourages the use, sale or supply of products, whether or not in conjunction with the supply of services, and whether or not the communication identifies particular products or services. (Refer B1.2.6)

Comments and suggestions made and questions asked included:

9. If an advertisement for a cosmetic in which a comparison is made with a therapeutic good to 'discourage the use' of a therapeutic product, would this meet the definition?
Examples of such advertising are to be provided to the Support Group.

10. Food advertising in which therapeutic claims are made. It was noted that this is an issue to be considered by the IAC at the next meeting. It is intended that where an illegal therapeutic claim is made, the advertisement would fall within this system of advertising controls, without the product necessarily being declared a therapeutic good. The implications of the amendment in the *Therapeutic Goods Amendment Bill (No. 2003)* proclaimed this day, where a food can now be declared to be a therapeutic good despite the applicability of a food standard, were noted;

11. It was suggested that, for clarity, consideration should be given to qualifying the definition immediately by placing the exemptions from the definition adjacent to it (i.e. B1.2.6 and B1.2.7). The issue of what goes into the Act (e.g. if the definition of 'advertisement' is in the Act, should the exemptions also be in the Act?), what goes into the Rules and what can be amended by the Managing Director on the advice of the Advertising Board was noted.

12. Clarification was given that the advertising of a service, which is a States and Territories issue, would not be subject to the Code. The example used was that of advertising a laser clinic, which would not be subject to the Code. If, however, the advertisement were to promote a particular branded device used for hair removal, the advertisement would be subject to the Code. This raises a potential issue for an advertiser continuing to use a device if the sponsor has for any reason removed the product from the Australian Register of Therapeutic Goods.

Legal advice is to be sought on this issue

13. Provision of generic information to healthcare practitioners:

- a) Factual information that does not advertise a product is exempt from the Code. It could be considered to be educational material.
- b) The provision of overseas papers on specific products and containing high level claims, in the context of 'educating practitioners' about products, needs further thought.
- c) Other than extemporaneous preparations, herbal medicines advertising will be included; advertising of the provision of services by healthcare practitioners will not be included.
- d) In answer to a question as to why should advertising to healthcare practitioners be confined to the listed indications for the product, as it is expected that a practitioner has the expertise and experience to distil information in such material, it was suggested that there is a distinction between pure educational material on the chemical profile and the advertising

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of product that is linked to approved indications for other claims, i.e. off-label claims.

- e) It was suggested that this arises not only for complementary products but also to prescription products in Australia, with the problem exacerbated by the direct to consumer advertising of prescription products allowed in New Zealand. Having different rules for prescription and complementary products was suggested but it was made clear that there should be a level playing field for all.
- f) It was noted that in all of the IAC discussion, there has been no attempt to limit the provision of genuine research-based material to healthcare professionals. Anything that has supporting evidence and is factual information can be presented.
- g) The kind of evidence required to support advertising claims for complementary products could be likely to include, for therapeutic claims, a revised form of the current evidence requirements for market entry.
- h) The liability of practitioners and their exposure in relation to 'off label' claims was raised.
- i) Another representative suggested that practitioners are bound by a duty of care under State, not Commonwealth law, and that preventing 'off label' claims would be too restrictive. It was noted that when the current system had been established there had been no intention to capture practitioner only material.
- j) It was noted that, unlike the current situation where generic information must comply with Clauses 4.1,2,3 and 4 of the Therapeutic Goods Advertising Code, editorial generic information will be excluded from all of the requirements of the Advertising Code.
- k) Generic material promoted by a company would be considered generic advertising. Currently such material is called generic information.
- l) Examples where interpretation could differ as to whether or not material was generic information or advertising included the approximation of 'editorial' to and advertisement, inclusion of an article by a reputable journal on an ingredient for a purpose other than on the ARTG included with advertising material in a mail out, educational programs on specific products.
- m) It was suggested that a reader would expect information to comply with requirements and that should there be a wish to make those claims, the product should be relisted or registered. There was recognition that registration is a lengthy and costly process.
- n) It was suggested that product license holders should be added to B1.2.7.

The issues outlined above are to be drawn to the attention of the IAC for further consideration of the issue of the application of the Advertising Code to advertisements directed to healthcare professionals.

14. The ACSMA representative raised issues relating to the status of hard surface cleaners and 'other therapeutic goods' such as disinfectants, in relation to the application of the Advertising Code where such products are advertised to purchase

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officers (e.g. hospitals and gaols etc). A request was made for the consideration by the IAC for either exclusion from the definition of advertisement or inclusion in B1.2.6 and B1.2.7 of information about products that are not normal items of commerce.

This issue needs consideration out of session.

Key Principles

15. The Key Principles will be in the higher level legislation, the Act, as well as in the Code.

Principle 2

16. There was clarification provided that “have been substantiated” means that someone, not necessarily the regulator, must have evaluated the claims before advertising. The ACCC representative noted that there are defences in the Trade Practices Act and State-based legislation. The TGA and the ACCC are working on the interface with the Trade Practices Act and regardless of how it is embodied in the legislation, the spirit and intent is captured in this principle.

17. Some people thought that it could be interpreted to mean an implication of ‘third party substantiation’ i.e. other than the advertiser, rather than the existence of evidence. It was suggested that some qualification of the term is needed.

The IAC is to consider this issue, particularly in further discussion with the Medical Devices Advertising Review Group.

Advertising Requirements

18. The terminology has changed from “Advertising Rules” to “Advertising Requirements” to avoid confusion with the term “Rules” in the legislation.

19. Dr Cumming noted that this is to be a ‘living’ Code which will remain under review and able to be fine-tuned.

Requirement 1

20. This was accepted as a given.

Requirement 2

Interpretation 1

21. It was suggested that the term ‘quantities’ is not applicable to products other than medicines, and that it does not apply to ‘use’.

22. The following amendment was proposed:

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“Advertisements must not encourage consumer to purchase use quantities of a product that may exceeds their needs....”

The MDARG is to consider the word ‘quantities’ in relation to devices.

23. Points made in relation to the examples given included:

- Competitions/buy one get one free/ heavily discounted offers should all be allowed;
- There is no such thing as excessive use of sunscreens;
- As worded, the interpretation could be considered anti-competitive;
- The focus should be on inappropriate use

24. It was felt by some people that the interpretation and examples given were too specific. It was noted that it is to be an interpretative system with checks and balances in the adjudication processes.

The IAC is to reconsider the examples provided in the interpretation.

Requirement 3 and sections B2, B3 and B4

25. The ACSMA representative noted that a number of exempt products would be caught inappropriately by B2.1.

26. There was a debate on the inclusion of a list of active ingredients (B2.1.(b) dot point 3. The meeting was informed that this is a matter currently under consideration by the IAC. Comments included:

- “Always read the label” as the alternative should remain;
- a full listing may be needed in direct or internet marketing;
- As excipients are not required on the label, it is not a true representation of the product;
- Should not have two standards – either all or none;

27. B1.2.(b) dot point 2. Any advertising claim must be consistent with the indications on the register. If wish to make an advertising claim for a related claim not on the register, that claim must be included in the database.

Requirement 4

Comments included:

28. Under the new regulations, medical devices have until the year 2007 to meet the requirements and be entered on the database.

29. There will, therefore, be a transition period for which advertising requirements will need to be considered.

30. The regulatory status for homeopathic products is still to be determined. If therapeutic claims are made and the products are presented as medicines, it is most likely to be considered a therapeutic product.

31. Exempt pharmaceutical products must comply with the Advertising Code.

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Requirement 5

Comments included:

32. Discussions between the TGA, Medsafe, ACCC and the New Zealand Commerce Commission and consideration of other codes of practice will ensure that there will be no double jeopardy.
33. The use of the term 'safe' is not acceptable because it implies it is safe for all. It is a market entry consideration, not an advertising one.
34. It was suggested that 'or associated risks' be added to cover devices.
35. It was suggested that not all products should be captured by interpretation 1, iv. For example, sunscreens, condoms, non-therapeutic SPF products.
36. Possible exclusions are to be considered by the IAC.

Requirement 6

37. Accepted and noted.

Requirement 7

Comments included:

38. This clause is under consideration by the National Coordinating Committee for Therapeutic Goods;
39. What constitutes a government agency is under consideration and a paper is being prepared for consideration by the TGACC and the IAC.
40. The wording needs to be considered in relation to including the register number in an advertisement.

Requirement 8

41. The need for a testimonial to be current was questioned.
42. Approvals and complaints mechanisms would assess what is 'typical' based on experience and other relevant factors.

Requirement 9

Comments included:

43. This part is the same as the current requirements in Australia.
44. The devices representatives raised the issue of consumers' need to be aware of available options for high risk devices, compared with relying on information provided by healthcare professionals.
45. It was noted, that for such medical devices, there is in place an extensive filtering process, i.e. it's not 'do it yourself' type surgery!, between the time of diagnosis and a decision taken as to the appropriate device.

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46. The definition of ‘healthcare practitioner’ needs to take account of surgery nurses when purchasing devices such and instrument grades and sterilants.

Prohibitions

47. It was noted that the system will remain as it is in Australia and New Zealand.

48. The ASMA representative noted the need to consider the products noted previously.

PART B

B1.2.3 Sponsorship advertisements

49. Concern was expressed at the word “shall” for the requirements.

50. B1.2.3(e). The feeling of the meeting was that this clause is unnecessary on its own and could create problems, for example, with innocuous sponsorship of children’s football jerseys.

B1.2.4 Reminder advertisements

51. The concept of a therapeutic claim only, without an association with a product may need to be accommodated.

B1.2.6 Bona fide news, bona fide editorial, bona fide public interest and bona fide entertainment programs

52. The meeting was informed by Dr Cumming, media representatives and other IAC representatives as to the proposed interrelationship between the Advertising Code and media regulatory processes, which is under consideration by the IAC.

B1.2.7 Education, research and professional advice

53. The IAC is to consider the inclusion of scientific papers in this clause for exclusion from the requirements of the Advertising Code.

B1.2.8 Internet advertising

54. Internet advertising must comply with the requirements of the Advertising Code.

55. The meeting was informed of the role of the ACCC in the international controls on internet advertising.

56. It was suggested that where a link is made from an Australian to an overseas website, it could be possible to require a page informing the reader that on leaving the Australian site, advertising material may not be compliant with Australian requirement.

57. The meeting was informed of the proposed education campaign and logo proposal.

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B2 Advertising Medicines to Consumers

58. It was noted that Part A applies in B2 and that B2 includes points of differentiation.

B2.1 requirements – interpretation

B2.1(b)(l)

Comments included:

59. Given there are other arenas where adverse reactions are dealt with, and because of the mandatory inclusion of “Always read the label”, inclusion of this clause in the Code is inappropriate.
60. The clause picks up what has been identified at risk assessment at the time of market entry.
61. From the New Zealand perspective, this clause is essential. Consumers could pay for a consultation before finding out that the product is contraindicated.
62. Very few advertisements would be involved, given the types of adverse reactions described in the clause.
63. There should be separate requirements for different categories.
64. Which warning statements should be included also in advertising could be negotiated at the time of market entry.
65. The requirement should be confined to those products with an inherent problem when used as directed.
66. The logistics of including so much material in an advertisement is a problem.
67. 15 second advertisements may need to be excluded from the requirement.
68. An evidence base is needed for the problem in New Zealand.
69. The advertisement needs to be looked at in its entirety. By not including important information, an advertisement could be misleading by omission.
70. Inconsistency between (a) dot point 2 and (b).
71. Clauses (a) and (b) need rewording to clarify the intent.
72. An advertisement offering mail order would require a full list of ingredients. It was suggested that this is currently the case.
73. One way or another and regardless of impost in industry, the consumer must know what they are buying. Simple ways must be found to meet the information needs.

B3 Advertising Medical Devices to Consumers

74. It was noted that this section is a work in progress. The TGA, MIAA and ACSMA will continue the work on this section.

B4 Advertising to Healthcare Practitioners

75. The application of the Advertising Code to healthcare practitioners was noted. It was explained that this section will identify what applied from the Advertising Requirements and incorporate a common set of principles that are embodied in the

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self-regulatory codes of practice, to extract common endorsement by the Advertising Code. The section is being written by a coalition of industry and professional bodies.

76. Representation of Australian complementary healthcare practitioners on the IAC by a New Zealand healthcare practitioner was questioned. It was explained the number of representatives on the IAC had been limited to enable timely dealing with the outstanding issues and that adequate and appropriate representation is important. There was a view that there is under representation of Australian complementary healthcare practitioners on the IAC.

An assurance was given that there will be an opportunity provided for consultation on this section.

B5 General processes

B5.1 Public Interest Criteria

77. The use of the word 'significant' in (c) was questioned.

Otherwise B5.1 was accepted.

B5.2 Approvals

78. Dr Cumming informed the meeting that while the rest of the system is being established, the current arrangements in Australia and New Zealand will remain in place, with the objective of harmonisation by 1 July 2005. She said that, in the period up to the end of 2004, the trial of the proposed delegated authorities system will be rolled out in conjunction with a comprehensive education campaign for consumers and advertisers. Initially, the delegated authorities will deal only with revisions although it is expected that, in time, they will deal with first time approvals as well.

Comments made in the following discussion included:

79. The education program will be funded through cost recovery.
80. Smaller companies will have the option of using industry associations with delegated authorities.
81. From experience, the delegated authorities system is extremely easy to use and is generally a good system.
82. With many delegations, it would be necessary for there to be a very effective monitoring to ensure consistency and high standards.
83. Not all advertising in New Zealand, particularly for 'below the line' material, goes through the TAPS system.
84. As some medicines in Australia don't currently require preapproval for advertisements, this issue will need to be addressed before establishing interim arrangements.
85. The New Zealand system is not well complied with by the direct selling industry.

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86. Concern was expressed at any increase in items requiring approval and costs relating to implementing delegated authorities.
87. Anyone who undertakes the training and achieves accreditation can become a delegated authority.
88. A central database will allocate a unique number for each approval.
89. Pharmacy Boards have yet to decide on a link between a marketing group (that would potentially be a delegated authority) and a pharmacist as to the responsibility for the advertisement.

The concept of delegated authorities was accepted by the meeting, as long as it is a matter of choice and there is a safety net for smaller companies.

B5.3 Complaints

Dr Cumming described the proposed complaints system:

90. A single point of access for all complaints, for consistency and monitoring; all advertisements directed to consumers will be dealt with by the Central Complaints Panel; all advertisements directed to healthcare practitioners will be dealt with by industry complaints bodies and complaints involving serious public health and safety risks will be dealt with centrally.
91. The structure of the CCP is to include an independent Chair with public health expertise, a nominee of the regulator, a nominee of consumer peak bodies and a practitioner in advertising.
92. Complaints received from consumers and competitor complaint involving a serious public health and safety risk will be dealt with for no charge. Frivolous complaints will be handled by the Chair at no charge. Significant competitor complaints that do not involve a serious public health and safety issue will incur a fee.

Comments included:

93. As a matter of course, for reasons of privacy and protection from defamation, consumers' names should be withheld.
94. An industry representative on the CCP is essential. It was noted that industry representatives in New Zealand are from the advertising and media industries.
95. The Panel can draw on expertise and parties to a complaint may choose to have an expert as part of the Panel.
96. The charging of fees is a fundamentally flawed concept that is incompatible with accessibility to the complaints process.
97. Removing the acceptability of receiving anonymous complaints will act as a deterrent to the making of complaints. The ACCC has supported anonymous complaints. In any case, it is not possible to determine that a complainant is a genuine consumer.
98. Cooption of experts to the Panel should not depend on the whim of the Chair.
99. If coopted experts were to be voting members, it could be possible to stack the Panel.
100. The Panel should be constituted appropriately for the complaints to be considered and include the expertise relevant to the complaints.

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101. Often it is impossible to know what expertise is required until well into consideration of the complaint.
102. A suggestion was made for there to be a small group for urgent cases and a more broadly representative group for the regular meetings.
103. Once the system is in place, it is difficult to make changes. Why not slow down, consult, and get it right.

An assurance was given that the comments would be taken into consideration by the IAC.

Sanctions

104. It was noted that there would be administrative sanctions and criminal penalties through co regulatory and self regulatory processes. Review and appeals mechanisms will be in place.
105. Any fines imposed would not be used to fund the CCP. There would be a separation of powers and process as appropriate.

Governance and ongoing monitoring, evaluation and adjustment.

106. It was noted that monitoring and evaluation would be ongoing and constant with reports provided annually.
107. Comment on the papers on governance and monitoring was invited, in the form of written submissions to the Support Group.

On behalf of the IAC members and the Support Group, Dr Cumming thanked all participants for their attendance and comments provided, which are of enormous value to the consideration of the issues by the IAC.

NOTE: Information on the proposed advertising arrangements can be found at:

www.tga.gov.au

**A-Z:
Trans Tasman
Advertising**