

STAKEHOLDER CONSULTATION MEETING

on

Proposals for a trans-Tasman regulatory advertising scheme for therapeutic products

Held on 22 September 2004 at Copthorne Towers Hotel, Wellington

RECORD OF COMMENTS AND RECOMMENDATIONS FROM THE MEETING

Participants requested that the following comments be provided to the Interim Advertising Council.

NOTE: Many of the comments came from individuals or sub-groups of participants at the meeting. They do not necessarily reflect the views of the stakeholder group as a whole. Participants were encouraged to provide additional written comments to the IAC Support Group where appropriate.

1. THE TRANS-TASMAN ADVERTISING CODE (VERSION 10)

Principle 1

- The relationship between the code and industry codes of practice needs to be made clearer.
- There is a need to ensure that compliance with the relevant industry code is required for all advertisers, regardless of membership of the industry association.

PART A

A3. APPLICATION

- Paragraph immediately following the dot points – There is a need to ensure that there is not costly duplication of effort checking website material that is already approved.
- Could include a description of what is meant by “branded advertising”.

A4.2 Approval of advertisements

- The wording under the heading “*Revisions to advertisements which have been approved by the Central Approvals Office or TAPS*” seems to preclude a consultant from acting as a Delegated Authority on behalf of a sponsor company. This should be amended to remove the requirement for the DA to be approving advertisements “within their own company”. The requirement should be for a suitably qualified person to be available to consider and approve advertisements. This may be a consultant acting on behalf of the company.

- There should be provision for a suitably trained Delegated Authority to approve new advertisements as well as revisions to previously approved advertisements.

A4.3 Complaints

- There was some concern about the chair of the ASCB having the discretion to withhold the name of the complainant, and some support for requiring the claimant's name to be provided but not releasing that information. Since it is useful for the advertiser to know the origin of a complaint, there was a suggestion that the name of the complainant be provided to the advertiser but withheld from public release.

A4.4 Review and appeals

- All steps in the appeal process should be available to all parties. Appeal to the trans-Tasman review tribunal should be available to a consumer complainant, not just the advertiser who is adversely affected by a regulatory decision.
- The wording should be amended to say "If either party is still dissatisfied, they may appeal to the Trans Tasman Review Tribunal...".
- The cost of an appeal by a consumer should not be borne by the industry. It was recognised that cost may act as a barrier to consumer appeals.

PART B

The introductory paragraph implies that Controlled Drugs cannot be advertised to consumers in New Zealand. This is not correct for all controlled drugs.

Requirement 1

- There was concern about the opportunity for varying interpretations of what would constitute "encouraging inappropriate or excessive use". For example, what does "dramatically discounted price" mean? This concern could be resolved by omitting the wording from "Examples of advertisements" through to the end of the first set of dot points and relying on the information in the second paragraph.

Requirement 2

- There was concern about the requirement to include all mandatory statements in advertisements such as shelf talkers, when the advertisement is co-located with the product, and the mandatory statements are included on the product label. A statement to the effect of "See the label" would be adequate.
- The statement "if symptoms persist see your healthcare professional" should be replaced by "...see your prescriber" in the case of an advertisement for a prescription medicine.
- "Serious adverse effects" needs to be defined. It would be useful of the product licence specified the adverse effects that were considered "serious" and required to be included in any advertisement for the product.

Requirement 4

- **R4.1(i)** needs to make it clear that if no side effects have been reported when the product is used as recommended, it is permissible to say so. This could be dealt with in guidelines for sponsors, rather than an amendment to the code.
- **R4.3** needs to clarify that the intent is to identify research funding linked to the company advertising the product, rather than the source of all research funding.
- **R4.4** appears to be out of place, since pharmacy assistants and retail sales persons are not “consumers”. Would be better placed in B3. Since a pharmacy assistant would be a retail sales person in this context, the heading could simply refer to “retail sales persons”.
- There was concern that the prohibition on incentives for sales people may be overly restrictive in relation to low risk products (e.g. many complementary medicines). If applied in the direct selling environment, this would be a serious problem as marketing is incentive- based. The IAC needs to reconsider the prohibition on personal incentives with a view to linking it back to those activities that encourage unsafe or inappropriate use. It was, however, considered that where there is an incentive in place for the sales person, this should be revealed to the consumer.
- **R5** needs to clarify what is meant by “...prey on the vulnerability...”. Some participants were uncomfortable with the listing of examples of potentially vulnerable groups. It was suggested that if the examples were given, they should refer to “people” in each case (e.g. aged people, people with mental health problems)

General comments on the Code

- The term “balanced” is currently used in different ways in different parts of the code. There needs to be more clarity about what is meant when this term is used.

2. APPROVALS

- Consideration should be given to allowing registration of a standard text that can then be used in a variety of different types of advertisement.
- The complementary medicines industry objects to paying a fee for notification when the sponsor is required to do all the work.
- The twelve-month review period may be too short, particularly for complementary medicines advertising. The review must focus on the best way of fixing anything that is not working well.
- The report needs to make it clear that sponsors using “below the line” advertising have a choice of either using the notification process or having advertisements approved by their delegated authority.

3. COMPLAINT AND APPEAL PROCESSES

- Concern was expressed that complaints that could be dealt with by industry associations would go into the central system, particularly as industry associations can impose financial sanctions, whereas ASCB does not. However, it was recognised that there was likely to be very little change from the current situation in New Zealand, other than improved powers to deal with repeat offenders.

4. SANCTIONS AND PENALTIES

- No specific comments.

5. GOVERNANCE

- There was unanimous support for the Central Support Unit being a division of the joint agency. Other options were considered cumbersome and expensive and would not provide an appropriate balance of New Zealand and Australian influence.
- Careful consideration will need to be given to the physical location of the Central Support Unit, as this will affect the available pool of staff and the functions the unit is able to perform. It was therefore recommended that the functions be identified and the staffing requirements identified before a decision on location is made. Since the main workload will relate to approvals and complaints for Australia, Sydney is likely to be the preferred location.

6. TRANSITION ARRANGEMENTS

- No specific comments.

7. COSTS OF THE PROPOSED ARRANGEMENTS

- Medical device industry does not support the concept of full cost recovery.
- Medical device industry does not support the imposition of uniform fees across all companies in the sector because some companies do not advertise and should not, therefore, have to contribute to the cost of the scheme.
- Industry should not be required to fund the cost of educating the public about the new scheme.
- The cost of the Australian complaints process should be borne by the Australian industry.
- Participants did not support the need to minimise cost margins between the two countries. This was seen as anti-competitive. Participants objected to what was seen as “price-fixing” in an attempt to prevent sponsors “shopping around”.

- There needs to be transparency about actual costs and revenues, good annual reporting, and avoidance of cross-subsidisation.

List of attendees

Susan Martindale (CHAIR) Medsafe	
Marilyn Anderson Medsafe	
Sharyn McGregor TGA	
Sharon Croudis Good Health Products	
Sheryl Williams Schering-Plough Corporation	
Lyle Hastings Health 2000	
Dean Stockwell FSANZ	
Lesley Clarke Researched Medicines Industry Association	
Jacqui Bennet Health and Herbs	
Malcolm Stobie Thompson Nutrition & Life-Span	
Garth Wyllie Direct Sellers Association	
Erin Gentry Roche Products (New Zealand) Ltd	
Mike Thompson Ethos Consulting Group	
Hilary Souter Newspaper Publishers Association	
Euan Galloway Pharmaceutical Society of NZ (Inc)	
Bridget Crooks Weleda New Zealand	

Rachel Mackay PHARMAC	
Faye Sumner Medical Industry Association of NZ	
Muir Hutchison Pharmacy Guild of New Zealand (Inc)	
Barbara Holmes Pfizer New Zealand Ltd	
Dr Andrew Hvizdos GlaxoSmithKline NZ	
Jo Fitzpatrick Women's Health Action Trust	
Shailer Cottier Nutra-Life Health & Fitness (NZ) Ltd	
Ursula Egan New Zealand Food Safety Authority	
Jenny Duncan Apotex NZ Ltd	
Michol Fisher NaturoPharm	
Glen Wiggs Advertising Standards Authority	
Jocelyn Keith Consumer representative	
Peter Pratt TAPS	
Dr Bob Boyd FSANZ	
Cameron McIver New Zealand Medical Association	
Katy Williams Day Pfizer Australia	