

# Interim Advertising Council

Meeting 4  
20/21 November 2003  
10 am – 5.30 pm  
8.30 am – 1.30 pm

The Masonic Centre  
Castlereagh Street, Sydney

## Minutes

### **1. Attendance**

Mr Mike Codd (Chair)	
Mr Pio Cesarin	Therapeutic Goods Administration
Mr Mike Cocks	Australian media/advertising industry representative
Ms Jean Drage	Consumer representative (NZ)
Mr Jeremy Irwin	Association of New Zealand Advertisers (NZ)
Ms Val Johanson	Complementary Healthcare Council of Australia (CHC)
Ms Jenny Bergin	Pharmacy representative (Aust and NZ)
Mr Tony Miller	New Zealand Self-medication Industry (SMI)
Dr Bruce Shaw (alt)	Medical profession representative (Aust and NZ)
Mr Kieran Schneemann	Medicines Australia (Aust and NZ)
Ms Juliet Seifert	Australian Self-medication Industry (ASMI)
Dr Derek Weir	Consumer representative (Aust)
Mr Glen Wiggs	Advertising Standards Authority Inc. (NZ)
Dr Fiona Cumming	Therapeutic Goods Administration and Executive Secretary, IAC Support Group
Ms Judith Brimer	Secretary, IAC Support Group
Ms Sharyn McGregor	IAC Support Group

### **2. Apologies**

Ms Susan Martindale	Medsafe
Mr James Hart	Natural healthcare profession (Aust and NZ)

### **3. Revised agenda**

The Chairman referred to a letter of request from the media for attendance by a representative from the Australian media and advertising industries' coalition ('the coalition') for the discussion on the definition of advertisement which had accompanied the second paper submitted by the media on this issue. Members agreed to the attendance of representatives from TV, radio and print media and the agenda was revised to enable further consideration of the inclusion of the concept of valuable consideration in the definition of 'advertisement', as well as consideration of item B 1.2.6 on page 13 of the Advertising Code, which outlines the linkage to the relevant media bodies for dealing with complaints under their regulatory regime, as the first item on the agenda.

Members agreed to the attendance of the MDARG representative (Ms Pam Davies, MIAA) for the discussion on the agenda papers relating to devices.

### **4. Minutes**

The following amendments were requested.

Page 2

Item 5, first line – include as follows “.....agreed by **the majority of** members...”

Page 16

Item 9.2.2, Dot point 1

Replace 'about' with 'in relation to the appropriate use of'.

Last paragraph on page 16

Replace 'general' with 'the majority' and insert 'relating to serious adverse effects' after 'mandatory warning statement'.

Page 14, Rule 5

Include the previously agreed amendment, i.e.

*Advertisements must not **directly nor** by implication, omission, ambiguity, **exaggerated claim** or comparison etc*

Page 6

Item 6.1, dot point 4

Delete '(and specifically if they carry therapeutic claims)'

**The ANZA representative agreed to provide IAC members with a copy of a paper written by Peter Pratt on the internal audit of delegated authorities.**

**The minutes were adopted as amended.**

## **5. Agenda Item 1 – Submissions received from IAC members**

Submissions had been received from the coalition (media and advertising industries), on media regulatory regimes and a proposed addition to the Advertising Code to ensure the exclusion of editorial content from the Advertising Code, and from the Advertising Standards Authority in which the New Zealand position on the definition of ‘advertisement’ was given.

The Chairman welcomed coalition representatives Alina Lieurance (Commercial Television Australia (CTVA)), Moses Kakaire (Commercial Radio Australia (CRA)) and Colin Harcourt (Australian Publishers’ Bureau (APB)) to the meeting.

The Chairman noted that discussion would centre on the two submissions and on Clause B 1.2.6 on page 13 of the draft Advertising Code.

A paper from Alan Limbury, on the interpretation of section 65A of the Trade Practices Act, was tabled for members’ consideration. The paper explained that section 65 A does not provide a basis for the inclusion of valuable consideration in the definition of advertisement, as the exemption specifically excludes the publication of advertisements. Therefore, publishers are not excluded from not being misleading when publishing advertisements.

The New Zealand representatives explained that the New Zealand Fair Trading Act is interpreted such that, if the media is unaware of any likelihood that material could be misleading, there is no liability for the publisher. Under the Medicines Act, everyone involved in an advertisement is liable i.e. the advertiser, the publisher and the advertising agency.

The coalition accepted that, under section 65A of the Trade Practices Act, where a publisher publishes an advertisement, it is subject to the consumer protection provisions of the Trade Practices Act. It was noted that the exclusion of a prescribed publication of matter (i.e. information that is not an advertisement) by a prescribed information provider provides a starting point for the carving out of editorial content. It was explained that the Australian Broadcasting Authority has taken a broad definition of advertisement at the high level, but, for regulatory purposes in determining breaches, the dividing line used for determining what is an advertisement and what is not an advertisement, is the element of valuable consideration.

The Chairman suggested that the approach taken by the Australian Broadcasting Authority is entirely consistent with the proposed approach in the Advertising Code, where there is a high level broad definition of ‘advertisement’ and lower level provisions that delineate what is or what is not an advertisement. The approach taken is that material that appears to be bona fide editorial or bona fide news is to be dealt with under the media’s own regulatory regime.

It was agreed by the coalition that, provided the ‘carve out’ is appropriately worded, they would be satisfied with the high level broad definition of ‘advertisement’.

The coalition said that the ‘carve out’ proposed in their submission is consistent with the approach of the Broadcasting Standards Authority governing legislation and media codes of practice.

### **Consideration of Clause B1.2.6, page 13, Advertising Code**

Discussion revealed that:

- there is no definition for bona fide news, editorial and public interest programs in the media regulatory processes but that decisions are made on the basis of case law;
- when a newspaper or broadcaster advertises publishes its own advertisement, although it is considered to be an advertisement it has different requirements from general paid-for advertisements;
- complaints about ‘own’ advertisements are considered by either the ABA or the Australian Press Council;

Members suggested that given that section 65A of the Trade Practices Act excludes editorial material and that there is case law that defines what are bona fide news, editorial and public interest programs, the exclusion for such material should be able to be made, while retaining adequate controls for consumer protection, without including valuable consideration. Concern was expressed at the difficulty of defining what has, or what has not, been for valuable consideration and it was suggested that the primary objective should be the protection of freedom of speech rather than using valuable consideration as the criterion.

The Chairman explained that it is understood that the media systems are the best place to determine whether something is actually an advertisement where it appears to be bona fide news. The proposed wording of clause B1.2.6 of the Advertising Code allows this decision to be made by the media processes, so that where material is determined by media to be an advertisement it would be referred to the therapeutic products regulatory processes. Otherwise, the material would be regulated by the media processes.

The Australian consumer representative said that, from a consumer point of view, public health and safety takes priority. Concern was expressed that processes should be sufficiently robust for decisions applicable across all media to be made as to whether material is an advertisement for therapeutic products or not.

It was noted that the difficulty that could arise with the inclusion of ‘valuable consideration’ as the dividing line as in both New Zealand and Australia there are TV stations that charge for a program. For example, the whole of a sports program could become an advertisement, because there has been valuable consideration involved.

Another area of difficulty discussed was that of experts engaged by a broadcasters for regular health programs and and/or retained by companies, whereby commentary which

should be considered bona fide news could be compromised by the ‘valuable consideration’ element.

When there was a suggestion that the principles of the Advertising Code should be reflected in the media codes, the coalition assured members of the high standards required by the media codes, including the requirement to present accurately and represent viewpoints fairly and the requirements to correct serious errors at the earliest opportunity.

The Chairman suggested that the operation of the proposed carve-out clause over the next twelve months would give an indication as to the effectiveness of the media regulatory processes in identifying what is actually bona fide news, editorial and public interest programs and what is actually an advertisement.

Members discussed the appropriateness of excluding entertainment programs from the requirements of the Advertising Code. It was suggested, for example, that talk back radio and films could be captured inadvertently and inappropriately by the requirements of the Advertising Code. It was noted that there can be payment for product placement in films, but that any inappropriate promotion of product would be treated very seriously by the media. It was felt that this is an area that could be reviewed over the next twelve months.

**The heading of Clause B1.2.6 was amended to include ‘bona fide entertainment’.**

**A last sentence was added to the first paragraph of B1.2.6, as follows:**

*Bona fide entertainment programs are also exempt from the provisions of the Advertising Code.*

Where there is doubt as to whether material is editorial or an advertisement, the responsibility for determining whether the material is editorial or an advertisement will rest with the media regulatory processes.

**The 5<sup>th</sup> line, second paragraph, was amended to read “if there is any doubt as to whether material is editorial or advertising, the complaint should be submitted to the appropriate media/advertising complaint body”.**

**The language of Clause B1.2.6 was accepted by members.**

**The coalition indicated that there would be further discussion with their members.**

**A means of assessing these arrangements as to how well they are working will be developed and applied over a period of twelve months.**

**To ensure that users of the Code are aware immediately of the exclusions for bona fide news, editorial, public interest programs and bona fide entertainment programs from the requirements of the Code, it was agreed that a reference to B1.2.6 will be included after the definition of ‘advertisement’.**

The Chairman thanked the coalition members for their attendance.

## **6. Agenda items 2.1 - the Advertising Code and 2.2 Disclosure of active ingredients**

As agreed at the last meeting, the former Guide to Advertising has been integrated into the Advertising Code (the Code). In order to prevent confusion with the legislated 'Rules', the former 'Advertising Rules' have been changed to 'Advertising Requirements'. The Code has been structured into two parts, Part A containing general provisions of the Code and Part B containing the application of the Advertising Requirements to specific sectors as well as general processes.

The issues of the inclusion of serious adverse reactions and of the disclosure of active ingredients were discussed first, followed by consideration of the rest of the Code, page by page from the beginning. For ease of reference, these minutes record the discussion in relation to changes to the Code in the order of the Code.

Members noted the following general points during the course of the discussion:

1. in order to prevent confusion with the legislated 'Rules', the former 'Advertising Rules' have been changed to 'Advertising Requirements'.
2. the Key Principles are to be incorporated in higher level legislation in Australia and New Zealand;
3. information in bold type in the Advertising Code (i.e. the Principles and the Requirements) are to be included in the Rules;
4. most definitions i.e. Presentation, Advertisement, Label, Healthcare Practitioner, Therapeutic Product, Therapeutic Use and Therapeutic Database to be captured by the Rules;
5. The remaining definitions ie. Advertiser and Sponsorship Advertisement, and other text in the Code are to be subject to determination by the Managing Director on the advice of the Advertising Board;
6. Some definitions, e.g. the definition of 'advertisement' could be included in the Act. The Act will contain the criminal penalties and so anything directly related to criminal penalties would be found in both the Australian and New Zealand Acts;
7. It is expected that there will be a reference to the Advertising Code in the Act(s).
8. The material other than the Key Principles, Requirements and definitions to be included in the Rules is either mandatory information or explanatory notes.
9. Mandatory information and explanatory notes in the Advertising Code can be amended by the Managing Director on the advice of the Advertising Board. This process is to be noted in the Preface to the Advertising Code. This material is to be called 'interpretation' and numbered appropriately.

10. The Joint Agency Board will have no role to play in the making of recommendations on advertising matters to the Ministerial Council or the Managing Director;
11. If the legislative framework is not available before February meeting, there will be a need for the final report to reflect the intent of the IAC.

## **Amendments to the draft Advertising Code**

An outline of the amendments and reasons for the changes are provided at Attachment B.

Version 6 of the Advertising Code, including tracked changes as a result of the above considerations, is to be found at Attachment A.

### **Consultation meetings 27 November, Sydney, and 28 November, Wellington.**

**It was agreed that a summary of the changes and a copy of Version 6 of the Advertising Code would be tabled on the day of the meeting.**

### **7. Agenda item 3 – Workplan update**

The Chairman noted the need for consideration of the way the industry codes fit into the overall system, including the authority given to these codes, and for this need to be addressed as a specific agenda item at the next meeting.

**A paper is to be developed by the Support Group, which covers the inter-relationship, authorization of the codes and/or a reference in the Rules for compliance with the codes as a standard condition of product licensing.**

It was agreed that an opportunity for involvement by the dietary supplements sector in New Zealand should be offered before the next IAC meeting to be held on 20 February 2004. It was suggested that an invitation be extended, as well, to attend the consultation meeting in Wellington on Friday 28 November 2003.

**A meeting with the dietary supplements sector in New Zealand is to be arranged in Auckland on Tuesday 3 February, should the New Zealand government decide to accept that these goods are to be regulated by the joint Agency.**

The workplan was noted.

### **8. Agenda item 4 – Report of Expert Committee on the role of complementary medicines in the health system**

Members were provided with a copy of the report.

Dr Cumming informed the meeting that the Expert Committee was very complimentary about the work of this committee. Other than two compelling issues (i.e. the handling of advertising of therapeutic products on the internet and that there must be no interference with the everyday business of healthcare professionals, educators and scientists) on which recommendations were made, the Expert Committee left other advertising considerations to the work of this committee.

## **9. Agenda item 5 – regulation of internet advertising**

A paper had been circulated with the agenda which outlined aspects of the internet in relation to healthcare, including the use of the internet in Australia and New Zealand for healthcare information, problems that have been identified, aspects of relevant research that has been undertaken, the role of the Australian Broadcasting Authority and the following recommendation of the Expert Committee.

*“Internet advertising should be considered part of mainstream advertising, and be subject to mainstream advertising requirements and protocols, including complaints resolution”.*

The meeting was informed that there is a lot of work in progress at the international level to develop trans national agreements for dealing with controls and sanctions on internet material. The Australian Consumer and Commerce Commission (ACCC) and New Zealand’s Commerce Commission are members of, and the ACCC currently chairs, the International Consumer Protection and Enforcement Network (ICPEN).

The Toogoolawa Report proposal for the development of a system of logo endorsed sites, in conjunction with a comprehensive consumer education program, was noted. Suggestions as to how this could work included the possibility of including a logo option, for a fee, at the time of approval of an advertisement or a campaign by a delegated authority. Whatever charge was imposed, the cost recovery above the approval costs could be used to fund the education program.

Points made during the discussion included:

- a) The regulation of the internet should take priority over the introduction of a logo, which would be a second phase proposition;
- b) Regulating the use of the logo could be problematic unless there was a way to prevent bogus copying and application of the logo;
- c) Monitoring the proper use of the logo could be a substantial undertaking;
- d) The Health of the Net (HON) foundation, based in Geneva, has a system of providing an encrypted seal for sites that meet specified criteria which are regularly monitored for compliance;
- e) The use of a logo would not be mandatory;
- f) An up front expenditure on education would be needed to raise awareness of the concept;

- g) As the approval process would be electronically based, with a central database for approvals logging the date and number of the approval, it could be possible for a link to be made from the database to the website to display the approval. This could be in addition to a logo; and
- h) Priorities in terms of work and cost implications need to be considered.

The Chairman suggested that the logo proposal would be included in the report to Ministers as an idea that should be developed after arrangements for transition are in place, presumably in mid-2004.

Amendments to the paper on the regulation of internet advertising were suggested as follows:

1. Change “National Association of Pharmacy Boards in Australia” to “National Association of Pharmacy Boards (NAPB); and
2. As the jurisdiction for the requirement of approval has yet to be decided, amend the first recommendation as follows: - **AGREE** that Internet advertising of therapeutic products should be subject to the same regulatory requirements as other advertisements for such products.

**The paper was noted, as amended.**

## **10. Agenda item 6 – Complaints**

Consideration of this item was deferred until the next day.

## **11. Agenda item 7**

The updated paper that had been circulated with the agenda papers was noted.

The meeting closed at 5 pm.

## **Day 2 of the meeting, 21 November 2003**

The meeting began at 8.30 am.

## **12. Agenda item 6 – Complaints**

The present complaints handling process in New Zealand is to remain the same.

The need to define ‘serious public health and safety risk’ had been identified at the last IAC meeting. Before considering the proposed complaints handling processes in Australia, the Chairman invited members firstly to consider the proposed definition in the complaints handling paper that was circulated with the agenda papers, as follows:

Public health and safety is generally considered in terms of quality, safety and efficacy. In an advertising context, this means the risk caused by advertisements that fail to protect the public by increasing the misuse, overuse and under-use of medicines, and by inappropriate use, increase medication problems such as adverse events. In particular those advertisements that:

- ⇒ make claims beyond the approved indications (Requirement 4 refers);
- ⇒ promote self-diagnosis and treatment of **serious** forms of diseases, conditions, ailments or defects, unless prior approval has been given (Requirement 9 refers) (the agreed definition of serious is given below);
- ⇒ contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects (Requirement 5 refers);
- ⇒ promote inappropriate use or excessive use which is contrary to warning statements or acceptable practice for that class of therapeutic product (Requirement 2 refers); and
- ⇒ fail to disclose adverse reactions\*, which have a high frequency in terms of severity and clinical importance, in advertisements (Requirement 3 refers).

“**Serious**” in the context of advertisements for therapeutic products means forms of diseases, conditions, ailments or defects, which:

- generally cannot be appropriately diagnosed and/or treated without consulting a suitably qualified healthcare practitioner, and/or
- generally are beyond the ability of the average consumer to treat safely without regular supervision by a qualified healthcare practitioner.

\* These types of adverse reactions would typically include those suspected of causing:

death, danger to life, admission to hospital, prolongation of hospitalisation, absence from productive activity, increased investigational or treatment costs and birth defects.

It was suggested that some of the situations identified above would be dealt with effectively by the co regulatory processes, and that formulation issues and the high profile advertising of, for example, illegal products, would be serious public health and safety risks which would be referred directly to the regulator.

Concern was expressed that the complaints system should not be costly and should be timely.

It was suggested that members consider the proposed definition of serious public health and safety risk in the context of all complaints from consumers being directed to the Central Complaints Panel in first instance and in terms of the sanctions that are available to the Panel for dealing urgently with cases that involve serious risk to public health and safety.

It was noted that the range of sanctions available to the Central Complaints Panel are not necessarily available to the industry panels. Therefore, it was suggested, option 1 would be setting up a two-tier system with two standards that would apply in the area of sanctions which would not be in the public interest.

There followed a discussion on the proposed jurisdiction of the Central Complaints Panel (CCP).

There was majority acceptance that the Central Complaints Panel would consider all complaints made by consumers.

The Chairman asked members to consider the two options put forward in the paper with respect to competitor complaints, i.e.

- Option 1

*Competitor* complaints that are identified as having serious risks to public health and safety would be dealt with by the Central Complaints Panel on a user pays basis. Other competitor complaints would be referred to the relevant industry sector complaint panel by the Central Complaints Panel within two working days of receipt.

- Option 2

All *competitor* complaints would be dealt with by the Central Complaints Panel on a user pays basis. This would avoid the necessity of the Central Complaints Panel determining matters of public health and safety. It is expected that this option would result in the Central Complaints Panel considering the majority, rather than the minority of complaints.

The ASMI view was that there should be a one-stop shop approach for all advertisements that are targeting a consumer audience. Industry associations should continue to apply their codes to all advertising to healthcare professionals. A number of problems about endorsement of industry codes, either by the Advertising Board or by other mechanisms put in place by the regulator, would then be reduced. The primary public interest concern of the application of one standard at all times would then be met.

The CHC representative regarded the retention of the self-regulatory complaints handling processes as very important and described the support given to the current system by the TGA, ACCC and the State government. It was felt that all complaints about advertisements directed to consumers going to a Central Complaints Panel would be contrary to self-regulation principles, and option 1 was supported.

The ASMI representative expressed the view that were the approvals system to remain much as it is now, and as no single industry code has been agreed by all industry sectors, a centrally controlled, consistent complaints system, where one set of standards are applied to everything, is essential.

The need for there to be no deterrent to the lodging of complaints was noted and it was suggested by some members that the handling of complaints on a fee for service basis could act as a deterrent.

The Chairman expressed the view that, were industry panels to deal with complaints while industry associations and individual companies were controlling the approval of advertisements through a delegated authorities system, there could be a perception of conflict of interest. In New Zealand, the pre-approval and complaints systems are dealt with under separate mechanisms. The Chairman noted, too, that for option 1 and with acceptance of the definition in the paper for public health and safety, in reality the Central Complaints Panel would deal with most of the complaints dealt with now by the industry association panels.

The NZSMI representative suggested that minor matters would be resolved between the parties.

It was noted that option 2 requires re-wording to clarify that the responsibility for dealing with complaints about advertisements directed to healthcare practitioners would rest with the industry complaints mechanisms.

The expectation of the pharmacy representative was that industry codes would contain principles and guidance for issues not covered by the single Advertising Code. It was felt that, in terms of consistency, complaints about issues in the Central Code, regardless of their source, should be handled centrally.

The AMSI representative said the association's members believe that the self-regulatory role for industry in relation to approvals is of primary importance, as this is where industry demonstrates its integrity and capacity to behave responsibly. However, it is recognised that given that position, the complaints system must allow everything to be judged in the same way.

The implications for liability insurance where an organization acts in both arenas i.e. acting as both 'judge and jury', was raised and seen as a potentially serious problem if industry was responsible for both approving advertisements to consumers and dealing with complaints about advertisements to consumers.

The ASA representative noted that the ASA had declined to establish a pre approvals system because of the potential conflict of interest with the complaints handling process.

Concerns were raised by some members at the proposal to introduce fees for consideration of competitor complaints by the Central Complaints Panel. It was suggested that if competitors were reluctant to submit complaints because of the prospect of substantial fees, there could be implications for public health and safety.

Members were reminded that, in New Zealand, there is no charge for all complaints from consumers or small competitors, for example, pharmacy vs pharmacy. Where there is a serious consumer interest in a complaint there is no charge, otherwise there is a fee. An alternative dispute resolution mechanism is in place for an industry issue complaint, such

as that involving market share. At any time a competitor can elect to pay and have a complaint fast tracked.

There was concern that option 1 could act as a disincentive to the lodging of complaints because of the association of ‘user pays’ with the handling of a complaint **after** a decision is taken as to whether or not the complaint involves a public health and safety risk.

In a discussion on the introduction of the proposed system of delegated authorities in Australia, the ASMI representative said that members had indicated preference for an arms length role through the industry association rather than acceptance of delegations and, therefore, supported retention the status quo for the approval of advertisements. The ANZA representative noted that companies with delegated authorities frequently deferred decision making to the central adjudicator.

After further discussion, there was acceptance of the following model for the handling of complaints:

- a) All complaints would be lodged centrally, logged on to a central data base and any serious public health and safety issue identified;
- b) All complaints about advertisements **directed to consumers** (whoever the complainant) (including internet advertisements) would be dealt with by the Central Complaints Panel;
- c) All complaints about advertisements **directed to healthcare practitioners** and/or trade (whoever the complainant) would be dealt with by industry complaints mechanisms, unless there is a serious public health and safety issue, in which case it will be dealt with by the CCP which may, if necessary, refer the matter to the regulator;
- d) Where complaints about advertisements directed to healthcare professionals are received by industry bodies, the industry body would be responsible for ensuring the complaint is logged centrally;
- e) All complaints made by consumers would be dealt with by the CCP free of charge;
- f) Any complaint made by a competitor about an advertisement directed to consumers in which a serious public health and safety is identified will be dealt with by the CCP free of charge;
- g) For all other complaints made by competitors about advertisements directed to consumers, a charge would apply (there could be a sliding scale of fees – to be developed). Having been given an estimate of the cost, the complainant would be asked if the complaint should proceed.
- h) Any complaint involving a serious public health and safety issue would be fast-tracked;
- i) The Chairman, on advice from the CCU, would have the power to deal with trivial or vexatious complaints. If the complainant, despite advice from the Chairman that a complaint is considered to be trivial or vexatious wished the complaint to be considered by the CCP, a charge would apply;

- j) Anonymous complaints would not be accepted. A consumer complainant may request non-disclosure of name and contact details. This approach will be monitored and evaluated after twelve months;
- k) Any expert advice, including trade practices advice, could be sought by the Panel;
- l) A party to a complaint could seek, but must pay for, the attendance of a trade practices lawyer or other expert as a member of the Panel.

The CHC representative requested the noting of her dissent, on the basis that the existing self regulatory complaints mechanism is widely supported and operates successfully and the introduction of fees for service for competitor complaints, as well as the non-acceptance of anonymous complaints, would discourage the lodging of complaints. ~~The resource, cost and timeliness implications should be investigated.~~

### ***Discussion on the membership of the Central Complaints Panel***

In further discussion on the proposed membership of the panel, some members argued the benefits of a broader representation for the reasons that it is not always possible, at first glance, to know whether or not the expert advice provided by industry or healthcare professionals would be of value, and that the quality of debate and consideration is enhanced by having broader representation.

The pharmacy representative expressed the view that it is important to have a balance of industry and healthcare practitioners in the constitution of the Central Complaints Panel.

For reasons of cost effectiveness and timeliness of operation, it was decided to have a four-member panel comprising an independent public health and safety expert in the Chair, a nominee of the regulator, a nominee from peak consumer bodies, and a practitioner in advertising.

It was noted that the constitution of the panel could be reconsidered after the operation of the panel has been monitored and evaluated over a period of twelve months.

It was agreed that at the time the complaints procedures are being developed, consideration should be given to the seeking of responses in the first instance from all parties to the complaint, including product licence holders, advertisers, advertising agencies and publishers.

Most members agreed that for the system outlined above, the proposed definition for 'serious public health and safety issue' is appropriate.

It is expected that the proposed system of complaints handling will be implemented on 1 July 2004, or shortly thereafter.

**The paper on the handling of complaints was accepted as amended.**

### **13. Agenda item 8 – Medical Devices – regulation of advertising**

The Chairman welcomed Ms Pam Davies, Medical Industry Association of Australia representative and Medical Devices Advertising Review Group (MDARG) member, to the meeting for a general discussion on relevant issues for devices to enable the development of a paper on the issues for consideration by IAC members at the 20 February meeting, at which the devices industry will be represented.

Ms Davies noted the recent significant changes to the regulation of devices in Australia and that the sector is to be regulated for the first time in New Zealand. She said that the purpose of the MDARG is, given that there is no direct representation on the IAC, to ensure that the Advertising Code takes into account the inherent differences for devices from the controls needed for medicines.

A paper on a dividing line for advertising pre-approvals for medical devices advertisements directed to consumers had been circulated with the agenda.

Issues addressed at this meeting, including earlier discussions on changes to Clauses B3(a) and B3(b), were as follows:

- The proposition that an advertisement for a service is an advertisement for a product. The example given was that of laser clinic and the advertising of the actual laser device where the provider of the device to the practitioner may have removed the listing from the ARTG but the practitioner continues to use it. There was clarification of the need to separate the service from any control of product. The provision of services is regulated under State and Territories legislation and by the ACCC. It was suggested that the language of B1.2 be clarified as to the identification of a particular product rather than a type of product.
- The proposed prohibition of advertising to consumers of high-risk devices. The example given was that of Cochlear implants. It was explained that there are provisions in the Code to allow, under certain circumstances, such advertising - either as generic information or by the granting of approval to use a restricted representation after the application of public interest criteria.

**The MDARG is to be invited to identify the high-risk devices and develop a set of public interest criteria for application at the time of considering the approval of a restricted representation for a high-risk device.**

- Requirement for approval of advertisements for devices. The ASA representative noted that in New Zealand, medical devices' advertising is not exempt from the requirement of pre-approval. It was noted that, for Australia, there is a need to agree on what requires approval taking into consideration a risk-based dividing line, a need for an estimate of the

volume of material that is likely to be involved and an assessment of the potential cost impact on the industry.

**The MDARG is to address these issues in the proposed paper for 20<sup>th</sup> February.**

- There was concern expressed as to the degree of awareness of the introduction of advertising requirements by companies that are not members of peak industry bodies and that this could be of the order of 2000 companies.

It was suggested that the experience of the industry associations in pre-approval would be built on in the first instance, with the consideration of introduction of the delegated authorities in time.

It was agreed that it would be more useful to consider the proposed dividing line for devices after the discussion by members of the approvals system for medicines.

The devices sector was urged to take into consideration future models for pharmacy when considering the issues outlined above.

Ms Davis noted the devices industry wish for direct representation on the Advertising Board.

**The Chairman, with the agreement of all members, indicated that an invitation will be extended to NZ devices sector representatives to attend the IAC meeting to be held in New Zealand on 8 December 2003.**

**The Chairman noted that representatives of the devices sector will be invited to attend the IAC meeting in Sydney on 20 February 2003, at which future membership of the Advertising Board also will be discussed.**

On behalf of all members, the Chairman thanked Ms Davis for her attendance at the meeting.

#### **14. Agenda item 9 – A scheme for approving advertisements for therapeutic products in Australia and New Zealand, including a risk-based dividing line.**

The Chairman noted that as the system of approvals currently operating in New Zealand would remain as it is, the discussion should be focussed on the proposed system for Australia.

As a result of the discussions at the last meeting, a revised paper was prepared and circulated to members.

A request was made for an amendment to the table on page 3 of the paper, for the number of complementary medicines advertisements approved to be changed from 416 to 800.

Two options were put forward in the revised paper for consideration, as follows:

#### Option 1

To require all advertisements for all therapeutic products, including medical devices to be approved prior to publication. This approach would be supported by a scheme of delegated authorities who would be authorised by the Managing Director to clear revisions of advertisements which had already been approved by a central approvals officer (known as the Central Adjudicator in New Zealand). In some cases this delegation would be extended to “first-time” advertisements, across all media. These delegated authorities could be individuals employed by companies within the therapeutic product industry, industry associations, advertisers or regulatory affairs consultants, similar to the process already operating in New Zealand.

#### Option 2

Incorporate into option 1, provisions to enable some advertisements to be exempt from the approval process, for example "Picture, price, outlet" advertisements or advertisements making either no claims (eg sponsorship advertisements) or low level general therapeutic claims.

The Chairman introduced the discussion by noting the general agreement that a more practical course would probably be rolling out the delegated authorities system, initially with a dividing line but not excluding the possibility of approval of all advertisements in time. The delegated system in Australia would initially be centred on the industry associations, with delegated authorities for companies not ruled out but not expected in the early stages. A central approvals office would have an approvals function where a delegated authority was withdrawn, and would provide quality control, education and training.

The ASMI representative argued for retention of the current media-based dividing line, at least in the short to medium term, until there is evidence to support its removal. Reasons given included: the unknown costs of the new system of advertising controls, the likelihood that delegated authorities would not be taken up by companies to the extent originally anticipated, creating a potential problem in terms of the quantity of material to be approved centrally. It was noted that the decision to handle centrally all complaints dealing with advertisements directed to consumers would act as an effective control mechanism in this situation.

There was support for this argument from the media/advertising industries' representative and from the CHC.

The Chairman was not in favour of a media-based rather than a risk-based dividing line. He indicated that the recommendation for implementation at 1 July 2005 should be for a

move to a risk-based or no dividing line. He inferred that it could be possible, for a transition period where a new model is being rolled out with education and training programs, to continue with the current system.

Views put forward in the discussion included:

- a) There is a need for good quality evidence on the levels of compliance of 'below the line' material;
- b) The difficulty of dealing with advertisements in campaigns where there is a media based dividing line;
- c) The reliance only on the complaints system for such material is a matter of concern;
- d) Provided the education campaign is effective, complaints would be engendered from a wide range of sources; and
- e) The medical profession is strongly of the view that the IAC should be working towards a position in which all advertisements require approval.

It was generally accepted that the proposed roll out of a system of delegated authorities should proceed, in conjunction with a comprehensive education and training program, including the circumstances under which a delegation would be withdrawn. Work could proceed towards the implementation of approval of either all advertisements or approval on a risk-based dividing line, but any decision taken to implement this approach would be based on evidence accumulated over the next twelve months.

It was agreed that, with the retention of the media based dividing line for approvals from 1 July 2004, the power of the Central Complaints Panel should include the power to order the advertiser to remove a claim found in breach from all forms of advertising.

It was noted that the media-based dividing line system would not be harmonised with the New Zealand system and that unless it is harmonised by 1 July 2005, there would be problems for the mutual recognition of approvals, not only for specified media but also for below-the-line advertisements.

The Chairman noted the expectation that the Australian legislation could be introduced by April/June 2004 and that, were the new complaints structure and powers to be given effect from 1 July 2004 in Australia, or shortly thereafter, the system could be trialled during the transition period.

**It was agreed that, for reasons of practicality and common sense, the present media-based dividing line in Australia should remain for the transition period from 1 July 2004, with recommendations to Ministers to proceed on developing an approvals system based on either a risk-based dividing line for the requirement of approval, or approval of all advertisements, for implementation by 1 July 2005.**

**The implications of either no, or a risk-based, dividing line will be researched, including the likely volume of material, the cost implications, and evidence on the operation of the New Zealand system. It is hoped that this work will be completed by the end of 2004.**

**Members agreed that the final report should include a recommendation for public funding of public education programs for the proposed advertising arrangements.**

### **15. Agenda item 10 – consumer input to the regulation of therapeutic product advertising**

The New Zealand consumer representative had prepared a paper on possible models for consumer involvement across all activities of the joint regulatory agency which are of special interest to consumers.

The Australian consumer representative gave a presentation to the meeting on the way in which consumers are involved in Australia in providing input to issues of concern to consumers. A paper on this subject was tabled.

The need for members to be aware that the IAC is not a decision making body, and that the report would contain only recommendations, was noted. As well, any recommendation for an advisory group for advertising issues may be incorporated into a recommendation for a consumer advisory group being considered for broader regulatory purposes.

The Chairman suggested that IAC members consider all of the material at the next meeting as the first substantive agenda item.

### **16. Other business**

Clause 1.2.7 of the Advertising Code was discussed in relation to advice given by pharmacy assistants and retail assistants.

The problem was noted and it was agreed that the Support Group revisit the wording of the clause.

### **17. Meeting dates**

The next meeting is to be held on Monday 8 December 2003, in Auckland. The suggestion that the meeting be held at the Waipuna Hotel is to be investigated.

The meeting closed at 1.30 pm.