

## **Minutes of the Stakeholder Consultation Meeting on**

### ***Proposals for a trans-Tasman advertising scheme for therapeutic products***

**held on 28 November 2003 at the Kingsgate Hotel, Wellington**

#### **1. Welcome and introductions**

Susan Martindale (Chair) welcomed the 23 participants (see attached list). Apologies were received from Bruce Wallace (NZ Television Broadcasters' Council) and Jeremy Irwin (Assn. of NZ Advertisers).

#### **2. About the advertising review**

Susan provided an overview of the process and progress to date on the advertising review (copy of slide presentation attached).

#### **3. Proposals from the IAC for consultation**

##### **The Advertising Code (Version 6)**

##### **Part A: General provisions of the Code**

##### **A2 - Objects of the Code**

- Amend first sentence to read: "The object of this Code is, through controls on advertising and promotion of therapeutic products, to safeguard public health and safety .....".

##### **A3 - Interpretation**

- The Code should be considered the minimum standard applied to advertisements.
- Reference to the "spirit and intent" of the Code was supported. It was recognised that this was open to interpretation and there would not necessarily be total consistency of decisions.
- It was noted that what is considered "socially responsible" is constantly evolving. There was concern from consumer groups regarding the potential for the Code to set, rather than follow, standards of social responsibility.

##### **Definition of "advertisement"**

The ASA uses three tests in determining whether something is an advertisement. These are:

- Was money paid?
- Who had control of the content (advertiser or media)?
- Does it look/smell/taste like an advertisement?

There may be a conflict between the stated definition and the third dot point on the slide showing what is not an advertisement.

Notification of a recall should not be considered an advertisement.

"Testimonials" presented at closed promotional meeting (e.g. those held by multi-level marketing companies and attended by distributors) would technically be captured, but controls would be unenforceable.

It was confirmed that the Code and legislation would cover product (not services) and only therapeutic products (not foods for which a therapeutic claim is made).

#### Definition of “healthcare practitioner”

It was noted that some care was needed with this definition to avoid confusion with “health practitioner” in the HPCA legislation. The two definitions are similar but not the same. For the purposes of the advertising Code, the definition must capture both the regulated and non-regulated practitioners. The IAC needs to consider whether “healthcare practitioner” is the appropriate term, and whether the definition is adequate in light of the above comments.

### **A6 - Key Principles**

#### Principle 2

This should include a requirement for an advertisement to include information on common side effects, interactions and contraindications.

#### Principle 3

Reference to “appropriate selection” could infer a requirement to discuss alternative treatments. This could be overcome by amending the wording to “.....through enabling appropriate selection and safe use of the therapeutic product being advertised”. The wording should also refer to “their advertisement” rather than “their advertising”.

Reference to “valid patient-oriented information” is too narrow as not all people wanting to access this information will be patients. It could be changed to “valid, relevant, accessible, easily understood information”.

### **A7 - Advertising Requirements**

#### Requirement 2

Extend the first sentence as follows “...that exceeds their needs or is not appropriate for their needs” to cover advertisements promoting “inappropriate use”.

It was noted that a “buy one, get one free” offer may contravene the code, even though such advertising would not be inappropriate for some types of low risk therapeutic products (e.g. sunscreens, patients wishing to access Vitamin E products for ongoing therapy at the recommendation of a cardiologist).

There is also a need to ensure that company incentives to retailers are not covered by this requirement.

Reference to advertisements to pharmacy assistants and retail sales assistants appears in Requirement 5 (Interpretation 4). This more correctly belongs in Requirement 2.

#### Requirement 5

Reference to “the superstitious” may be offensive, and is not appropriate in a multi-cultural society. This can be resolved by deleting the words “exploit the superstitious or,”

Point (iv) may prevent advertisers from saying that not using condoms may lead to transmission of STDs. Such safe sex messages must not be prohibited. A similar problem could arise in respect of advertisements for vaccines.

#### Requirement 6

Add the words “Advertisements must not be unduly emotive in style.”

Remove the words “the vulnerability of” in the heading. In the interpretation, remove the words “vulnerable audiences” and replace with “particular audiences may”. It may be offensive to some members of the particular groups to be referred to as vulnerable, when not all members will consider themselves to be vulnerable.

### Requirement 7

Promotional material frequently refers to a product being FDA approved or CE marked. This applies particularly to medical devices. The IAC needs to consider the implications of this requirement for an established practice that does not appear to pose a problem.

### Requirement 8

Is it the intention of the IAC that testimonials must be unsolicited? If so, this should be clearly stated. (Although a good idea, this may be unenforceable).

### Requirement 9

As worded, this could prevent an advertiser from stating that a product is suitable (or not suitable) for use by people with certain diseases (e.g. diabetes).

The heading for Requirement 8 needs to be reworded to clarify its meaning. The words “any claim” should be replaced by “their claim”, and the entire sentence re-ordered.

## **A8 - Prohibitions**

In paragraph 2, the reference should be to “Class A, Class B and Class C Controlled Drugs other than Exempted Controlled Drugs”.

In paragraph 3, the second dot point should read “prior approval for the claim ....”.

## **Part B: Application of Advertising Requirements for Specific Sectors**

### **B1 – Interpretation of application**

1.2.1 (c) – the cross reference should be to Section B 1.2.5.

1.2.2 It may not be appropriate to identify categories of product that are exempt. It is also very unclear what requirements they are exempted from. This whole section needs reviewing.

There was concern that the Code does not adequately cover the advertising of prescription medicines in New Zealand, with the consequence that application of the Code would reduce the controls currently applied to such advertisements in New Zealand. It is believed that the current controls need to be strengthened, and recent changes to the RMI Code have gone some way to achieving this. The Advertising Code must not move in the opposite direction.

A disease state campaign may relate to use of an OTC medicine.

1.2.3 This would kill sponsorship. As worded it applies to advertisements for all types of medicines and may be too restrictive for low risk medicines or other therapeutic products such as sunscreens, but not go far enough for prescription medicines.

The last paragraph should not be limited to “sporting events”.

1.2.4 It was noted that reminder advertisements are generally only used for prescription medicines. Consumer groups do not support reminder advertisements aimed at consumers. The RMI does not support prescription medicine reminder advertisements aimed at consumers, but considers them appropriate if aimed at health professionals.

1.2.6 There was concern that “press releases” containing promotional material will proliferate and that the Code needs to capture this material.

### **B2 – Advertising medicines to consumers**

The term “medicine” is used in the heading. This may need to be reviewed once final decisions on terminology are made. These requirements should be split and set out to cover different risk categories to clarify what relates to which type of product.

- (a) There is a need to clarify the intent of this paragraph.
- (d) Remove the word “significant” from the statement “...contraindicated for a significant group of people...”.
- (e) “Prescription Medicine. Consult your Doctor.....” needs to be broadened to include other prescribers. For prescription medicines, the reference should be to a registered health professional.  
Amend the reference to “restricted/pharmacy only medicine” to “restricted/pharmacist only medicine”.  
Instead of “A charge applies....”, more specific information such as indicative pricing is requested by consumer groups.
- (f) Reference to information in catalogues would have a significant impact for companies if it were to include price lists etc.

### **B3 – Advertising medical devices to consumers**

Change reference from “medicines” to “medical devices” in (a).  
It is essential that the requirements capture “alternative/complementary” devices.

### **B4 – Advertising to healthcare practitioners**

Concern was expressed over the lack of involvement of the New Zealand medical profession in developing this section.

### **B5 – General processes**

5.1 (a) Avoid reference to “vulnerability” (as discussed earlier).

Delete (f).

### **Complaints process**

As a number of participants had not received the agenda paper on this topic, it was agreed that the paper would be resent on Monday 1 December, and those who wished to comment would do so in writing by Wednesday 3 December.

- The Pharmacy profession supports the present New Zealand complaints process, backed up by adequate disciplinary measures. The involvement of professional associations should be limited to situations of ongoing offending by a member.

### **Approvals**

As a number of participants had not received the agenda paper on this topic, it was agreed that the paper would be resent on Monday 1 December, and those who wished to comment would do so in writing by Wednesday 3 December.

- If there is no dividing line between what does and does not require pre-approval for advertising to consumers, there will need to be an adequate transition mechanism and timeframe to enable material such as point-of-sale leaflets to be incorporated into the scheme.

### **Sanctions and penalties**

- There must be appropriate boundaries around the power of the MD to suspend or cancel a product licence as a result of breaches of the advertising rules.

- There should be a clear distinction between offences such as using an expired approval number, and more serious breaches such as publishing a non-compliant advertisement.
- The concept of the Advertising Standards Authority “punishing” advertisers is seen as too harsh and is not consistent with the current New Zealand approach.
- The involvement of industry associations in disciplinary matters must be optional – not all will wish to have this level of involvement.
- Consumers do not always consider the outcomes of complaints to be satisfactory. There must be adequate penalties provided for in cases of blatant repeat offending.

### **Governance**

- The three existing dotted lines in the Governance diagram should be deleted and a single dotted line inserted between the Managing Director and the Advertising Board.
- A proposal is being developed for a “Consumer Council” to feed into the Advertising Board. Consideration should also be given to an “Industry Council”.

### **General discussion**

- Participants asked where the funding was coming from for the required consumer education programme in relation to the advertising requirements. Susan explained that some funding had been allocated for set-up costs. It was agreed that there must be clarity about who is paying for what.

### **4. Next steps**

- It is important that the outcomes from the IAC Meeting on 8 December are sent to all members of the Stakeholder Consultation Group for comment, since it is not intended to hold another meeting of stakeholders.
- Congratulations were passed on to those running the consultation process, which has resulted in considerable progress being made on a complex topic involving many players.