

**DRAFT**  
**Advertising Consultative Meeting**  
**Centra Auckland Airport**  
**10:30am – 4pm**  
**3 July 2003**

**Participants:**

Pablo Saud	Health & Herbs International Ltd
Brett Edmonds	Health & Herbs International Ltd
Keith Norris	NZ Direct Marketing Association
Glen Wiggs	Advertising Standards Authority
Hilary Souter	Newspaper Publishers Association
Jeremy Irwin	Association of New Zealand Advertisers
Andrew Hvizdos	GlaxoSmithKline NZ Ltd
Bridget Crooks	Weleda (NZ) Ltd
Bruce Wallace	NZ Television Broadcasters' Council
Richard Prosser	Television Commercial Approvals Bureau
Cameron McIver	NZ Medical Association
Lesley Clarke	Researched Medicines Industry (RMI)
Roger Smart	Douglas Pharmaceuticals Ltd
Mark Mathews	Nutralife/NNFA
James Hart	NZ Association of Medical Herbalists
Rob Shaw	Dietary Supplements Manufacturers Association
Mark Crotty	Researched Medicines Industry/Pfizer
Jo FitzPatrick	Womens Health Action, Consumers
Janice Priest	Healthy Options Ltd, Publisher
Linda Morris	Reckitt Benckiser, Consultant
Sanya Ram	Boots Healthcare/NZSMI
Warren Smith	Douglas Pharmaceuticals/NZSMI
Tony Miller	NZSMI
Juliet Seifert	ASMI
Simon Twigden	MIANZ
Linda McLauchlan	Pharmaceutical Society of New Zealand
John Wickens	AstraZeneca
Jo Bayley	McCann Healthcare
Barbara Homes	Pfizer NZ
Susan Martindale	Medsafe
Alison Cossar	Medsafe

**Welcome**

Susan Martindale welcomed the group and thanked them for taking the time to consider the three documents under discussion: the Key Principles, The Advertising Code and the Advertising Guidelines. A similar meeting with stakeholders was held in Australia a few days prior. The comments from both these meetings would be forwarded to the Interim Advertising Council (IAC) for their consideration.

**Joint Agency Outline**

An outline of the proposal for a joint trans-Tasman Therapeutic Products Agency and its relationship with advertising was presented. The key points were:

- Both Governments have agreed to establish a Joint Agency (JTA) to regulate medicines and medical devices but at this stage the New Zealand Government has only given an agreement in principle that the joint agency would regulate complementary medicines. It will make a final decision on complementary medicines after the Health Select Committee has reported back on its inquiry into the proposed JTA.
- Work is progressing on legislation, and advertising is one of the key inputs into this process.
- The Codd Report was released in March 2003. There is in principle support for the recommendations of this report. As a result, there was a strong call for an interim advertising scheme to be set up as soon as possible. The establishment of the IAC and consultative meetings has achieved this. The Codd Report key elements are:
  - The recommendations are a basis for an advertising model, with high level principles in the proposed legislation;
  - Central advertising Codes and guidelines
  - A governing body
  - A pre-approval process
  - A complaints system
  - An appeals system
  - Mutual recognition between Aust and NZ of decisions

The Codd Report found many aspects of the current NZ advertising scheme to be workable.

- Powerpoint presentation (attached electronically). Issues that arose from this presentation are:
  - Most of the detail of the advertising scheme should be put into Ministerial Rules, as it is easier to amend them, and if placed in the Acts, they are more difficult to change and there is a greater possibility for divergence.
  - There are many other stakeholder groups who would like to be involved in the consultation process. Information can be passed to these groups and their input sought.

Glen Wiggs noted that the proposed ASA revision of the current Advertising Code has been put on hold pending finalisation of the new Code.

## **Key Principles Paper**

### Principle 1

The Advertising Principles will be expressed in the Australian Act and the New Zealand Act. The Code will be in the Ministerial Rules. The Ministerial Rules are the equivalent of what we currently know as Regulations. The Ministerial Council will approve the Rules, following normal consultation processes. It is likely that the Advertising Guideline will be issued as a Managing Director's Order or be adopted by reference through the Code.

Treaty	Definitions
Acts [2]	Principles
Ministerial Council Rules	Code
Managing Directors Orders	Guidelines

### Principle 2

There was discussion that the word “truthful” was ambiguous and tighter wording should be considered. It was raised that the principles need to be wide to accommodate many scenarios and therefore the wording should not be tighter but emphasis put on the word “misleading”, rather than “truthful”. The definitions for these words must be accurate and objective, as they will be tested in the courts.

The consumer representative noted that there is no mention of the impact of the Principles on consumers. The current ASA Code always refers back to consumers and this should be emphasised in these Principles.

It was clarified that an advertiser will not need to provide substantiation upfront, but must hold that information before advertising the therapeutic claim (i.e. cannot make claim then find information to substantiate it). The levels of substantiation required will be in the Ministerial Rules, not in the Acts.

The need to provide information on warnings and contraindications to provide balance to an advertisement is captured in Principle 2. Detail on this will be spelt out in the Code, rather than the Principles.

**Action:** IAC to discuss:

- The terms “truthful” and “misleading”
- Reference back to consumers.

### Principle 3

This principle captures the most important part of the whole system. The definition of “social responsibility” will be determined by the decisions of the Board. It was noted that the ASA will shortly be posting examples of “social responsibility” on their web site ([www.asa.co.nz](http://www.asa.co.nz)).

There was discussion on the variable use of “must” and “should” in the Principles. It was considered that “should” implied that no requirement would have to be met.

**Action:** The IAC to review the text changes suggested (Appendix 1).

## **The Advertising Code**

### *Object of the Code*

It was considered that paragraph 2 was misplaced, and would work better as a preamble. The web site address could be removed. The WHO criteria paper is quite old, and was possibly outdated?

It was agreed that there needed to be an objective reflecting the “joint” nature of the Code, but not one reflecting “trade”.

The consumer’s representative proposed a new objective: “consistency for consumer benefit”. There was discussion on the definition of “consumer”, and whether it also refers to healthcare professionals. In some cases there should be no distinction

between the general public and healthcare professionals, and this can be captured by using the term “consumers”.

**Actions:**

- The Medical Association offered to provide copies of the World Medication statements, which are more recent, to the IAC;
- Move paragraph to a preamble;
- IAC to develop an objective reflecting the joint nature of the Code;
- IAC to consider the ‘consumer benefit’ objective;
- IAC to consider definition of the term “consumer”.

*Interpretation*

It was proposed that the first paragraph be amended (see Appendix 2) to reflect more accurately the intention. The first sentence of the second paragraph should be removed as the reference to pre-approval is a separate issue and doesn't belong here.

It was suggested to remove the last sentence for similar reasons, but it was decided that it would be best to check whether the work of pre-assessment people would be compromised by the deletion.

**Actions:** The IAC to review proposed amendments.

*Definitions*

Advertisement: The definition of ‘*advertisement*’ as proposed in the Code, was considered unsatisfactory. There was confusion as to whether it included editorials, Internet advertising, and press releases. With regard to editorials it was proposed that the IAC check whether Australia is happy with the Snow-Churchill decision, and whether this would be a satisfactory cut-off point. It was decided that Internet advertising was covered by the definition. The difference between media releases to news organisations and media releases to health professionals has to be clear in the Code. An interim definition was proposed (see Appendix 2).

Healthcare Professional: With the introduction of the Health Practitioner’s Competence Assurance Bill (HPCA) in New Zealand, it was queried whether the term used in that legislation – ‘*Health Practitioner*’ – was a more appropriate term. This should be checked with Australian counterparts.

The reference to joint Schedules led to the discussion that there is still a possibility of two separate Schedules (Aus and NZ).

Sponsorship advertisement: This definition should contain the addition of ‘product’ to the list (see Appendix 2). It was advised that Peter Pratt (formerly Medsafe, now TAPS) may be able to provide examples of this to support its inclusion in the definition.

**Actions:** The IAC to:

- check whether Australia is happy with the Snow-Churchill decision;
- consider the suggested interim definition of media release;

- consider the term “health practitioner” as an alternative to “health professional”;
- review the definition of “sponsorship advertisement”.

### *Application of the Code*

Refer to Appendix 2 for changes in text.

The definition of the term ‘*therapeutic product*’ does not include services. This should be considered by the IAC. However, this would make the definition different from the JTA definition.

Under ‘Advertising to Health Professionals’, the final sentence should be moved to a more appropriate place. The sentence also reflects the Australian situation, as in New Zealand sponsors can choose the ASA or industry representative body.

- Actions:** The IAC to:
- review suggested text changes;
  - review the definition of “therapeutic product”;

### *Principles*

See corrections in Appendix 2

Advertising Rules: It was noted, in relation to Rule 4, that some products won’t currently have approval as therapeutic products, and won’t be approved until the JTA transition period is complete. Additionally, it was noted that advertisers don’t have to include all known indications, but the Product Licence should be a useful reference for approved indications.

One participant suggested that Rule 6 be amended to include that advertisements should not be unduly emotional, dramatic in style or unduly glamorised, e.g. the Xenical advertisements. The NZ Television Broadcasters’ Council opposed this view, as this stifled highly creative advertising. It was noted that the current NZ rule asks that advertisements do not portray unrealistic outcomes.

Rule 7 should be amended to include an example of government agency (see Appendix 2)

Rule 9 has slight text changes. ‘Subordinate manner’ is defined as a brand that is secondary to the event, e.g. Propecia Rally of New Zealand.

Rule 10 requires clarification of the term ‘approval’.

- Actions:** The IAC to:
- consider amending Rules 6, 7 and 9 as suggested;
  - consider a definition of the term “approval”.

### *Prohibitions*

**Actions:** It was suggested that the paragraphs in this section be rewritten to clarify further.

## The Advertising Guidelines

There was concern that the definition of the word ‘sponsor’ is too narrow and should be expanded to include health professionals etc.

### 1.1(a)

- The term ‘The Internet’ should be changed to ‘web sites’ as it is more accurate (see Appendix 3).
- There was concern that some advertisements direct people to 0800 numbers. It is requested that the IAC ensures that this practice is covered in the Guidelines.

### 1.1(b)

- ‘Promote’ also refers to sponsors and health professionals (see Appendix 3).

### 1.1(d)

- It was considered that ‘Labels’ should not be in this document.

### 1.1(f)

- There was a lot of discussion about ‘generic information’, and whether Codes and Rules that apply to advertisements also apply to generic information (unbranded, a substance). The complementary medicines industry strongly resists this, and queried if such rules would capture the use of Martindale and other similar texts.
- It was suggested a definition for ‘generic information’ may be “information that is intended for the end-user, put out by the sponsor”. An additional term should be ‘generic advertisement’. This is to be discussed by the IAC.
- It was noted that there is a need to ensure that standards are met on any information obtained by consumers. Currently there is a lot of uncontrolled ‘point-of-sale’ information.
- The New Zealand view appears to be that unbranded advertisements should come under the Code and meet minimal standards, but may not need pre-vetting.

There was significant discussion as to whether government health advertising, e.g. immunisation, should come under the Code. Many participants wanted to ensure that there was no barrier to industry running public health campaigns. It was decided that the IAC could discuss and clarify advocacy advertising.

### 1.1(g)

- It was queried whether it would be appropriate to clarify that pre-approval is needed.
- Some text modification (see Appendix 3).
- It was suggested that the term ‘consumers’ should mean the general public and health professionals.

### **Actions:**

The IAC to:

- consider the suggested text changes (see Appendix 3);

- ensure that the 0800 number issue is included in the Guidelines;
- revisit the definition of ‘promote’;
- consider whether “labels” should be in this document;
- discuss “generic information” and “generic advertisement”;
- discuss advocacy advertising
- clarify the definition of “consumer”

### *Social responsibility in advertising*

#### Introductory paragraph

- There was some discussion on modification of this paragraph (Appendix 3)..

#### 2.1(a)

- The comment was made that this paragraph was difficult to understand. It failed to be clear as to whether pharmacy products are exempt from this requirement, whether price lists are advertising or whether point-of-sale advertising needs all the required information. It was noted that ‘direct marketing’ defines a philosophy not an activity and will have to be defined more clearly. The paragraph also has to identify who has responsibility for ensuring these requirements. (See Appendix 3). This paragraph is a major issue for the IAC, who should access the RMI work on this issue.

#### 2.1(b)

- Some text modification (see Appendix 3).
- It was noted that required addresses vary between Australia and New Zealand. In Australia, the full street address is required, while in NZ only the town or city is required. It was decided that while web site addresses could be included in the advertisement, the postal address should also be provided.
- An additional dot point of the strength of the active ingredient is proposed.
- It was queried whether a general dot point should be included about mandatory warnings, etc.
- The exceptions contain some terms that required clarification or comment, for example ‘direct marketing’ is considered to wide, and ‘internet marketing’ is taken to include banner advertisements. Exception (ii) should be deleted.

There was discussion whether reminder advertising should be allowed, and while some thought it was legitimate marketing, others were concerned that if consumers only see reminder advertising then they may not be getting all the information intended. The RMI Code prohibits reminder advertising for prescription medicines.

#### 2.1(c)

- It should be made clear in this section that if a product has serious adverse reactions, warning or contraindications, then these should be obvious to the consumer (see Appendix 3).
- It was commented, in relation to the table in this section, that warnings should be given for all products, not just particular Schedules.
- The terms used in the column “Schedule of therapeutic product” are not those used in New Zealand. New Zealand terms should also be included.

- The statement “Use Only As Directed” etc should be against every schedule entry in the table.
- The Medical Association indicated that they support the retention of the word “Doctor” in the “If Symptoms Persist...” statement rather than replace it with “Healthcare Professional”.

### 2.3

- There was a general agreement that while specific statements can be useful for industry for some products, prescriptive, separate statements are not supported, such as those in 2.3(a)-2.3(c). The group indicated that these sections should be removed as they could not see why these products are singled out.

### 2.4

- There was a general opinion that a statement should go into the Guide indicating that there should be no advertising for under-18s unless relevant, and that this first paragraph and list be removed. It was commented that it appeared as if guidance was being fitted to existing criteria, not a new scheme. The “Public Interest Criteria” was considered to be valuable in providing guidance for advertising to minors, but it is suggested the IAC rework this section.

### 2.5

- It was considered that this section should be removed from this part of the document, but the IAC is to determine if it fits somewhere else as it applies to every advertisement.

### 2.6

- This section had some text modification (see Appendix 3). It was commented that tag lines are currently in breach of dot point 2. The IAC should decide if it should be prohibited. There should be no implication of intentional use, and the advertisement must have the trade name and generic name.

### 2.7

- This section should be moved to Definitions. It should also include international agencies such as the FDA.

### 2.8

- This section should be removed from the Guide but ensure it is included in industry codes. It was noted that inclusion of this section in the Guide is supported by Australia.

#### **Actions:**

The IAC to:

- consider suggested text modifications (Appendix 3);
- rework section 2.1(a) to provide clarification on the issue;
- decide required address details;
- revisit the definition of “direct marketing” and “internet marketing”;
- discuss reminder advertising;
- review the reasons behind including sections 2.3(a)-(c) in this document;

- rework section 2.4;
- revisit section 2.5;
- decide if tag lines are to be prohibited;
- consider moving section 2.7 to definitions;
- consider removing section 2.8.

3.

- Remove the word “valid” throughout this section.

3.1.

- This section should refer to the levels of evidence document.

3.2.

- It was considered that much in this section is too rigid and that it is already covered in the Social Responsibility section.

3.3.

- (this section is currently numbered 3.2 and should be corrected). It was queried whether the last sentence referred to the advertisement or the journal. There was also comment that the financial sponsor can be difficult to identify – perhaps using the word “independent” or otherwise could be used instead of the actual name and that this information should be available, but does not need to be in the advertisement. A reference for how scientific information can be handled can be found in the RMI Guidelines. The IAC should consider rewording this section.

**Actions:** The IAC to:

- consider suggested text modifications (Appendix 3);
- ensure reference to the “Levels of Evidence” guidance document;
- consider removing section 3.2;
- reword section 3.3.

4.

- It was felt that all of section 4 did not belong in this document.

**Actions:** The IAC to:

- consider deleting section 4.