

**Interim Advertising Council
Consultation Meeting
Tuesday 1 July 2003
YWCA, Wentworth Ave, Sydney**

Participants

Mr Martyn Goddard	Australian Consumers Association
Ms Anne Cowlshaw	Association of Therapeutic Goods Consultants
Ms Clare Martin	Association of Therapeutic Goods Consultants, ATGC spokesperson for OTC medicines
Dr John Aloizos	Australian Pharmaceutical Advisory Council (APAC)
Mr John Huston	Chair, Australian Publishers' Bureau
Mr Andrew Sinclair	Australian Publishers' Bureau
Mr Colin Harcourt	Australian Publishers' Bureau
Mr John Moursounidis	Australian Self-Medication Industry
Ms Stefanie Jager	Beiersdorf, Australian Consumer & Specialty Products Association, Consumer's Health Forum
Dr Derek Weir	Consumer's Health Forum
Mr Alan Barclay	Consumers' Health Forum
Ms Kirsty Machon	Consumers' Health Forum
Ms Josefa Fernandez	Director Corporate Communications, Blackmores Ltd
Mr Justin Lovelock	Director, Australian Natural Therapists Association
Mr Jim Olds	Director, Australian Natural Therapists Association
Mr Nigel van Reyk	General Manager, Hilton Healthstream (subsidiary of Herron Pharmaceuticals)
Ms Robin McConville	Johnson & Johnson
Ms Joyce Tsang	Johnson & Johnson
Ms Filomena Maiese	Marketing Manager, Pfizer Australia Consumer Healthcare
Ms Pam Davis	Medical Industry Association of Australia
Ms Penny Adams	Medical Industry Association of Australia
Mr Tony Wade	Pharmaceutical Health And Rational Use of Medicines (PHARM) Committee
Ms Kay Sorimachi	Pharmaceutical Society of Australia
Mr Robert Forbes	President, Association of Therapeutic Goods Consultants
Ms Alice Gock	ReckittBenckiser, Australian Consumer & Specialty Products Association
Mr Anbu Jaya	Regulatory Affairs Manager, Wyeth Consumer Healthcare Pty Ltd
Mr Steve Scarff	Scientific Affairs Manager, Allergy/Eyecare Pfizer
Ms Karen McKernan	Senior Project Officer, Compliance Strategies Branch, Australian Competition and Consumer Commission
Mr John Graham	Unilever Australasia, Australian Consumer & Specialty Products Association
Mr Jason Korke	Mayne Consumer and the alternate representative for the Australian Direct Marketing Association on the TGACC
Ms Di Ford	Generic Medicines Industry Association of Australia
Puneet Narang	Category Manager - Healthcare Reckitt Benckiser Consultant
Marie Kelly	Pharmacy Guild of Australia
Mr Ken Bickle	Pharmaceutical Society of Australia
Mr Ron Natoli	Pharmaceutical Society of Australia
Mr Peter Carroll	Pharmaceutical Society of Australia
Dr Frank Doughty	Australian Veterinary Association
Mr Darryl Reed	Roche Pharmaceuticals
Ms Tricia Campbell	Advertising Services Manager, Complementary Healthcare Council of Australia
Doug Anderson	Manager Regulatory Affairs, Procter & Gamble Australia Pty. Ltd.
Mr Les Dell	Direct Selling Association of Australia

1. Welcome

In welcoming everyone to the meeting, Dr Fiona Cumming, Director of the Office of Complementary Medicines, TGA, explained her role with the Trans Tasman Group as that of overseeing the development of the joint Australia New Zealand advertising project. Appreciation was expressed to those attending for taking the opportunity to participate in the development of such an interesting and constructive project and investing time to consider the three documents for discussion.

2. Background

Dr Cumming noted that the driver for the meeting is the development of the trans Tasman Joint Agency for the regulation of therapeutic products. The main points outlined by Dr Cumming were:

- There is government support in Australia and New Zealand for the development of a Joint Agency for the regulation of therapeutic products
- Advertising arrangements are a significant part of the Joint Agency project
- A review of advertising of therapeutic products in Australia and New Zealand was undertaken in 2002 by the consultant Mr Mike Codd. A draft report was released in August 2002 with 37 submissions on the draft received prior to release of the final Codd Report (the Report) in March 2003
- The objective of the review was to develop a joint advertising regime and, in doing so, to streamline the assessment processes in both countries, ensure best complaints handling processes and good integration between regulation, co-regulation and self-regulation.
- The system is to be based on best practice principles and ensure ease of access, cost effectiveness, timeliness and transparency for industry and consumers.
- The Dennis Pearce review of 2000, which had examined complaints and approvals processes in Australia and made recommendations, had provided a basis for moving forward with the Codd Review.
- There was in-principle support from stakeholders for the development of a trans-Tasman advertising scheme and for the recommendations of the Report. There was a call to have, if possible, some kind of joint scheme ahead of the establishment of the trans Tasman joint agency in 2005. This led to the establishment of an Interim Advertising Council (IAC) to take forward the unresolved issues from the Report, the composition of which reflects the proposed representation for the Advertising Board.
- The key elements of the Report were:
 - High level principles established in legislation
 - Single advertising code and guidelines
 - Establishment of a governing body
 - Central processes for advertising pre-approvals, complaints and appeals, all underpinned in the legislation
 - A strong industry role
 - Mutual recognition of decisions

- Both the Pearce and Codd reviews favoured a ‘one stop shop’ approach, or single entry point for preapproval of advertisements.
- The Report advocated a strong self-regulatory role for the industry associations in ensuring compliance with advertising requirements.
- Governance – the Joint Agency is proposed to be overseen by a Ministerial Council, comprising the Australian and New Zealand Health Ministers. An Advertising Board, reporting to the Ministerial Council, is proposed to be established to oversee all advertising issues
- Legislation - Advertising arrangements will be embodied in the legislation of the Joint Agency at three levels.
 - The primary legislation will include high-level principles
 - A single advertising code, subject to approval by the Ministerial Council, will provide the standard for approval, complaints and appeals
 - Guidelines, subject to approval by the Advertising Board, will contain detailed requirements and will be responsive to the needs of users.
- The legislation is proposed to be supported by industry codes embodying the high-level principles and the code and recognised by the Advertising Board.
- Outstanding issues include:
 - The dividing line for pre-approval of advertisements
 - Complaints and appeals handling processes
 - Legal issues
 - Sanctions
- To facilitate the implementation process, Mr Mike Codd has been appointed to Chair the Interim Advertising Council and the Therapeutic Goods Advertising Code Council.
- The consultation process for Australia and New Zealand was outlined. It was noted that comments from consultation meetings would be provided to the IAC for its consideration.
- A Working Group has been established to facilitate the integration of devices advertising into the system. This group will inform the IAC.

A copy of the powerpoint presentation is attached.

Issues that were raised in the discussion included:

- The delay in the release of the Codd Report, which occurred through the process of obtaining agreement from both governments and the status of the recommendations from the Report.
- There are many stakeholders (including media/advertising agencies) who would like more direct representation on the IAC, the size of which is limited by the need for a workable group. The broad consultation process is to provide opportunity for input.
- The definition of ‘advertisement’ is an outstanding issue.
- The establishment of an IAC Support Group to provide secretariat and technical support for the Committee. This group is a virtual office which includes Dr Cumming, Sharyn McGregor and Paula Zylstra, TGA, Judith Brimer and a Medsafe nominee.

- The need for industry associations to work towards trans Tasman harmonisation of the industry codes.

3. Draft Key Principles, Advertising Code and Guidelines

General comments on the discussion documents included:

- Amendment of ‘should’ to ‘must’
- The documents need to reflect the importance of the takeout message by the consumer rather than the intent of the sponsor or advertiser
- Everybody who could be considered to be an advertiser, not just sponsors, should be included, i.e. the person responsible for the material that appears either as published or broadcast material.

3.1 Key Principles

The Key Principles are proposed to be embodied in high-level legislation, that is, in the Act for the Joint Agency in both Australia and New Zealand. It was noted that because this is legislation that will take time to change, the principles must be able to withstand the need for change. The Code will expand on the Principles and will be established in the Rules (equivalent of Regulations). They will, therefore, be more easily amended. The Guidelines providing the detailed requirements, will be referenced in the Code, and be amended by order of the Managing Director of the Advertising Board.

Issues raised in the discussion included:

- The Principles are meant to establish the spirit of the legislation. It was suggested that more explanation be provided to cover the gap between complying with the ‘technical’ requirements and the ‘spirit’ of the code.

Principle 1

- Definitions
The definition of therapeutic product forms part of the trans Tasman regulatory work still to be resolved.
- Sanctions
General overriding principles could be subjective and therefore raise difficulties for the application of sanctions. Sanctions are likely to be established at several levels in the legislation. The legal issues are to be resolved.

Principal 2

- Substantiation of claims
 - A section on substantiation requirements in the Guidelines was suggested.
 - The medical devices sector representative suggested that ‘have been substantiated’ could imply substantiation by the regulator or approval officer, and this could impose a new layer of regulation on the devices industry. It was explained that the intent is that substantiation would have been undertaken by someone, not necessarily the regulator or approval officer but more probably by the sponsor, for products that can be advertised.
 - It was noted that evidence would need to be held by the advertiser for all claims made about a product.
 - The relationship between the Trade Practices Act and Therapeutic Goods Act and potential for “double jeopardy” needs consideration.

- Decisions would be likely to be made based on all the materials provided and on a case-by-case basis.
- Meaning of the term ‘valid’

It was felt that the inclusion of the term ‘valid’ implies appropriateness as well as truthfulness and not being misleading. It captures, too, the sense of product containing sufficient quantity of an active ingredient to produce the effect claimed.

Principle 3

- It was suggested that the Principles should include a statement on the intention to support the quality use of therapeutic products, so as to reflect both quality use and the fact that advertising often is directed to vulnerable parties.

There was agreement that the proposed Principles embody the spirit of what would be expected from all advertising of therapeutic products.

3.2 Therapeutic Products Advertising Code and Guidelines

Object

- As the WHO criteria relate to medicines and do not refer to devices, it was suggested that the following amendment be made.
*The Code **as it applies to medicines** is generally consistent etc.*

Interpretation

- A possible conflict between the impact on a ‘reasonable person’ in the Object of the Code and exploitation of a vulnerable minority under Advertising Rule 5 was raised. It was suggested that such a situation would be considered on balance on a case-by-case basis.
- The Guidelines, referenced in the Code, will have legal standing.

It was suggested that the following amendment should be made:

Replace

The Code is to be read in conjunction with the Therapeutic Products Advertising Guidelines.

With

The Code shall be applied in conjunction with the Therapeutic Products Advertising Guidelines.

Definitions

Advertisement

Views put forward in discussion on the definition of advertisement included:

- Opposition to the proposed definition by the APB representative who suggested a need for different definitions according to media in which the advertisement appears. It was suggested that a definition applicable to mainstream media should include the concept of valuable consideration.

- The words “used or appearing to be used” present a problem commercially in that they are too subjective.
- The wording must not capture bona fide news.
- Great concern was expressed at the increasing use of advertorial, public relations and internet sites which are ostensibly ‘consumer’ sites but are actually a front for manufacturers and suppliers. It was suggested that the definition should go further than it does at present so as to preclude any possibility of such activity.
- ‘Education’ programs are used as a cover for promotion of product.
- The ACA representative, supported by PHARM, IAC consumer and PSA representatives indicated that there would be no support for any Council or Code process that allowed the activities outlined in the two dot points above.
- In considering the internet there should be no intrusion into provision of generic information and freedom of speech.
- The inclusion of a definition of ‘bona fide news’

Advertising Rules

Advertising Rules (AR) are an expansion in the Code of the Key Principles in the Act.

The following points were made in the discussion:

- For consistency within the document, the Advertising Rules could reflect the definition of quality use, i.e. appropriate, judicious, effective and safe use of therapeutic products. It was suggested that these could be expressed in positive rather than negative terms.
- The Code could include a reference to public interest criteria.
- The devices representative reported that the Devices Advertising Working Group has suggested the development of two sets of Guidelines, one for medicines and the other for devices advertising.

AR1 – a given

AR2 – Guideline 2.5

The issue of price promotion was the subject of a debate in which the following points were included:

- Price promotion activities do not fit with quality use of medicine principles as there is inducement to purchase more product than needed.
- The quality use of medicines issue is about use, not purchase. Retailers should be allowed to use any standard merchandising activity to promote the purchase of therapeutic products.
- Such an approach would breach any reasonable quality use or social responsibility code.
- Therapeutic products require different controls from other utilities, including the judicious use of medicines.
- There is need to be careful of basic trade issues.
- More detail on social responsibility issues could be built in to the Guidelines.

AR 3 – Guideline 2.1

- A separate section for material directed to healthcare professionals was suggested.

AR4 – Guideline 3.1

- As this contains two concepts, it was agreed that a suggestion to split this into two parts is a good idea.

AR5 - Guideline 2.8 and Guideline 3

- It was noted that this Rule has been accepted as a policy issue by the TGACC with a change to the Therapeutic Goods Advertising Code to include the paragraph in Guideline 2.8 imminent.

AR6 – Guideline 2.4

- It was suggested that if the public interest criteria included all of the criteria to be applied to additions to the list of products able to be advertised to minors, the need for a separate set of criteria would be removed.

AR 7 – Guideline 2.7

- It was noted that the Australian Commonwealth and States and Territories governments did not support any endorsement of product by government agencies under any circumstances.

AR 8

- It was suggested that an exceptional case should not be used as the basis for an advertisement, as the only meaningful testimonial is one that is typical and therefore obtainable by the average consumer.
- Because AR 8 allows the representation of an exceptional case, this could interfere with the operation of AR 5.

AR 9 – Guideline 2.6

- It was noted that this clause has been included as a result of New Zealand experience.

AR 10 – Guideline 4.2

- This clause is in line with current code prohibitions and restricted representations but needs modification to accommodate the advertising of devices.
- The wording needs amendment to clarify the permissible advertising of S2 medicines.

The meeting endorsed the approach taken with the Key Principles, the Advertising Code and the Advertising Guidelines.

4. Next steps

The minutes of the meetings held in Sydney and Auckland, together with a brief summary of the key issues of concern identified through other consultative processes, will be included in the agenda papers for the next IAC meeting (4 August 2003). The draft advertising documents will be reviewed in light of the comments noted at the consultation meetings held in Sydney and Auckland and any written submissions received. These revised documents will also be included in the agenda papers for further consideration at the next meeting of the IAC.

5. Thank you

On behalf of the IAC, Dr Cumming thanked all participants for their invaluable input at the formative stage of developing the Key Principles, the Advertising Code and the Advertising Guidelines.