

Interim Advertising Council

Meeting 9

12 / 13 October 2004

8.30 am – 6.00 pm

7.30 am – 2.30 pm

The Stamford Airport Hotel
Sydney

Ratified Minutes

1. Attendance

Mr Mike Codd (Chair)	
Ms Jenny Bergin	Pharmacy representative (Aust and NZ)
Mr Pio Cesarin	Therapeutic Goods Administration
Ms Lesley Clark	Researched Medicines Industry (NZ)
Mr Mike Cocks	Australian advertising industry representative
Ms Pam Davis	Medical devices industry representative (Aust and NZ)
Ms Jean Drage	Consumer representative (NZ)
Mr Colin Harcourt	Australian media industry representative
Mr Jeremy Irwin	Association of New Zealand Advertisers (NZ)
Ms Val Johanson	Complementary Healthcare Council of Australia (CHC)
Mr Raymond Khoury	Natural healthcare professional (Aust)
Ms Susan Martindale	Medsafe
Mr Tony Miller	New Zealand Self-medication Industry (SMI)
Dr Robyn Napier	Medical profession representative (Aust and NZ)
Mr Kieran Schneemann	Medicines Australia (Aust)
Ms Juliet Seifert	Australian Self-Medication Industry (ASMI)
Mr Rob Shaw	Dietary supplements industry (NZ)
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

Apologies

Mr James Hart	Natural healthcare professional (NZ)
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2. Minutes of the meeting held 26 August 2004

The following amendments were accepted:

1. Item 3, page 3, fourth last dot point, replace 'authorisation' with 'endorsement'

Moved: Pio Cesarin

Seconded: Glen Wiggs

Acceptance of the minutes of the meeting held on 26 August 2004 in Auckland, New Zealand, as amended.

Carried

3. Matters arising from the minutes

3.1 Membership of the Advertising Council and the management sub-committee

Members agreed that IAC report should clarify that the Chief Executive Officer of the Central Support Unit would normally be expected to attend, and report to, meetings of the Advertising Council and its management sub-committee.

3.2 Anonymous complaints

While not specifically discussed at the previous IAC meeting, members agreed that it was their intent that the IAC report should reflect that the identity of a complainant should only be routinely withheld where the complainant was a consumer.

4. Agenda item 1 – Trans Tasman Therapeutic Products Advertising Code (TPAC)

The third and final series of stakeholder meeting was held in Sydney, Australia on Monday 20 September 2004 and in Wellington, New Zealand on 22 September 2004. Members noted that a record of these meetings along with the 20 written submissions received from stakeholders were included in their agenda papers and agreed to a systematic review all of the notes from the stakeholder meetings and the written submissions. These minutes and the attachments note the changes made and some of the more extended discussions resulting in amendments to the Code and/or the draft report, as well as matters for further consideration during implementation of the regulatory model, as approved by the Interim Ministerial Council.

A summary of the resultant amendments to the Code is at Attachment A. The revised TPAC is at Attachment B.

Media releases

Members noted that a bona fide media release must be provided directly to journalists. “Media releases” which do not contain information that is newsworthy or whose target audience is not limited to journalists, could be considered to be an advertisement for therapeutic products.

Serious adverse effects

There were many views put forward by stakeholders on the potential introduction in Australia of the requirement to include those warnings of serious adverse effects and contraindications that are required on labels or in Consumer Medicines Information leaflets. Several stakeholders were of the view that a definition of ‘serious adverse effects’, which would indicate which warnings need to be included in advertising, should be included in the Code.

Stakeholders from the complementary medicine sector expressed concern as to how this requirement would be applied to complementary medicines in particular multi-ingredient products, which often require multiple warning statements to be included on the product label. Several stakeholders called for further research to be conducted to show that the addition of these statements to advertisements was likely to lead to better self-selection of products by consumers before being implemented.

The requirement in Requirement 2 for inclusion in advertising of known serious side effects or contraindications provoked discussion by IAC members on a number of concerns, including:

- Whether a different approach should be taken for advertising of prescription and non-prescription products;
- There is a strong body of opinion that the inclusion of such material in advertising is ineffectual and that directing consumers to ‘always read the label’ is the most appropriate approach;
- Requiring all (multiple) warnings in an advertisement could be problematic in many instances;
- There is a need to differentiate between what really is needed and when ‘always read the label’ direction is sufficient;
- Degrees of risk should have been assessed at market entry and, once allowed on the market, safety should not be an issue in advertising. If the product is used as directed, there should be no problem and requiring warnings in advertising could give rise to unnecessary alarm;
- There is a need for consumers to be warned at the time of advertising before purchase of the product not relying on reading a label after having purchased it.

It was suggested that in order to address concerns from stakeholders that advertisers would be required to judge what is a “serious adverse effect”, the regulator could impose any additional warning statements required on advertising as a condition of the product licence. This suggestion was not supported as it did not reflect the co-regulatory nature of the proposed advertising scheme.

However, members recognised that there is clearly a need to identify which warnings are appropriate to be included in advertising. It was proposed that further guidance could be provided through the development of a common sense guideline as to what constitutes serious

adverse effects and/or contraindications for a known group of people. It was noted that this would need to be done for advertisements directed to consumers and those directed to healthcare practitioners, and that the definition may be slightly different in these two contexts. IAC members agreed that the proposed implementation group could produce this guideline with appropriate input from expert committees. It was expected that this guideline would be released with the Code.

It was agreed that the wording in the Code should be retained and the report should include a reference to the development of a guideline as per the suggestion above.

Shelf talkers

Currently under the Therapeutic Goods Advertising Code, it is technically a requirement for mandatory statements to be included on shelf talkers. It was suggested that while it was expected that a common sense approach would prevail, it would be appropriate for the IAC to consider exempting certain types of advertising from the need for mandatory information (including serious adverse effects) where this is impractical due to the limited size of the advertisement and its immediate proximity to more comprehensive information and warnings.

The requirement to include mandatory statements on shelf talkers was seen by many stakeholders as unrealistic and unreasonable. Other stakeholders were of the view that once a therapeutic claim is included, all mandatory statements should be required, i.e. the status quo.

After considerable discussion it was accepted that there were two options which should be included in the IAC report:

Option 1

All of the mandatory information should be included in advertisements for therapeutic products which include therapeutic claims, irrespective of the form or location of that advertisement.

Option 2

To require that shelf-talkers and shelf-wobblers which make therapeutic claims need only include contraindications for known groups of people, where the shelf-talker / shelf-wobbler is co-located with product. Any material separate from the advertised product would require all of the mandatory statements.

It was agreed that this particular issue should be referred to the proposed implementation group to be resolved during the implementation period.

Unbranded advertising, generic advertisements, disease awareness campaigns

In response to a view from some stakeholders that separation of these types of advertisements may be confusing, it was suggested by some members that unbranded and generic advertising could be considered as subsets of disease state advertising and that bona fide disease awareness campaigns are not, actually, advertisements.

Because advertisers loosely use these terms, it was agreed that the current structure in the Code is intended to address all possibilities and ensure the application of the appropriate requirements of the Code.

Requirement 4.3 Scientific Information

The practical difficulty of total disclosure of the financial sponsor of research and the need for disclosure of those with a vested interest was discussed.

It was agreed that an additional clause be added to the last sentence of Requirement 4.3, as follows:

“..., where that sponsor directly or indirectly has a commercial interest in the product, its ingredients/components.”

Industry Codes of Practice

Requirement 6 and the RMI Code of Practice

The apparent discrepancy between Requirement 6 and the Researched Medicines Industry (NZ) code of practice regarding the endorsement of therapeutic products by healthcare practitioners prompted a discussion on the application of industry codes of practice to direct to consumer advertising and the possibility of inconsistency of complaints outcomes with the availability, in New Zealand, of two avenues for complaints about direct to consumer advertising of prescription products.

The Chairman explained that the TPAC applies to all advertising of therapeutic products, but, in the case of advertising of prescription products in New Zealand, it would provide the minimum standard, and, as well, the additional provisions of the industry code would apply at both approval and complaint.

As a result, it was agreed that the first paragraph of B1 should be amended to include the following statement:

“Where prescription medicines are advertised to consumers in New Zealand, compliance with any additional advertising requirements or limitations included in the RMI code of practice is required.”

Other industry codes of practice

The reasons for introducing the proposed practice of endorsement of all industry codes of practice by the Joint Agency was questioned by one member, on the basis that it appeared to be inconsistent with the principle of self-regulation and that it could be onerous and confusing for approvals officers to be expected to be familiar with several codes of practice in the complementary medicines area.

The endorsement of industry codes of practice, and the requirement for non-members of associations to comply with at least one of these codes (in addition to the Advertising Code) as a condition of a product licence, was supported generally, its value being seen, in particular, as members and non-members of industry associations being required to comply with similar self-regulatory standards which would be legally enforceable. A member confirmed that compliance with the Medicines Australia Code of Conduct is currently a condition of registration for prescription medicines in Australia and that this arrangements supports the ongoing working relationship between Medicines Australia and the TGA .

In recognition that the industry codes of practice can overlap between countries and industry sectors, it was suggested that a product licence applicant could nominate which industry code of practice would apply to the product's advertising at the time of submission of the application for a product licence. Assuming that there was an appropriate level of harmonisation between the endorsed industry codes, this approach would prevent the possibility of forum shopping.

A member from New Zealand noted that it was unlikely that a self-regulatory code for complementary medicines would be in place in New Zealand by mid 2005.

Members agreed in principle with the need for endorsement of industry codes by the Joint Agency. They suggested that there were some issues, including the need for education, that need further thought and that, as part of the implementation process a small industry group could address the harmonisation of industry codes and their interfaces.

The wording of Requirement 6 was amended as per Attachments 1 and 2.

Requirement 4.4 Advertisements directed to pharmacy assistants and other retailers

The value of this clause in terms of public interest was not in question, although there was some concern expressed as to the extent of the practice in New Zealand and reliance on this practice for remuneration.

It was agreed that such inappropriate practice would be more appropriately addressed in industry codes of practice and that this clause should be removed from the Code. The IAC report is to note that provisions should be included in industry codes of practice as part of the development of new industry codes of practice or reviews of existing industry codes during the implementation period.

References in advertisements to other material

Members noted that a considerable number of comments were received at the stakeholder meetings and in written submissions on the proposal that approval officers should be able to consider other material referenced in an advertisement which is relevant to the product being advertised.

Written advice was tabled from the Australian Government Solicitor indicating that if an advertisement is exhorting the reader to look at other material (such as a website), the material to which reference is made in the advertisement should be approved at the time of approval of the advertisement. A judgement would be made as to the prominence of the invitation compared with, for example, a website address as a footnote only.

After further discussion of the implications of this advice, members agreed that the wording of the clause in the Code related to this issue should be retained.

First time approvals by delegated authorities

There were concerns expressed in relation to the notion of introducing the ability for delegated authorities to approve first-time advertisements, including:

- the implications for ANZA in permitting consultants to be accredited as delegated authorities who could then approve advertisements for any other company ;
- there could be pressure to move to first time approvals before adequate training and accreditation programs were in place; and
- an earlier timeframe for the roll out of first time approvals by delegated authorities in New Zealand could undermine the roll out in Australia.

It was agreed that the text of the Code should remain unchanged. The timing of the roll out in each country would need to be addressed during the implementation period.

The Schoombie Report

In considering the results of the research conducted (by Deon Schoombie in association with Oceania Consulting) into comparing rates of compliance with the Therapeutic Goods Advertising Code (TGAC) between advertisements for medicines which had been approved and those which had not been required to be approved, some stakeholders had expressed the view that part of this report (breaches of clause 6.2 TGAC) was based on an interpretation which may not necessarily accord with that made by others.

It was emphasised that in previous IAC discussions on this report, it was the high percentage of advertisements which did not require approval which were found to have serious breaches (eg use of restricted representations and unapproved therapeutic claims) that was the key concern, rather than lack of compliance with clause 6.2 which focuses on the mandatory information.

It was agreed that because of the interpretative nature of the TGAC, the way the issue is outlined in the report should be amended to place the emphasis on the serious breaches encountered in the survey rather than the overall percentage of non-compliance.

Education

The implementation group will need to address, amongst other things:

- the need for professional groups to be made aware of the requirements of the Code;
- general education on the requirements for websites.

Bona fide education, research and professional advice

In reviewing this part of the draft Code, it was suggested that the commercial practice of pharmacy could be adversely affected by the current wording of the clause which relates to provision of private advice. Members therefore agreed to remove the second part of the clause on the basis that there is provision in professional and industry codes to deal with inappropriate behaviour in the provision of private advice and that this is to be noted in the report.

Advertisements for foods or cosmetics in which therapeutic claims are made

Members were firmly of the view that similar regulatory requirements should apply to any advertisement in which a therapeutic claim is made. In agreeing that it was not appropriate

for a product which was clearly in the traditional form of a food to be regulated as a therapeutic product, it was suggested that consistency could be achieved by encouraging the development of a code of practice for the advertising of foods that is based on the Therapeutic Products Advertising Code.

Members agreed that the wording of this section of the TPAC should be amended to state that where “a food product contains a claim for therapeutic use.....the product may be declared to be a therapeutic product.”

Members were unanimous in their view of the need for a level playing field and that this should be reinforced more strongly in the report. The wording in the report should be such that claims for therapeutic use, other than any which may be described in the Food Standards Code, should not be able to be made in food advertising and that adequate standards and enforcement should be instituted to ensure the level playing field.

5. Agenda item 2 – Approvals process and dividing line

Stakeholders at the consultation meetings had been informed that it has been proposed that, for medicines, all advertisements directed to consumers in mainstream media (redefined) will require approval that is valid for two years and that the approval number be displayed in print media.

All other advertisements for therapeutic products directed to consumers will be required to participate in a notification process, involving entry of product, date, sponsor/advertiser, range of media for publication or broadcast, as well as certification of compliance with the Code, on a central database, which will automatically issue an advertiser identifier in the first instance and a notification number for each advertisement entered by that advertiser.

It is anticipated that there will be a regular review of a certain percentage of notified advertisements and, as an incentive for advertiser responsibility, power given to the Central Approvals Office and TAPS to “call in” advertisements for review. Appropriate sanctions would be applied for knowingly or repeatedly making false certifications or for failing to notify advertisements.

The approval requirement for medical devices would be required through a risk-based approach, i.e. restricted medical devices require exemption and approval and advertisements containing a ‘verifiable’ claim require approval. All others would be subject to the notification process described above.

The outcomes from the September stakeholders’ consultation meetings relevant to the proposed approvals process and dividing line for approvals for advertisements prior to broadcast or publication as outlined above were provided for the consideration of the IAC.

Points of discussion by IAC members included:

Notification system and timeframes

It was suggested that if compliance of below-the-line (BTL) material is not clearly demonstrated by the end of the first twelve months, moving immediately and automatically towards the requirement of 100% approval of all advertising may be neither practical nor appropriate. A judgement would need to be made by the Advertising Council at the time as to

options available for an appropriate way forward after analysing the evidence gathered from the first year of operation.

Some members were concerned that the approach taken should not be open-ended. It was suggested that targets could be set and criteria on which to judge the level of compliance within the twelve month timeframe could be put in place, on which the decision could be based.

Notification system and delegated authorities

Whether or not a delegated authority should have the capacity to approve below-the-line material was discussed. There were differing views as to how this could work in New Zealand and Australia.

It was felt by New Zealand representatives that there should be a choice available between either notifying BTL material, certifying compliance and paying a fee, or having it formally pre-approved, registered and paid for as approved material. It was suggested that companies with a delegated authority in-house should not have to pay twice via the annual delegated authority fee imposed for accreditation and, as well, by notifying advertisements.

It was noted that applicants for Delegated Authority status in New Zealand (either for revisions of first-time ATL advertisements or first-time approvals for BTL advertisements) would be assessed on a case by case basis.

The application of such a scheme in Australia, which currently has a self-funding system that deals only with ATL material, would need to be thought through in terms of whether it should be funded by an initial annual fee or by applying the same charges for BTL as for ATL material.

Issues which would need to be considered by the implementation group include:

- The development of training and accreditation programs for application in both countries;
- Costing implications of options for BTL material, i.e. notification/approval by DAs;
- Timeframes for the roll out of properly accredited delegated authorities in both countries;
- Timeframes for the roll out of first time approval of BTL approval by DAs in Australia and New Zealand;
- The status of BTL already in the market place.

In the first instance, from the commencement of the new regulatory model for advertising, contracts would need to be in place with relevant Australian industry associations and the Association of New Zealand Advertisers for provision of services related to approvals of advertisements. Members agreed that the Advertising Council should oversee the co-ordinated roll out, at a later stage, of Delegated Authorities to approve “first-time” advertisements for ATL material in Australia and New Zealand.

Roll over of notification numbers

In response to concerns raised by stakeholders that the cost of reprinting all BTL material every two years to include new notification numbers would be excessive, it was agreed that notification numbers would have validity for a period of two years, after which the number could be ‘rolled over’ as long as there had been no change to the material.

From 1 July 2005, there would be a requirement for all new BTL material produced to be notified and, after that date, any reproduction of existing material in the market place also would require notification.

Notification content – concept notification

When some members suggested the possibility of notifying blocks of text on the basis that if the text remains exactly the same in different presentations, the material should constitute one notification, other members pointed out the importance of the context of such material and were of the view that each advertisement should be notified. However, it was agreed that an advertisement placed in various media should only be notified once, as long as the advertisement is identical in each media in which it is to appear, and that all of the forms of the media were listed.

Co-location of approval officers

It was agreed that the report would contain the options of physical and virtual co-location.

Particular problems faced by the direct selling industry

Members noted that the direct selling industry had raised concerns regarding the impact of the TPAC requirements on its modus operandi, in particular the requirement to notify all BTL material. It was explained that as communications from the CEO and the heads of marketing and sales sections within companies promote product to people who are both consumers and sellers, the potential volume of material likely to be considered to be advertising (which would then require notification) is enormous.

Members suggested that the problem could be addressed by requiring notification of the first iteration of the promotional material only, provided that the only subsequent difference through the layers of consuming and selling is the contact details on the promotional material.

Advertisements approved by adjudicators/approval officers

In reviewing comments submitted by the CHC, members considered whether approvals officers should only approve advertisements for the type of therapeutic products associated with the industry association they were employed by, or whether because there are many companies that advertise products from more than one sector, they should have a broad ability to approve any advertisement.

The CHC representative said that feedback from the current CHC Advertising Service Managers was that they prefer to clear advertisements only for complementary products.

Members agreed that the role of approval officers would be to assess advertisements for compliance with the TPAC. To that end, all officers should be trained to a common standard. It was suggested, however, that it should be optional for approval officers either to clear only for one sector or across the board and that the choice of approval officer should be left to companies.

The ASMI representative supported this approach and noted that it would be in line with the operation of NZ adjudicators and would improve consistency in Australia. It was suggested that processes need to be built in to ensure information sharing and discussion on decisions between approval officers.

Members noted that it was expected that the current arrangements would continue in New Zealand, whereby the TAPS approvals officers can approve advertisements for any type of therapeutic product.

It was felt that in the first instance, it may be sensible to have a sector specific approvals officer for medical devices advertising, but that once properly trained that person would be able to apply the skill to any advertisement.

While it is reasonable to expect that device companies would submit their advertisements for approval to MIAA, the sharing of information and decisions may be facilitated if ASMI and CHC could both approve any advertisements for medicines, particularly given that many companies sponsor both complementary and OTC medicines. The effectiveness of this arrangement should be part of the 12-month period post implementation review of the regulatory model.

It was agreed that with a robust training program, it would be both possible and desirable to minimise difference in standards between Australia and New Zealand and between sectors.

Members agreed that, after appropriate training, all approvals officers would be able to approve advertisements from any sector.

6. Agenda item 3 – Complaints, appeals and sanctions

Stakeholders at the consultation meetings had been informed that the central complaint body in each country is to exist as an independent statutory body, established under the Rules to deal with complaints about advertisements for therapeutic products and reporting to the Ministerial Council through the Managing Director of the Joint Agency.

Members recognised that the centralized database will be an extremely important factor in the harmonization for the system, not only in relation to complaints but also for approvals processes, monitoring and evaluation, accreditation and education.

It is intended that the jurisdiction of a newly established Central Complaints Panel (CCP) in Australia will include all complaints about any advertisement directed to consumers and any complaint about other advertisements that involve serious risk to public health and safety. Its function would be to receive, consider and determine complaints, take action and make recommendations. The pharmacy representative requested that the IAC report note that the Pharmacy Boards would need to be engaged in discussions on the process for handling complaints involving advertisements published by pharmacists during the implementation period.

The proposed increased power of the CCP made by delegation from the Managing Director to enable it to make orders was noted. The role of the Central Support Unit in providing secretariat support and responsibilities for receiving complaints and entry on the central database was described.

The proposed membership for the CCP (reduced for efficiency to 4 members, including a healthcare practitioner, regulator, consumer representative and advertising expert), its ability to seek expert advice where necessary and options for the provision of legal advice were outlined.

The existing central complaints body in New Zealand (Advertising Standards Complaints Board (ASCB)) has a membership of 4 public members plus 4 media and advertising industry representatives. It is proposed that it would continue to receive all complaints about advertisements directed to consumers. Competitor complainants would continue to have the choice of having the complaint heard by an industry association complaints panel. Similarly, for advertisements directed to healthcare practitioners, there would be a choice of forum. However, it would be expected that where a complaint involves any serious risk to public health and safety, the central body, i.e. the ASCB, would hear it.

It is expected that all industry codes will embody the Advertising Code. Where the Managing Director of the Joint Agency has endorsed an industry code, on the recommendation of the Advertising Council, compliance with that code may be nominated by a product licence applicant as a condition of the product licence.

There would be a responsibility for industry and professional bodies to advise the CSU of any complaint and its outcomes for entry on the central database.

IAC members discussed the stakeholder comments from the meetings and the written submissions.

Input to the complaints process by approvals officers

It was suggested at the stakeholder meeting in Sydney, that where a complaint was lodged which involved an advertisement which had been centrally approved, the approval officer should be able to make a submission to the complaints handling body. There were various points of view put forward by members as to the type of contribution approvals officers could make to assist in the consideration of complaints. Members felt that giving approvals officers a right to defend a position taken by the complaints panels may be likely to convey a defensive culture.

It was agreed that prior to the CCP or the ASCB hearing a complaint, submissions should be invited from the approvals officer, publisher and the advertiser, where this would facilitate the proper consideration of the complaint. Where the advertisement is not the same as the approved advertisement it is likely that input from the approvals officer would not be required.

It was suggested that the procedure to be followed could include an assessment as to whether the complaint is trivial in the first instance. If the complaint were found to be trivial or vexatious, it could be dealt with by a letter from the Chairman and recorded in the complaints database. If not, responses would be sought from the respondent. The Support group would check the advertisement against the approved advertisement, seeking submissions from all parties, including the approval officers, where appropriate.

The informal approach taken in some circumstances in New Zealand, whereby an approvals decision is reviewed after an approach by a potential complainant to an adjudicator and corrective action taken by the advertiser (if necessary) on a voluntary basis was seen to have value, in terms of timeliness, as an option. It was suggested that were such an approach to be taken, for the first twelve months at least the CCP or ASCB should be notified of the complaint as well. Any such complaints would be part of the overall review of the effectiveness of the advertising model after 12 months of operation.

Members were reminded that the legal requirement for approval is not a guarantee of an advertisement's compliance with the therapeutic product legislation. The responsibility for compliance rests with the advertiser.

The Australian media representative tabled a paper on proposed procedures for the Central Complaints Panel as a catalyst for any consideration by an implementation group. It was noted that the proposed procedure made provision for an appeals process that allowed the CCP to reconsider a complaint on the basis of a response to a determination. Members were of the initial view that it would not be appropriate for the same body as made the determination to undertake a review of a complaint and that all relevant evidence should be provided to the Panel in the first response. It was explained that the CCP would be exercising a delegation from the Joint Agency and so an appropriate appeals process would be built in. As well, a statement of reasons can always be sought by either party to a complaint. This is an issue for further consideration during the implementation period.

The role of industry codes of practice

Clarity was sought as to the jurisdiction and responsibilities of industry codes of practice. It was suggested that sponsors need to be educated and for consumers to be made aware of the fact that, in New Zealand, complaints can be dealt with by an industry association with the potential for the application of significant financial sanctions.

The value of endorsing industry codes and making compliance with them a condition of market entry was reiterated, as making possible the application of relevant codes to non-members and the application of the same stringent financial penalties as those applicable to members of associations. It gives the regulator leverage, through the role of cancelling product, if there is non-compliance with the industry code.

It was noted that all endorsed industry codes of practice would have the TPAC as their core. At market entry, a sponsor would decide as part of the application for a product licence, to which industry code of practice the advertising of the product would comply.

One member questioned the need to have industry codes of practice endorsed, with compliance being a condition of product licence, if the CCP does not apply the industry codes of practice in the consideration of complaints. The potential for the involvement of a large number of codes was seen as potentially being a problem. It was noted by the Chairman that the reason for taking this approach is that industry and government have a joint interest in dealing with non-compliance.

Members discussed at some length a proposal that, where an industry code of practice has been endorsed by the Joint Agency (on the advice of the Advertising Council) and compliance with that code made a condition of market entry, it should be possible for the central panel to

apply both the TPAC and the relevant industry code of practice in the consideration of a complaint. This would provide a centralised system for all advertising to consumers, precluding duality and provide an opportunity to impose the same sanctions as can be applied by industry associations. Such a centralised approach would prevent forum shopping and take advantage of the best of both worlds.

In considering this issue, it was clarified that it was not generally expected that the industry codes would impose additional or more stringent requirements relevant to advertising than the TPAC (other than the New Zealand Research Medicines Industry Code of Practice which deals specifically with the advertising of prescription medicines to consumers in New Zealand). In terms of advertising, it was expected that the industry codes of practice would provide additional guidance on the TPAC and focus on related matters involving ethics and behaviour.

It was noted that the application of both codes at the time of approval would also be relevant. For approval and complaint, only the advertising components of the industry codes would be relevant. Associations would have to affirm the possible breach of the industry code referred by the CCP and apply the recommended sanction/s. Matters of conduct would be dealt with by the industry association. Where both issues arose, the panel could refer a provisional judgement to an industry association.

Members agreed that this proposal is worthy of further consideration by the implementation group.

It was agreed that a clear description of the process for the handling of complaints would need to be included in the educational program for industry on the new model, possibly including a flow chart.

Membership of the Central Complaints Panel in Australia

The Chairman outlined three issues raised by stakeholders, which required further consideration by IAC members:

1. Whether the Chairperson should be designated rather than drawn from the membership of the Panel;
2. The inclusion on the Panel of industry representatives; and
3. Whether a legally qualified person should be included on the Panel as a permanent member.

After considerable debate, it was agreed that the proposed membership of the Central Complaints should be as follows:

A total of 8 members, including at any one time 6 voting members:

- 2 persons with public health expertise and experience in community practice in a healthcare profession;
- 1 person with expertise in consumer issues;
- 1 regulator
- 1 person with expertise in advertising issues;

3 industry sector representatives drawn from the OTC, complementary and medical devices sectors, each with voting rights only for complaints relevant to the sector.

Each industry sector would have the right to choose an alternative representative, to preclude any conflict of interest and allow the appropriate person to participate.

There was general support for the suggestion that ideally the public health experts should provide an appropriate balance of experience in medical practice, pharmacy and complementary healthcare practice.

It was agreed that the report should note the AMA view that one of the two public health experts should be a medical practitioner.

It was agreed that the Chair should be drawn from members with either public health expertise or expertise in consumer issues.

Members were divided as to whether a person with legal expertise should be included as a full member of the Panel or relevant expert legal advice should be sought on an as-need basis. It was suggested that during the confidence building period it would be sensible have a non-voting legal expert in attendance at all meetings.

Members agreed that option 2 in the report should be reworded to reflect the view that where there is no relevant legal expertise held by any other panel member, a legal expert will be included as a non-voting member. This arrangement is to be reviewed after 6 months.

7. Agenda item 4 - Governance

At the 7th and 8th meetings of the IAC (6 / 26 August 2004), members discussed various options for the establishment of the Central Support Unit in Australia, particularly in regard to:

- the proposed employment arrangements for staffing of the CSU;
- the CSU being able to enter into contracts for the provision of services relevant to the regulation of advertising of therapeutic products and to be granted delegations;
- whether the CSU would actually hold the advertising budget; and
- the need for this unit to reflect the co-regulatory nature of the proposed advertising model.

The three options previously considered by the IAC for establishing the Central Support Unit were:

1. As a business unit of the Joint Agency;
2. As a non-profit company limited by guarantee (formed by members of the management sub-committee)
3. The appointment of a Statutory Office Holder

While noting that the IAC had indicated a preference for option 1 at this point, the ASMI representative of the IAC restated her concerns at the Sydney stakeholder meeting that option 1 failed to recognize the agreement for a co-regulatory and self-regulatory approach for all

advertising arrangements and that placing the Central Support Unit as a business unit within the Joint Agency represented an abrogation of industry's responsibility and could be perceived as undermining the co-regulatory approach. Other members of the IAC suggested that, provided there were sufficient trust between all parties and checks and balances in the system, the strength of the co-regulatory system would not be diminished.

After it was suggested at the Sydney stakeholder meeting that there appeared to be a lack of understanding about the potential advantages offered by either of the other options and that no decision should be taken until the costs implications were known, stakeholders overwhelmingly supported the reconsideration of this approach by the IAC at the next meeting, after further exploration of the implications of all options.

At the New Zealand stakeholder meeting there was unanimous support for the Central Support Unit being a business unit of the Joint Agency. Other options were considered cumbersome and expensive and would not provide an appropriate balance of New Zealand and Australian influence.

Stakeholders expressed the view that 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.

The Support Group tabled further information on aspects of each of the three options outlined in the draft report for the consideration of members.

Physical location of the CSU

It was noted that some of the submissions argued that the CSU should be separately located from the Joint Agency. It was noted, too, that it is intended that the Joint Agency will have offices in Canberra, Sydney, Melbourne and Wellington. Members generally agreed with the view that there should probably be at least one member of the Support Group in Wellington (potentially to undertake evaluation, monitoring and Secretariat functions) and that, otherwise, the most appropriate location would be in Sydney.

There was concern expressed about perceptions in relation both to co-location of approvals and complaints personnel and to locating the CSU within Joint Agency offices. It was argued that such perceptions would make a strong argument for the company option, which would provide the greatest degree of independence from the Joint Agency.

Most members were of the view that for reasons of efficiency, convenience and cost it would be sensible to co-locate all of the functions of the CSU. It was suggested that, were the CSU to be a business unit of the Joint Agency, it could be possible to locate it separately from any regulatory function of the Joint Agency.

The ASA representative tabled a document on perceptions and consumer focus for consideration by the implementation group.

Consideration of Option 3

Having noted the content of the one-pager tabled at the meeting by the support group relating to this option, members agreed that this option would be difficult to implement in the context of reflecting the joint arrangements between Australia and New Zealand and that there should be no further investigation of this option in the implementation period.

Consideration of Options 1 and 2

Although Option 2 was seen to give maximum benefit in terms of the independence of the co-regulatory model, it was apparent that directors would be required to accept responsibility and be accountable for the successful operation of the company while having no direct control over revenue-raising. In addition, liability issues could act as a disincentive to acquiring suitable directors. It was noted that the Australian government does not generally grant indemnity to contractors.

It was suggested that care would need to be taken in managing the relationship between directors and members who are not directors to prevent any feeling of disenfranchisement, although this could be addressed in the constitution of the company.

The New Zealand representatives were concerned at the perception that a company structure would involve an Australian organization established in Australian law, although it was recognised that there could be mechanisms available to enable registration in both countries.

It was suggested by the CHC representative that because the whole system is co-regulatory in nature, and because the relationship between the regulator and other stakeholders has matured over time, Option 1 would be acceptable.

Significant concerns, both real and perceived, were raised by the other industry sectors about Option 1, as per the reasons outlined by the ASMI representative at the stakeholder consultation meeting. It was felt that Option 2 more closely reflects the current responsibility held by industry for the administration of the system. The obligation on industry to ensure the system's success was seen as an extremely important component of industry's commitment to the system, and that this could be lost by having the administration again within the domain of the regulator. The potential for loss of flexibility, transparency and efficiency were also noted with concern.

The Chairman concluded that, based on the material before them, most members appear to prefer the proposal put forward in Option 1. However, it was suggested that in taking the discussion forward by the implementation group, the report needs to provide an opportunity to explore other legally or contractually based options.

Most members agreed that the report should put forward Option 1 as the preferred position. The dissent of Medicines Australia, ASMI and MIAA to this recommendation, as well as one abstention by the representative from the Australian advertising industry, is to be recorded in the report.

Two approaches were put forward as a variation to Option 1. Firstly, that staff would be ongoing employees of the Joint Agency, appointed on the advice of the Advertising Council and, secondly, that staff, including the CEO, could be employed under contract to the Joint Agency on the advice of the Advertising Council.

- **The majority of members agreed that the report is to recommend that the CSU be established as a unit of the Joint Agency (option 1) while noting the dissenting views and reasons for these views.**
- **The report is also to note that members were unanimously of the view that further work should be done by the implementation group in considering an alternative legally or contractual-based option for the employment of the CSU in the future.**

It was noted that staffing arrangements for the CSU would be developed further during the implementation period.

The TGA representative informed the meeting that there is an evolving model for the transfer of the current Advertising Unit of the TGA to a proposed structure for the Joint Agency. It is likely that this unit could be located within the enforcement area of the Joint Agency. In light of this revised structure, it is anticipated that representatives from the Joint Agency appointed as members of committees associated with the regulation of advertising would be likely to be drawn from the relevant product evaluation /assessment stream rather than the enforcement area.

8. Agenda item 5 – Transition arrangements

The following proposed transition arrangements for various aspects of the scheme were considered.

IT Working Party

A provisional report was provided on the status of the work of the IT Working Party which has been established by the Joint Agency Establishment Group to develop the user specifications for an IT system to track and record details of approvals and complaints.

The report included recommendations and a proposal for establishing central databases for approvals and complaints handling. The proposal is based on the New Zealand experience of a purpose built, user friendly system tested through four stages of development. IAC members recognised the generosity of the Advertising Standards Authority (NZ) in offering to provide this software at no charge.

Members noted that the recommendations need to be considered within the context of the Joint Agency IT strategic plan.

IAC members agreed to commend the proposal and recommend that the final report from the IT Working Party should be referred to the implementation group.

The provisional report from the IT Working Party was noted and the Chair and members of the Working Party thanked for the work done.

The Therapeutic Products Advertising Code, approvals and notifications

The proposed early introduction of a modified version (to reflect existing law) of the TPAC in New Zealand, to be accepted in November and introduced at the beginning of February, was noted.

It was noted that consideration of a proposed introduction of a hybrid version of the Therapeutic Goods Advertising Code by the Therapeutic Goods Advertising Code Council has been deferred to the December meeting to allow time for consideration of the proposed TPAC by the Interim Ministerial Council.

The Chairman suggested that the report should reflect industry's preference for retention of the two-year validity of advertisements approved before implementation and note the TGACC review in December.

It was noted that from 1 July 2005, all advertisements must comply with the TPAC (irrespective of the media in which they are published).

The ASMI representative suggested that consideration be given to recommending retaining the validity of all two year approvals granted before 1 July 2005, on the basis that advertisers notify and certify their advertisements' compliance with the TPAC and, for those advertisements that do not comply, seek their re-approval (at a reduced rate). It was suggested, too, that it would advantageous to have the new Code introduced simultaneously in Australia and New Zealand.

The Chairman suggested that if the TGACC were to accept a hybrid TGAC in December which became effective from 1 January 2005, there would be a six month advance on the length of the transition period and this would be in line with the introduction of the modified TPAC in New Zealand.

The proposal put forward by the ASMI representative in relation to re-approval is to be given further consideration by the implementation group.

Members accepted that advertising material already in the market place would not require notification but would be subject to the usual complaints process.

While therapeutic products currently included on the Australian Register of Therapeutic Goods (ARTG) cannot be advertised with therapeutic claims which are inconsistent with those recorded in the ARTG, it was noted that for a limited period after commencement of the joint scheme, complementary medicines (previously supplied in New Zealand as dietary supplements) will not have a similar point of reference. This situation will need to be considered in relation to the implementation of the advertising regulatory model.

9. Agenda item 6 – Cost recovery

At the 7th and 8th meetings of the IAC (6 / 26 August 2004), members discussed various options for cost recovery and agreed that the proposed model for fees and charges should meet the following principles:

- fees should be set to recover full costs consistent with Australian and New Zealand government cost recovery principles;
- fees and charges should be based on “user pays”;
- there should be equity between Australia and New Zealand;
- any price differential should be minimised to avoid influencing behaviour;
- impact on business in year one should be minimised; and
- the need for monies to cross-over between bodies should be avoided.

The IAC agreed that based on these principles the cost recovery model should:

- retain the current component attributable to advertising activities in the annual product registration charge;
- include an approval fee which funds the cost of approvals with a slight increase for Australia;
- include a notification fee of no more than \$10 in Australia and \$7 in New Zealand;
- include an annual fee for the training of delegated authorities which should be self-funding.

Taking these principles into account, a cost recovery model was developed by the IAC Support Group which was estimated to raise the amount required to fund the activities which form part of the proposed regulatory model.

An updated cost recovery model was presented by a member of the IAC Support group and an explanation given as to the reasons for the updated figures for the delegated authority accreditation program. The inclusion of additional paragraphs in the draft report acknowledging the self funding by industry and professional bodies, the anticipated reduction in costs of the regulator's advertising unit and on the estimated costs of the development and implementation of training programs for delegated authorities were noted.

Stakeholder comments from the consultation meetings and in writing were all noted.

Stakeholders at the Sydney meeting called for the IAC report to acknowledge the Australian Productivity Commission Report on Cost Recovery by Government Agencies. It was noted that the draft IAC report has been updated to refer to the Australian Government's response to this report in the context of the proposed cost recovery model. A copy of the Australian Government's response to that Report was tabled.

It was noted that particular issues that are still to be resolved include:

- The differentiation between members and non-members in approvals fees in New Zealand and the implications of such an arrangement for Australia;
- Whether the approvals cost should cover the cost of the process only or include an additional component to cover education; or
- Whether education costs should be drawn from annual fees and charges.

Members also noted that:

- there will need to be very close monitoring and review of the cost recovery model implemented to ensure an accurate level of cost recovery;
- actual costs and revenues will be public information reported annually to Ministers;
- there is a need to minimize any cross subsidization;
- for clarity, figures should be presented without GST;
- if possible, contracts need to be structured in such a way as to not require the inclusion of GST;
- the costs for the proposed system are not very different from the overall current costs.

The revised cost recovery model was noted.

10. Agenda item 8 – other business

Draft report

IAC membership

Members agreed that sequential appointment of IAC members and their attendance at each meeting should be presented in the report by means of a table.

Australian policy with respect to the direct to consumer advertising of prescription medicines

It was agreed that the report should clarify that the prohibition on direct to consumer advertising of prescription products (DTCA) in Australia was outside of the IAC's terms of reference and that the proposed regulatory model was intended to accommodate the current differing policies on DTCA in Australia and New Zealand.

Thank you

The Chairman thanked all members for their patience, good humour and constructive contribution to the IAC process and wished everyone well for the implementation phase of development.

The Head of the IAC Support Group, in thanking the Chairman on behalf of all members, referred to the admirable and skilful way in which the meetings had been conducted and extended particular thanks for the care with which the job had been done. She also commended all members of the IAC for their important contribution to the work undertaken by the IAC. She then proposed a vote of thanks to her fellow members of the Support Group which was further reiterated by the Medsafe representative.

List of amendments to the Therapeutic Products Advertising Code agreed at the IAC meeting held on 12 and 13 October 2004.

PRINCIPLE 2

Advertisements must be truthful, balanced and not misleading.

Claims must be valid and have been substantiated.

All claims, not just therapeutic claims, that are made in an advertisement must be truthful, valid and have been substantiated. Substantiation means that the advertiser is satisfied that there is sufficient evidence to support the advertised claim.

Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

The reinstatement of this wording reflects the intention that evidence to support claims should be held by advertisers before any advertising for the product is undertaken.

A3.1 Exemptions from the Code

- Bona fide education, research and professional advice (page 6)

Paragraph 3

Last clause of the sentence, add 'or' before 'prominently' to read

and any consideration received has been explicitly acknowledged and/or prominently displayed.

Last dot point on page 6

To address a potential problem of involving terms of trade as a consideration or incentive, the last dot point was amended by deleting "~~unless they have received any consideration in return for the promotion of branded material or products~~"

Delete

~~'Consideration' is anything provided or promised in exchange for something else. It does not include the salary of a person employed in the ordinary course of business.~~

A3.2 Application of the Code to specific types of advertisements (page 7)

- Unbranded advertising

To give clarity it was agreed to amend the first sentence from ‘and’ to ‘**and/or**’. The sentence now reads:

An unbranded advertisement promotes the use or supply of product by inviting the consumer to seek further information about symptoms or conditions **and/or** their treatment or management while not referring overtly to any particular branded product

- **Generic advertising**

The words ‘blood pressure’ were removed from the example to remove any confusion arising from the inclusion of a restricted representation.

- **Label Presentation**

It was felt that this heading should reflect the content and context of the clause that the reference to labels is in the context of presentation.

Advertisements for foods or cosmetics in which therapeutic claims are made (page 9)

The amendment of ‘shall’ to ‘may’ in the first paragraph was made to reflect legislative reality but is set in the context of the unanimous and strong IAC view of the necessity for a level playing field.

.....Food Standards Code, the product **may** be declared to be a therapeutic product.....

A4.2 Approval of advertisements (page 11)

Pre-approvals and revisions to advertisements which have been approved by the Central Approvals Office or the TAPS

Sponsors and other advertisers which have a properly qualified and trained **employee or consultant (acting under contract)** to consider and approve advertisements are encouraged to apply for accreditation as a Delegated Authority (DA) to approve **advertisements or revisions of** advertisements which have already been approved by either the Central Approvals Office in Australia or the TAPS in New Zealand.

This clause has been amended to reflect the possibility of consultants being employed under contract by delegated authorities, and the intention to allow, over time, the first time approval of advertisements by delegated authorities.

A4.4 Review and Appeals

Appeal of a decision not to approve an advertisement or withdraw an approval

Where the applicant is dissatisfied with the decision of the Managing Director, an application can be made to the Trans Tasman Review Tribunal that will provide an independent merits review of the Agency's regulatory decisions.

Appeal of a decision made in dealing with complaints about advertisements

Australia

If the Central Complaints Panel (Australia) decides that an advertisement breaches the therapeutic products legislation, including the Code, the Panel can order certain action/s be taken by the advertiser/sponsor, such as withdrawal of the advertisement, publication of a retraction or correction, withdrawal of a representation and/or impose penalties. If the ~~request order~~ is not complied with within 14 days, the Panel may make recommendations to the Agency to pursue regulatory or court action. In extreme cases, regulatory action to remove the product from the market may be necessary.

Both parties to the complaint ~~are able to~~ can request that the Managing Director review the determination of the complaint and any orders issued against the advertiser/sponsor. If ~~the advertiser/sponsor either party~~ is still dissatisfied with the internal review, an appeal can be made to the Trans Tasman Review Tribunal, which will be drawn from a merits review panel.

The matter can also be taken to the Federal Court of Australia or the courts of an Australian State or Territory.

New Zealand

If the Advertising Standards Complaints Board decides that an advertisement breaches the therapeutic products legislation, including the Code, the Board can request that the advertisers/sponsors withdraw the advertisement. If the request is not complied with within 14 days, the Board may refer the matter to the Agency to pursue regulatory or court action. In extreme cases, regulatory action to remove the product from the market may be necessary.

~~Both parties~~ Either party to the complaint ~~are~~ is able to request that the Advertising Standards Complaints Appeal Board (ASCAB) review the determination of the complaint and, if dissatisfied with that review, a request can be made for an internal review by the Managing Director of the Joint Agency. If ~~the advertiser/sponsor either party~~ is still dissatisfied, ~~they may~~ an appeal can be made to the Trans Tasman Review Tribunal which will be drawn from a merits review panel.

The matter may also be taken to the New Zealand court.

The amendments above correct a spelling error and reflect the IAC view that a consumer complainant as well as a respondent should have a right of review by an external merits tribunal. In this situation, the appellant would need to be able to demonstrate to the tribunal that they were directly adversely affected by the regulatory decision against which they were appealing.

PART B1

Advertising Medicines to Consumers (page B1-17)

In New Zealand, advertising of all medicines directed to consumers is legal, other than those which contain controlled drugs which are not **exempted or partially exempted controlled drugs** as defined in the *Misuse of Drugs Act 1975*.

Where the Researched Medicines Industry Association of New Zealand (RMI) Code of Practice contains additional **requirements or limitations, advertising must comply with those provisions.**

The rewording of this introductory paragraph reflects the application of the RMI Code of Practice to direct to consumer advertising of prescription products and more correctly defines medicines which may be advertised directly to consumers in New Zealand.

Requirement 1 (page B1-17)

There was support for the removal of the examples (and the part of the sentence introducing the examples) in paragraph 1 as unnecessary elaborations on the requirement and, in any case, were covered in industry codes of practice.

Requirement 2 (page B1-17)

Advertisements (~~other than labels~~) must contain the mandatory information to encourage responsible use.

Any advertisement for therapeutic products must include all of the required statements in paragraphs (a) to (e), other than where:

- the advertisement does not contain a therapeutic claim and displays only the brand **and/or** name **and/or** picture of the therapeutic products or the name of the sponsor and/or the price and/or point of sale; or
- the advertisement is an unbranded, or a reminder, or a sponsorship advertisement.

[The inclusion of and/or was seen by IAC members as precluding the need for a separate definition for brand-only advertisements]

All required statements in paragraphs (a) to (e) must be prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or be heard and understood.

For all required statements, other than 'Always read the label', words conveying the same meaning may be used.

(a) (i) Advertisements to consumers for medicines, must contain:

- the trade name; and
- indications consistent with those included in the database of therapeutic products maintained by the Agency; and
- where the advertising of prescription medicines is permitted in New Zealand, a list of the active ingredients; and
- for all medicines (**except for prescription medicines where they may be advertised in New Zealand**) the following mandatory statement:

ALWAYS READ THE LABEL

[The additional wording qualifies which of the mandatories apply to non-prescription medicines]

- and the following statement or words with the same meaning:

USE ONLY AS DIRECTED

- and the following statement, or words with the same meaning, where relevant to the product i.e. if the indication is for symptomatic relief, or a similar indication.

IF SYMPTOMS PERSIST SEE YOUR HEALTHCARE PRACTITIONER

- (ii) If the product, when used according to the directions:
- has known serious adverse effects (in terms of severity and clinical importance); or
 - is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI),
an appropriate warning of those effects must be given.

(Where a warning which reflects the regulatory requirements for the label or the Consumer Medicine Information (CMI) **refers to a serious condition, disease or disorder**, an approval for use of a restricted representation is not required).

Most prescription medicines would be likely to meet the above criteria. Categories of non-prescription medicines which would be likely to meet the above criteria include sedating anti-histamines, pseudoephedrine and non-steroidal anti-inflammatory drugs.

(The IAC recommends the development of common sense guidelines by an expert committee to provide parameters for the inclusion of warnings relating to the severity and the clinical importance of adverse effects and contraindications appropriate for the category of product).

- (iii) Additional mandatory statements based on the scheduling classification of the therapeutic product, as follows:

- If it is a restricted/pharmacist only medicine (New Zealand) or Schedule 3 and listed in Appendix H, SUSDP (Australia), the words:

**YOUR PHARMACIST'S ADVICE IS REQUIRED; or
AVAILABLE ONLY FROM YOUR PHARMACIST**

- If it is a Schedule 4 (prescription medicine) able to be advertised in New Zealand:

**PRESCRIPTION MEDICINE, CONSULT YOUR DOCTOR [OR OTHER REGISTERED
HEALTHCARE PRACTITIONER PRESCRIBER] TO SEE IF THIS MEDICINE IS
RIGHT FOR YOU**

- For New Zealand, if there is a charge for a prescription medicine in excess of the standard prescription fee, this should be indicated, e.g.

A CHARGE APPLIES, CONSULT YOUR DOCTOR OR PHARMACIST

- (iv) Where an advertisement is for the sale or supply of therapeutic products by mail order, direct mail, or the internet, the advertisement must contain, in addition to the above:
- any mandatory advisory statements required to be included on the product label, prominently displayed on each page that features the relevant therapeutic product/s;

- if the product, when used according to the directions:
 - has known serious adverse effects (in terms of severity and clinical importance); or
 - is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI);
 an appropriate warning of those effects must be given (where a warning reflects the regulatory requirements for the label of the Consumer Medicine Information (CMI), an approval for use of a restricted representation is not required);
- a full list of the active ingredients. (Where the product name is also the single active ingredient, the pack shot displaying the product name will be sufficient to meet this requirement).

(b) Where the advertising of prescription medicines is permitted (New Zealand), consumers must be notified that additional product information can be obtained, and the methods for doing so. Such information shall include the name and quantities of the active ingredients, authorised uses, appropriate precautions, contra-indications, and adverse reactions. *Various acceptable methods include, but are not limited to, instructions for consumers to contact their doctor, pharmacist or health practitioner; referring consumers to the labelling of the product or the Consumer Medicine Information; provision of a toll-free telephone number; the advertiser's internet website address; the advertiser's postal address; reference to the Consumer Medicines Information, where applicable, and referring consumers to advertisements with full information appearing concurrently in other media.*

(c) In addition to the requirements specified above, analgesics require the following statement:

INCORRECT USE COULD BE HARMFUL

An advertisement for analgesics must not represent that:

- (a) analgesic consumption is safe; and/or
- (b) analgesics will relax, relieve tension, sedate or stimulate.

(d) An advertisement for vitamins must not represent that vitamin supplements:

- are a substitute for good nutrition or a ~~balanced~~ healthy diet; and/or
- are superior to, or more beneficial than, dietary nutrients or that normal health may be affected by not taking vitamin supplements.

(e) Advertisements for therapeutic products containing claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, must have an appropriate balance between those claims and references to healthy energy-controlled diet and physical activity

[To allow a consistent meaning of the term 'balanced', the word 'balanced' has been replaced by 'healthy' in the context of nutrition and diet.]

Requirement 3

Explanatory note, first paragraph

Sponsors / advertisers are required to hold appropriate, balanced, comprehensive and credible evidence to support advertised claims. That is, when the claim is considered in the overall context of all information available at the time of advertising, it is, on balance, substantiated. ~~Substantiation means that the~~

~~advertiser is satisfied, before the claim has been advertised, that there is sufficient evidence to support the advertised claim.~~

Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

Refer Principle 2

Requirement 4.1 (page B1-20)

Explanatory note – for clarity

*Claims as describe in iv) are **may be** restricted representations....*

R4.3 Scientific information

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, **where that sponsor directly, or indirectly, has commercial interest in the product or its ingredients or components** .

This amendment addresses a practical difficulty of identifying the researcher at all times while providing transparency for consumers where there is a vested interest by a sponsor.

R4.4 Advertisements directed to pharmacy assistants and retail sales persons (page B1-21)

Entire clause deleted – refer to minutes

Requirement 5 (page B1-21)

Dot points – replace ‘those’ and ‘the’ with ‘people’

Requirement 6 (page B1-21)

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and ~~cannot be misconstrued~~ is not presented as an endorsement of a product.

Unless prohibited by endorsed industry sector codes, advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not in any way imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain,

prominently displayed, the name of the endorser and acknowledgement of any valuable consideration.

Examples which would be taken to represent an endorsement by a government agency and therefore are prohibited include:

- *“approved by, ~~licensed by~~ the Trans Tasman Therapeutic Products Agency” (or any other terminology in the trans Tasman legislation which implies approval)*

These amendments clarify the intent of the clauses and allows for the relevance of industry sector codes. Members noted that a distinction needs to be drawn between ‘endorsement’ and promotion of government guidelines.

Requirement 7 (page B1-22)

Paragraph 2

The advertising approval officer, at the time of assessing an advertisement for approval for publication, ~~is likely to~~ will request evidence of the above, including that it is typical, and ~~is likely to request~~ is entitled to require a signed statutory declaration, and/or a copy of the signed testimonial, from the person making the testimony. If the substance of the testimonial in the advertisement has been altered from the original testimony, the advertisement may not be approved for publication.

Members were concerned that approval officers/adjudicators should be able to require the provision of evidence with legal status.

Requirement 8 (page B1-23)

Change the italicized text to bold. Change the last line to:

This means that they must not (either expressly or by implication) refer to the self-diagnosis of, or the treatment, management, prevention or cure of, serious forms of diseases, conditions, ailments or defects which are those diseases, conditions, ailments or defects (or symptoms of the aforementioned) which are generally accepted as not being suitable for treatment, management, prevention or cure by consumers.

Prohibitions (page B1-24)

Paragraph 2

2. *In New Zealand, advertisements for Class A, Class B and Class C controlled drugs other than exempted or partially exempted controlled drugs, as defined in the Misuse of Drugs Act 1975, may only be directed to healthcare practitioners and in appropriate media.*

The additional wording reflects the New Zealand legislation.

PART B2

Advertising Medical Devices to Consumers

This part has been amended to reflect appropriately the changes made above.

PART B3

Advertising Directed to Healthcare Practitioners

Preface

Paragraph 3

All advertising directed to healthcare practitioners must encourage the responsible and quality use of therapeutic products. Because healthcare practitioners have expert and professional knowledge in their relevant fields, and are able to discriminate between information of value and advertising hyperbole, not all of the Advertising Requirements in Sections B1 and B2 (i.e. advertising directed to consumers) apply. **There is no requirement for pre-approval of advertisements directed to healthcare practitioners.**

This sentence has been replaced to ensure clarity as to there being no requirement for pre-approval of advertisements that are directed to healthcare practitioners.

R4.3 Scientific information

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

Extracts from scientific studies must not be ambiguous or mislead as to the content or results of the study or the performance of the therapeutic product. Inserting selected abstracts from scientific papers or medical reports, which do not accurately reflect the results of the study or report, into an advertisement, has the potential to be ambiguous and may mislead by omission or implication. Titles of publications, or parts thereof, must not contravene the Code.

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, where that sponsor directly, or indirectly, has commercial interest in the product or its ingredients or components .

Members were of the view that the relevant parts of R4.3 should be included in Part B3.

Australia New Zealand

**Therapeutic Products
Advertising Code**

17 November 2004

Version 11

CONTENTS

Throughout the Code, explanatory notes, interpretations and examples are in italics.

PART A

Part A of the Code sets out the common obligations that must be met by advertisers of therapeutic products in Australia and New Zealand and common processes which support the implementation of the Code.

Definitions

Preface

- A1 Object
- A2 Interpretation
- A3 Application
- A4 General processes - public interest criteria, approvals, complaints, appeals
- A5 Failure to comply with the Code

PART B

Part B of the Code sets out the requirements for specific types of advertising of therapeutic products and, to particular audiences. Each Section of Part B is a stand-alone document, which must be read in conjunction with Part A of the Code.

- B1 Advertising medicines to consumers
- B2 Advertising medical devices to consumers
- B3 Advertising therapeutic products to healthcare practitioners

DEFINITIONS

Advertisement	means any communication which promotes or discourages the use, sale or supply of products (whether or not in conjunction with the supply of services, and whether or not the communication identifies particular products or services). (Refer A3)
Advertiser	means any person who, or entity which, communicates, or arranges for the communication of, an advertisement.
Approval Officer	means any person (or industry association) to whom the Managing Director has delegated the central authority to approve an advertisement in any media under Section x of the Rules.
Delegated Authority	means any person outside of the Joint Agency or the central approvals offices in Australia and New Zealand to whom the Managing Director has delegated certain limited authority to approve an advertisement under Section x of the Rules.
Exempt product	for the purposes of the Code, means a product for which a sponsor is not required to hold a product licence.
Government agency	means any department, ministry, agency, board, organisation, authority, etc of the governments of Australia or New Zealand or international government agencies (such as the Food and Drug Administration (USA)). Refer to the following government internet sites for examples of government agencies - www.gold.gov.au or www.govt.nz
Healthcare practitioner	means (I) for the purposes of determining whether an advertisement is directed to healthcare practitioners, a person who is described in a Schedule (to be developed jointly by Australia and New Zealand) to the Rules and, (II) for the purposes of representations made in advertisements, a person represented so as to be likely to be taken to be a healthcare practitioner.
Label	means a display of printed information upon, or securely affixed to, a container and any primary pack containing the products.
Presentation	in relation to therapeutic products, means the way in which the products are presented for supply, and includes matters relating to the name of the products, the labelling and packaging of the products and any advertising or other informational material associated with the products.
Promote	means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.
Restricted medical device	means a medical device which is intended to be administered or used only by a healthcare practitioner.

Mainstream media

in relation to an advertisement means:

- a. any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions media; or
- b. broadcast media where the information is disseminated electronically in a visible or audible form or a combination of such forms; or
- c. cinematography film; or
- d. displays about products, including posters:
 - i. in shopping malls (except inside individual shops);
 - ii. in or on public transport; and
 - iii. on billboards.

**Sponsorship
Advertisement**

means a representation that the advertiser (product, brand, company) is sponsoring a person, competition, activity, program or event.

Sponsor

in relation to therapeutic products means:

- (a) a person who exports, or arranges the exportation of, the products from Australia or New Zealand; or
- (b) a person who imports, or arranges the importation of, the products into Australia or New Zealand; or
- (c) a person who, in Australia or New Zealand, manufactures the products, or arranges for another person to manufacture the products, for supply (whether in Australia, New Zealand or elsewhere);

but does not include a person who;

- (d) exports, imports or manufactures the products; or
- (e) arranges the exportation, importation or manufacture of the products;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangement, is a resident of, or is carrying on business in, Australia or New Zealand.

Therapeutic database

means the register of licensed therapeutic products maintained by the Joint Agency (refer Section [*insert no*] of the Rules).

Therapeutic product

This definition is copied from the Treaty³

(a) means:

- (i) a product that is represented in any way to be, or that is, whether because of the way in which the product is presented or for any other reason, likely to be taken to be for therapeutic use;
 - (ii) an ingredient or component in the manufacture of a product referred to in subparagraph (i) above;
 - (iii) a container or part of a container for a product, ingredient or component referred to in subparagraphs (i) or (ii) above; or
 - (iv) a product falling within a class of products the sole or principal use of which is, or ordinarily is, a therapeutic use;
- and

(b) includes:

- (i) a product which the Rules provide shall be treated as a therapeutic product for the purposes of the Agreement; and
- (ii) a product which is declared to be a therapeutic product in an Order made under paragraph 2 of Article 10, but

(c) does not include:

- (i) a product which the Rules provide shall not be treated as a therapeutic product for the purposes of this Agreement; or

³ Refer to the *Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products* at website <http://www.jtaproject.com>

- (ii) a product which is declared not to be a therapeutic product in an Order made under paragraph 2 of Article 10.

Therapeutic use

- (a) means use in or in connection with:
 - (i) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in humans;
 - (ii) influencing, inhibiting or modifying a physiological process in humans;
 - (iii) testing the susceptibility of humans to a disease or ailment
 - (iv) influencing, controlling or preventing conception in humans;
 - (v) testing for pregnancy in humans; or
 - (vi) the replacement or modification of parts of the anatomy in humans; and
- (b) includes any other use which the Rules provide shall be treated as a therapeutic use for the purposes of the Agreement³; but
- (c) does not include any use which the Rules provide shall not be treated as a therapeutic use for the purposes of this Agreement.

Verifiable claim

in relation to the advertising of medical devices means any claims that need verification including statements about facts, research results, comparisons, quotes, testimonials, and endorsements or other information about the device not covered under the Therapeutic Products legislation for the essential principles for medical devices.

PREFACE

All products supplied for therapeutic use in Australia and New Zealand must be licensed and entered on the Trans Tasman therapeutic product database, unless exempt.

The advertising of therapeutic products in Australia and New Zealand is controlled by a combination of:

- statutory measures (with both criminal and civil sanctions) enforced by the Trans Tasman Joint Agency (the Agency);
- co-regulatory processes for the approval of advertisements and handling of complaints about advertisements; and
- self-regulation through industry, healthcare professional and media codes of practice or ethics.

Three key *Advertising Principles* are established in the Australian and New Zealand therapeutic products legislation (Act(s)) and provide the foundation for the Australia New Zealand Therapeutic Products Advertising Code (the Code). *Advertising Requirements*, established in the Rules, expand on these principles and are also incorporated in the Code. Other than changes to the *Advertising Principles* and *Advertising Requirements*, which require approval by the Ministerial Council, the Code can be amended by order of the Managing Director of the Agency on the advice of the Advertising Council. The Advertising Council is broadly representative of key stakeholders.

PRINCIPLE 1

Advertisements must comply with the Therapeutic Products Act(s) and Rules and the Therapeutic Products Advertising Code.

Advertisements for therapeutic products must comply with the Code and the therapeutic products legislation developed for the Trans Tasman regulatory scheme.

Therapeutic products that are substances in Schedule 3, or Schedule 4 or Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which are not also in Appendix H (as amended from time to time) or contain substances in those Schedules, cannot be advertised to consumers in Australia, because the therapeutic products legislation as it applies in Australia prevents the advertising of these therapeutic products. The advertising of all Schedule 3 and Schedule 4 products to consumers is allowed in New Zealand, other than those products specifically prohibited by the Misuse of Drugs Act 1975.

Compliance with the requirements of the Code does not absolve sponsors and other advertisers from the need to comply with other common law and statutory requirements of the country where the advertisement is published, in particular, the trade practices legislation in Australia and New Zealand.

Approval of an advertisement does not guarantee compliance with any legislation.

PRINCIPLE 2

Advertisements must be truthful, balanced and not misleading.

Claims must be valid and have been substantiated.

All claims, not just therapeutic claims, that are made in an advertisement must be truthful, valid and have been substantiated. Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

For example, a claim that a particular therapeutic product is “the most popular” or “the world leader” would need to have been substantiated.

Advertisers should be aware that the Agency, the advertising approval officer and the complaints handling bodies can require the advertiser to produce balanced, comprehensive and credible evidence to support any of the claims or representations made in an advertisement.

PRINCIPLE 3

Advertisements must observe a high standard of social responsibility.

Advertisers have a responsibility to ensure that the content and presentation of their advertisement promotes responsible use through encouraging consumers to select management options wisely, to choose suitable therapeutic products and to use them safely and effectively. In the lawful advertising of prescription medicines (ie as permitted in New Zealand), advertisers should consider the need for consumers readily to access valid, relevant, easily understood information to enable them to make informed healthcare choices in consultation with their healthcare practitioners.

The provisions for compliance with Advertising Principle 1 are to be found in the legislation and the Code

In order to comply with Advertising Principles 2 and 3, the Advertising Requirements, which are established in the Rules, must be observed. These requirements, with explanatory notes, can be found in the sector-specific sections of the Code (i.e. Sections B1, B2, and B3).

PART A

A1. OBJECT

The object of the Code is, through controls on advertising, to:

- safeguard public health and safety;
- protect the public interest; and
- support the quality use of therapeutic products and informed healthcare choices.

The Code sets the standard for the regulation of advertisements for therapeutic products in Australia and New Zealand in order to ensure that the advertising of therapeutic products is socially responsible, does not mislead or deceive and supports consumers:

- selecting management options wisely;
- choosing suitable therapeutic products; and
- using them safely and effectively¹.

The Code provides the minimum advertising standard for the industry codes of practice and healthcare practitioner codes of ethics in Australia and New Zealand.

A2. INTERPRETATION

The Code is the standard applied to all advertisements and in the consideration of approvals, complaints and appeals. In interpreting the Code, the total presentation and context of the advertisement will be considered in terms of the content, as well as the spirit and intent, of the Code.

The conformity of an advertisement with the Code will be assessed in terms of its probable understanding by the reasonable person to whom the advertisement is directed.

A3. APPLICATION

The definition of “advertisement”, in relation to therapeutic products, is broad and includes any form of communication that either directly or indirectly promotes or discourages the use, sale or supply of a therapeutic product. For example, an advertisement about a health service or treatment program that includes a reference to the use, sale or supply of a medicine or medical device is also an advertisement for that medicine or medical device. However, an advertisement for a service, which only incidentally references a type of therapeutic product, is not covered by this definition (e.g. laser hair clinic).

While the definition of “advertisement” is broad, there are a number of exclusions to the definition, as outlined in Section A3.1.

The Code applies to all advertisements for therapeutic products (including products which are exempt from product licensing).

The Code applies to all advertisements directed to consumers and healthcare practitioners.

The Code applies to advertisements disseminated in all forms of media, including, but not limited to:

- Television, radio, cinema;
- Newspapers, consumer magazines, trade / professional journals;
- Outdoor displays e.g. billboards, taxi signs, bus sides, shopping mall displays;
- Direct mail, including addressed and unsolicited mail;
- Catalogues;

¹ Refer Australian National Medicines Policy and National Strategy for Quality Use of Medicines at <http://www.health.gov.au>.

- Point of sale material (eg brochures, pamphlets, posters, displays, shelf-talkers); and
- Websites, e-mails, SMS messages and any other electronic means.

Where an advertisement includes a reference directing consumers to obtain further information (such as a phone number, website, mailing address or book), the information in the referenced material relevant to the advertisement may be taken into account in considering the advertisement.

The oversight of the application of the Code resides with the Advertising Council.

A3.1 Exemptions from the Code

- **Bona fide news, bona fide editorial, bona fide public interest programs and bona fide entertainment programs**

The Code does not apply to bona fide news, bona fide editorials, bona fide public interest programs and bona fide entertainment programs which meet the definition for such material as described in the relevant media industry codes of practice.

News stories, editorial comment and public interest information about therapeutic products are important sources of health information for Australian and New Zealand consumers. Consumers expect that, as distinct from advertisements for therapeutic products where the commercial interest of the advertiser is understood potentially to bias information content, genuine news, editorial and public interest programs comprise independent and objective journalism, free of assertions made by an advertiser/sponsor. This information thus is expected to be objective and impartial, and commentary/interpretation about the information to be independent of the advertiser. Bona fide entertainment programs are also exempt from the provisions of the Code on this basis.

This exclusion recognises that while the media has the freedom to broadcast or publish news or editorial matter, the broadcast or publication of news, editorial, public interest and entertainment programs is subject to the requirements of relevant industry codes of practice. These codes of practice form part of the regulation of broadcast and print media and draw a distinction between the regulatory treatment of editorial content and that of advertising. This distinction is based principally on whether or not the publisher or broadcaster has received any payment or other valuable consideration in return for the broadcast or publication.

If there is any doubt as to whether material is “editorial” or advertising, the complaint should be submitted through the appropriate media complaints process. Through that complaints process, the material will be assessed for compliance with the appropriate advertising, broadcasting or print code of practice; and, in the case where the material is determined to be advertising, the matter will be referred to the usual central complaints processes for the advertising of therapeutic products.

- **Bona fide education, research and professional advice**

The Code does not apply to:

- bona fide educational material, including material containing scientific information and/or information based on traditional use, prepared by healthcare professionals, academics and other scientists and educators, provided that;

for branded therapeutic products -

the context of the presentation of the material or the material itself does not promote the commercial use, sale or supply of branded therapeutic products and no consideration has been received in return for the public promotion of the branded therapeutic product that is the subject of the educational material;

for generic substances / ingredients or unbranded therapeutic products -

the context of the presentation of the material or the material itself does not promote the commercial use, sale or supply of branded therapeutic products; and any consideration received has been explicitly acknowledged and/or prominently displayed;

or

- private advice provided by healthcare practitioners and retailers or their employees to consumers in the ordinary course of their business;
- or
- communications between consumers.

A3.2 Application of the Code to specific types of advertisements

- **Unbranded advertising**

An unbranded advertisement promotes the use or supply of product by inviting the consumer to seek further information about symptoms or conditions and/or their treatment or management while not referring overtly to any particular branded product. Unbranded advertisements must comply with Advertising Requirements 1, 3, 4, 5, 6 and 8 of the Code.

A typical example of an unbranded advertisement:

"Did you know that there is a new product available for controlling {medical condition}? If you are suffering from {symptoms / conditions} ask your medical practitioner about appropriate treatment options."

- **Generic advertising**

A generic advertisement promotes the benefits of a particular category of therapeutic products, substance, ingredient or medical device component and is not related to any particular branded product. Generic advertisements must comply with Advertising Requirements 1, 3, 4, 5, 6 and 8 of the Code.

A typical example of a generic advertisement:

"Have you considered the benefits of {substance}. Recent research has shown that {substance} in combination with exercise reduces oxidative stress in older adults. Call (phone number) for more information on products which contain this substance."

- **Disease awareness campaigns**

Disease awareness campaigns, comprising information that aims to raise awareness regarding specific diseases, including public health campaigns, must be factual and balanced, and support consumers in making informed healthcare choices.

Disease awareness campaigns must not identify a therapeutic product. Any campaign that directly, or indirectly, promotes the use, sale or supply of therapeutic products is advertising and, therefore, subject to the Code.

Such information usually would focus on encouraging consumers to seek healthcare practitioner advice about the diagnosis, treatment or prevention of a disease or condition.

Advertisers need to be aware that where there is only one therapeutic product available to treat or diagnose the specified disease, or where a new therapeutic product has just been released for the treatment or diagnosis of the disease state, it is possible that information about the disease state, taken in context, could be considered to be unbranded or generic advertising.

Further advice can be sought from the central approvals office in Australia or the central adjudicator in New Zealand.

Where a disease awareness campaign includes material which contains a reference directing consumers to obtain further information (such as a phone number, website, mailing address or book), the information in the referenced material relevant to the campaign material may be taken into account when considering the campaign material.

- **Sponsorship advertisements**

Sponsorship advertisements, in relation to therapeutic products, are any form of communication publicising sponsorship of any person or activity, such as a competition, event or program by a brand name therapeutic product by anyone with a commercial interest in the therapeutic product.

Sponsorship advertisements shall:

- a) clearly and primarily promote the team, individual, competition, event or activity being sponsored;
- b) not contain a direct or implied claim or a sales message for a therapeutic product, other than a brand name, or, in the case of devices, a purpose for use;
- c) not show a therapeutic product or product packaging;
- d) not imitate or use any parts of therapeutic product advertisements from any medium; and
- e) only briefly and in a subordinate way mention or portray the product sponsor's name and/or brand or product name and/or logo, orally or visually.

Sponsorship advertisements (other than advertisements for prescription medicines in New Zealand), which meet the above criteria, are exempt from the mandatory information described under Advertising Requirement 2.

If the brand name of a medicine, medical device or other therapeutic product is used in the sponsorship of a major sporting event (eg "ABC company fun run" or "{product name} fun run"), the billboards at the event and any advertisements for the event that included the brand name of the medicine or device are sponsorship advertisements, provided they meet the above criteria.

- **Reminder advertisements**

Reminder advertisements are advertisements directed to consumers that are designed only to remind the reader of the name of the product or to act as a "lead in" to a full advertisement. They are permitted, provided they do not include both the name of the product and a direct or implied therapeutic claim, and they are linked to "full advertisements" within:

- the same publication (written advertisement); or
- the same program/announcer (spoken advertisement),

as part of a broader campaign.

If these conditions are not met, the full requirements of the Code, including the mandatory information, apply.

Reminder advertisements that are directed to consumers are not permitted for prescription medicines (where prescription products are otherwise permitted to be advertised in New Zealand).

Reminder advertisements in a campaign must not straddle media (i.e. have the main advertisement in one form of media and reminder advertisements in other forms of media).

Any advertisement which contains the name of the product and a therapeutic claim (including where the claim is implied in the product name) is not a reminder advertisement and must meet the full requirements of the Code, including the mandatory information.

- **Presentation**

As part of acceptable presentation (as defined in Rule XX), any written, pictorial or other descriptive matter supplied or displayed with or on any therapeutic product must be truthful, valid and not misleading.

For the purposes of the Code, a label is not an advertisement unless it forms part of an advertisement. For example, where a pack shot is included in an advertisement.

- **Internet advertising**

All advertisements for therapeutic products on Australian or New Zealand websites on the internet must comply with the Code. Any complaint received about an advertisement published on the internet is subject to the usual complaint processes.

Where an Australian or New Zealand website includes an advertisement which has links to other international websites containing advertisements for therapeutic products, the reader must be made aware that they are leaving the Australian / New Zealand website and that other linked advertisements may not comply with the Code.

Where an Australian or New Zealand website is linked to an overseas website, advertisers also are encouraged to alert consumers to the possibility that therapeutic products advertised on the overseas websites may not be available in Australia or New Zealand and, therefore, may not meet Australian/New Zealand regulatory requirements for safety, quality or efficacy.

Where an advertisement includes a reference directing consumers to obtain further information (such as a phone number, website, mailing address or book), the information in the referenced material relevant to the advertisement may be taken into account in considering the advertisement.

Further information on the use of the internet for providing educational material to consumers, including Product Information and Consumer Medicines Information, is included in relevant industry codes of practice.

- **Advertisements for foods or cosmetics in which therapeutic claims are made**

Where an advertisement for a food product contains a claim for therapeutic use, other than a nutrition or health related claim as specifically prescribed by any standard for nutrition, health and related claims in the Food Standards Code², the product may be declared to be a therapeutic product subject to the full provisions of the therapeutic product legislation, including compliance with the Code and all other regulatory requirements.

Any cosmetic product advertisement which contains a therapeutic claim is subject to the full provisions of the therapeutic products legislation, including compliance with the Code and all other advertising regulatory arrangements.

² Published by Food Standards Australia New Zealand – refer website <http://www.foodstandards.gov.au>

A4. GENERAL PROCESSES

A4.1 Public Interest Criteria

The following public interest criteria are to be applied when making decisions relating to:

- consideration of complaints; and
- Advertising Council recommendations on advertising to vulnerable audiences and restricted representations (refer Advertising Requirement 5 and Advertising Requirement 8) made in relation to products or classes of products, including:
 - (a) consumers', or certain groups of consumers', vulnerability when:
 - faced with having a disease, condition, ailment or defect,
 - seeking to manage a condition (eg pregnancy), or
 - seeking to avoid a disease, condition, ailment or defect.
 - (b) for non-prescription medicines, the likelihood that the audience has the knowledge and maturity to self-diagnose and self-manage the condition(s) for which the products are to be advertised;
 - (c) the likelihood that advertising of the products to the likely audience could reasonably be expected to deliver to them health benefits or improvements to their quality of life;
 - (d) whether a representation would be likely to result in consumers not seeking timely professional advice where appropriate (such as where timely professional advice is important to prevent negative health consequences or serious deterioration or progression of disease);
 - (e) whether a representation would be likely (alone or through repetition or together with other references) to have a negative impact on public health (or to have an adverse effect on persons other than those to whom the advertisement is directed); and
 - (f) such other aspects of the public interest as may appear to be appropriate.

For non-prescription medicines:

The World Health Organization notes that responsible self-medication can:

- help prevent and treat symptoms and ailments that do not require medical consultation;
- reduce the increasing pressure on medical services for the relief of minor ailments, especially when financial and human resources are limited;
- increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult; and
- enable patients to control their own chronic conditions.

For medical devices:

Paragraphs (a) and (b) of the public interest criteria are not relevant in the context of determining whether a restricted medical device should be able to be advertised (refer Part B2 - Requirement 8).

Additionally, applications to advertise a restricted medical device also must address the following points:

- Whether the content of the advertisement is balanced and adequately references warnings, contra-indications and risks particularly for those devices used in invasive procedures;
- Whether the advertisement is likely to arouse preconceived expectations of the outcomes;
- Whether the advertisement clearly identifies the important role of the healthcare practitioner and the advice he/or she provides; and
- Whether the advertisement could be construed to claim or imply that the use of the device or procedure is suitable in all cases.

A4.2 Approval of advertisements

Advertisements for medicines directed to consumers

Advertisements which appear in mainstream media, other than the internet, must be approved by the Central Approvals Office in Australia or the Therapeutic Advertising Pre-vetting Scheme (TAPS) in New Zealand for compliance with the Code prior to publication or broadcast. This is a requirement under the Joint Therapeutic Product Rules. A fee is payable on the basis of the time taken to approve the advertisement as outlined in the Joint Therapeutic Product Rules for fees and charges.

Details of all other advertisements must be included on the central approvals database as a notification. As part of this notification process, the sponsor/advertiser is required to certify that the advertisement complies with the Code. A unique notification number will be allocated. A fee is payable which will be invoiced on a quarterly basis. The Central Approvals Office in Australia or the TAPS in New Zealand may be contacted if a sponsor/advertiser wishes to seek further advice on whether a particular advertisement complies with the Code.

Advertisements for medical devices directed to consumers

Advertisements for medical devices which:

- contain a verifiable claim; or
- promote a restricted medical device;

must be approved by the Central Approvals Office in Australia or the TAPS in New Zealand for compliance with the Code prior to publication or broadcast. This is a requirement under the Joint Therapeutic Product Rules.

Details of all other advertisements must be included on the central approvals database as a notification. A unique notification number will be allocated. A fee is payable which will be invoiced on a quarterly basis. The Central Approvals Office in Australia or the TAPS in New Zealand may be contacted if a sponsor/advertiser wishes to seek further advice on whether a particular advertisement complies with the Code.

Revisions to advertisements which have been approved by the Central Approvals Office or the TAPS

Sponsors and other advertisers which have a properly qualified and trained employee or consultant (acting under contract) to consider and approve advertisements are encouraged to apply for accreditation as a Delegated Authority (DA) to approve advertisements or revisions of advertisements which have already been approved by either the Central Approvals Office in Australia or the TAPS in New Zealand.

Applications to become a Delegated Authority are considered by the Advertising Council (or a relevant sub-committee) which then makes recommendations to the Joint Agency. The DA is issued with a unique number which is recognised by the media for the purposes of placing the advertisement. The responsibility for assessing advertisements is vested only with that person. The DA can call the Central Approvals Office or the TAPS free of charge for advice, if necessary.

For further details refer to

Advertisements for therapeutic products directed to healthcare practitioners

These advertisements do not require approval in Australia. In New Zealand, approval through the TAPS office is strongly encouraged, on a self-regulatory basis.

Whether or not requiring approval, all advertisements for therapeutic products in Australia and New Zealand, including advertisements for therapeutic products on the internet, must comply with the Code.

An approval number or notification number must be stand-alone, located in the bottom right hand corner of a print media or internet advertisement and able to be read easily from a normal viewing distance.

The process for the approval of advertisements is set out in the Rules. Irrespective of the country in which the approval is granted, the approval applies to advertisements communicated in any media in

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either Australia or New Zealand, other than advertisements for prescription and certain non-prescription medicines directed to consumers that may only be advertised in New Zealand.

Withdrawal of approval

An approval for an advertisement can be withdrawn by an approvals officer or the Joint Agency as a result of an upheld complaint or legislative change.

Seeking prior approval for the use of certain restricted representations for medicines or restricted medical devices

For an application for approval for the use of a restricted representation or a restricted medical device:

- for medicines, to refer directly or by implication to serious diseases, conditions, ailments or defects in an advertisement, or,
- for medical devices that are intended to be used and/or administered solely by healthcare practitioners,

the approval decision will take into consideration the public interest criteria listed in section A4.1.

A4.3 Complaints

Complaints about advertisements thought to be in breach of the Therapeutic Products Act(s) or Rules, including the Advertising Principles, Advertising Requirements and the Code, can be lodged² with:

- the Advertising Standards Complaints Board (ASCB), for advertisements published or broadcast in New Zealand; or
- the Central Complaints Panel (the Panel), for all advertisements published or broadcast in Australia, through the Central Support Unit.

The functions and powers of the Central Complaints Panel established in Australia and the Advertising Standards Complaints Board in New Zealand are set out in the Rules.

In support of a fair and transparent complaints system, anonymous complaints are not accepted.

New Zealand

Any person can submit a complaint about an advertisement to the Advertising Standards Complaints Board. The Chair of the ASCB has the discretion to withhold the name of the complainant. Complaints that are submitted by consumers or competitors about advertisements directed to healthcare practitioners, which do not involve matters of serious public health and safety, may be referred to the appropriate industry sector panel for consideration. If the complainant wishes to pursue the complaint, the industry sector panel may apply a charge.

Australia

Any person can submit a complaint about an advertisement to the Central Complaints Panel in Australia. So as not to act as a disincentive for the making of complaints, where the complainant is a consumer, the complainant's name is withheld from the other party and from public release. The Central Complaints Panel handles all complaints about advertisements directed to consumers, and complaints involving matters of serious public health and safety. Complaints that are submitted by consumers or competitors about advertisements directed to healthcare practitioners, which do not involve matters of serious public health and safety, are referred to the appropriate industry sector panel for consideration. If the complainant wishes to pursue the complaint, the industry sector panel may apply a charge.

A4.4 Review and Appeals

Review of a decision not to approve an advertisement or to withdraw an approval

² Lodgement should preferably be in writing. However, where this is not possible, complaints will still be accepted provided that the identity of the complainant can be confirmed and the exact nature of the complaint.

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If an advertisement is not approved or approval is withdrawn, a request to review the decision can be submitted to the Managing Director (refer Rule {insert Rule number}) to reconsider the merits of the decision to refuse approval in Australia and New Zealand.

The request for review can be considered by a senior delegate of the Managing Director, who was not involved in the initial decision making process.

The initial decision will stand until the decision is varied or revoked.

The request must be made within 30 days after the notice of the decision and the applicant must, at the same time, send a copy of the request to the Advertising Council. In reviewing the decision, the Managing Director may take into account any recommendation made by the Advertising Council.

Appeal of a decision not to approve an advertisement or withdraw an approval

Where the applicant is dissatisfied with the decision of the Managing Director, an application can be made to the Trans Tasman Review Tribunal that will provide an independent merits review of the Agency's regulatory decisions.

Appeal of a decision made in dealing with complaints about advertisements

Australia

If the Central Complaints Panel (Australia) decides that an advertisement breaches the therapeutic products legislation, including the Code, the Panel can order certain action/s be taken by the advertiser/sponsor, such as withdrawal of the advertisement, publication of a retraction or correction, withdrawal of a representation and/or impose penalties. If the order is not complied with within 14 days, the Panel may make recommendations to the Agency to pursue regulatory or court action. In extreme cases, regulatory action to remove the product from the market may be necessary.

Both parties to the complaint can request that the Managing Director review the determination of the complaint and any orders issued against the advertiser/sponsor. If either party is still dissatisfied with the internal review, an appeal can be made to the Trans Tasman Review Tribunal, which will be drawn from a merits review panel.

The matter may also be taken to the Federal Court of Australia or the courts of an Australian State or Territory.

New Zealand

If the Advertising Standards Complaints Board decides that an advertisement breaches the therapeutic products legislation, including the Code, the Board can request that the advertiser/sponsor withdraw the advertisement. If the request is not complied with within 14 days, the Board may refer the matter to the Agency to pursue regulatory or court action. In these circumstances, regulatory action to remove the product from the market may be necessary.

Either party to the complaint may request that the Advertising Standards Complaints Appeal Board (ASCAB) review the determination of the complaint and, if dissatisfied with that review, a request can be made for an internal review by the Managing Director of the Joint Agency. If either party is still dissatisfied, an appeal can be made to the Trans Tasman Review Tribunal which will be drawn from a merits review panel.

The matter may also be taken to the New Zealand court.

A5 - FAILURE TO COMPLY WITH THE CODE

Non-compliance with the Code is an offence under Section X of the Trans Tasman Therapeutic Products Act(s). Regulatory action also can be taken by the Agency under Section X of the Rules to suspend or cancel a product licence for breaches of the Code.

Compliance with the Code is encouraged through broad stakeholder representation on the Advertising Council, the consultative processes in place for any proposed changes to the Code and education programs run by the peak therapeutic products and advertising/media industry associations in Australia and New Zealand.

To deal with non-compliance with the Code, a range of administrative sanctions and criminal penalties can be applied by the Agency. A range of enforcement tools is necessary to ensure that the regulatory response is commensurate with the seriousness of the offence and recognises that, in many cases, minor offences can be resolved without the need for punitive action. Often this range is considered in terms of a pyramid with the lower levels based on advice and persuasion to prompt a voluntary response. The next level involves the issuances of formal directions to undertake certain action/s and/or infringement notices, which are intended to be a light punitive action where there is a clear breach of a non-serious nature. Where there is the need to escalate the matter, regulatory action can be taken to suspend or cancel a product licence. At the top of the pyramid is criminal prosecution, which would apply only to the most serious breaches or repeat offenders.

PART B1

ADVERTISING MEDICINES TO CONSUMERS

The advertising of prescription medicines, and certain non-prescription medicines, directly to consumers is prohibited in Australia (refer B1-23). In New Zealand, advertising of all legally supplied medicines directed to consumers is permitted, subject to compliance with this Code, other than those which contain controlled drugs which are not exempted or partially exempted controlled drugs, as defined in the *Misuse of Drugs Act 1975*. Where the Researched Medicines Industry Association of New Zealand (RMI) Code of Practice contains additional requirements or limitations for the advertising of prescription medicines, advertisers must comply with these provisions.

Requirement 1

Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.

Advertisements must not encourage consumers to purchase or use quantities of a medicine that may exceed, or is not appropriate for, their needs.

In determining whether or not an advertisement is likely to encourage a consumer to use a medicine inappropriately or excessively, all circumstances relating to the advertisement will be taken into account, including the target audience and, where appropriate, the following factors:

- *the nature of the advertisement;*
- *the nature and quantity of the medicine offered as part of a price promotion, as samples or giveaways, or required to be purchased as a condition of entry to a competition;*
- *prizes offered in association with the medicine;*
- *the risk of the medicine advertised; and*
- *the design/conditions of any competition.*

Requirement 2

Advertisements must contain the mandatory information to encourage responsible use.

Any advertisement for a medicine must include all of the required statements in paragraphs (a) to (e), other than where:

- the advertisement does not contain a therapeutic claim and displays only the brand/name/picture of the medicine or the name of the sponsor and/or the price and/or point of sale; or
- the advertisement is an unbranded, or a reminder, or a sponsorship advertisement.

All required statements in paragraphs (a) to (e) must be prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or be heard and understood.

For all required statements, other than 'Always read the label', words conveying the same meaning may be used.

(a) (i) Advertisements to consumers for medicines must contain:

- the trade name; and
- indications consistent with those included in the database of therapeutic products maintained by the Agency; and
- where the advertising of prescription medicines is permitted in New Zealand, a list of the active ingredients; and
- for all medicines (except for prescription medicines where they may be advertised in New Zealand) the following mandatory statement:

ALWAYS READ THE LABEL

- and the following statement or words with the same meaning:

USE ONLY AS DIRECTED

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- and the following statement, or words with the same meaning, where relevant to the product i.e. if the indication is for symptomatic relief, or a similar indication.

IF SYMPTOMS PERSIST SEE YOUR HEALTHCARE PRACTITIONER

(ii) If the medicine, when used according to the directions:

- has known serious adverse effects (in terms of severity and clinical importance); or
- is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI),

an appropriate warning of those effects must be given.

(Where a warning which reflects the regulatory requirements for the label or the Consumer Medicine Information (CMI) refers to a serious disease, disorder, or condition an approval for use of a restricted representation as per Requirement 8 of the Code is not required).

(The IAC recommends the development of common sense guidelines during the implementation period, with appropriate input by relevant expert committees, to provide parameters for the inclusion of warnings relating to the severity and the clinical importance of adverse effects and contraindications appropriate for the category of product).

(iii) Additional mandatory statements based on the scheduling classification of the therapeutic product, as follows:

- If it is a restricted/pharmacist only medicine (New Zealand) or Schedule 3 and listed in Appendix H, SUSDP (Australia), the words:

YOUR PHARMACIST'S ADVICE IS REQUIRED; or AVAILABLE ONLY FROM YOUR PHARMACIST

- If it is a Schedule 4 (prescription medicine) able to be advertised in New Zealand:

PRESCRIPTION MEDICINE, CONSULT YOUR DOCTOR [OR OTHER PRESCRIBER] TO SEE IF THIS MEDICINE IS RIGHT FOR YOU

- For New Zealand, if there is a charge for a prescription medicine in excess of the standard prescription fee, this should be indicated, e.g.

A CHARGE APPLIES, CONSULT YOUR DOCTOR OR PHARMACIST

(iv) Where an advertisement is for the sale or supply of therapeutic products by mail order, direct mail, or the internet, the advertisement must contain, in addition to the above:

- any mandatory advisory statements required to be included on the product label, prominently displayed on each page that features the relevant medicine/s;
- if the medicine, when used according to the directions:
 - has known serious adverse effects (in terms of severity and clinical importance); or
 - is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI);

an appropriate warning of those effects must be given.

(Where a warning reflects the regulatory requirements for the label of the Consumer Medicine Information (CMI), an approval for use of a restricted representation as per Requirement 8 of the Code is not required);

- a full list of the active ingredients.
(Where the product name is also the single active ingredient, the pack shot displaying the product name will be sufficient to meet this requirement).

(b) Where the advertising of prescription medicines is permitted (New Zealand), consumers must be notified that additional product information can be obtained, and the methods for doing so. Such information shall include the name and quantities of the active ingredients, authorised uses, appropriate precautions, contra-indications, and adverse reactions. *Various acceptable methods include, but are not limited to, instructions*

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for consumers to contact their doctor, pharmacist or healthcare practitioner; referring consumers to the labelling of the product or the Consumer Medicine Information; provision of a toll-free telephone number; the advertiser's internet website address; the advertiser's postal address; reference to the Consumer Medicines Information, where applicable, and referring consumers to advertisements with full information appearing concurrently in other media.

- (c) In addition to the requirements specified above, analgesics require the following statement:

INCORRECT USE COULD BE HARMFUL

An advertisement for analgesics must not represent that:

- (a) analgesic consumption is safe; and/or
- (b) analgesics will relax, relieve tension, sedate or stimulate.

- (d) An advertisement for vitamins must not represent that vitamin supplements:

- are a substitute for good nutrition or a healthy diet; and/or
- are superior to, or more beneficial than, dietary nutrients or that normal health may be affected by not taking vitamin supplements.

- (e) Advertisements for medicines containing claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, must have an appropriate balance between those claims and references to a healthy energy-controlled diet and physical activity.

Requirement 3

To assist consumers to make informed decisions, advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated and:

- a) for medicines – must be consistent with the indications included on the database of therapeutic products maintained by the Trans Tasman Therapeutic Products Agency; and**
- b) for exempt therapeutic products – must be compliant with the Code.**

Sponsors / advertisers are required to hold appropriate, balanced, comprehensive and credible evidence to support advertised claims. That is, when the claim is considered in the overall context of all information available at the time of advertising, it is, on balance, substantiated. Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

Evidence may be requested to verify any claim included in an advertisement. Where the advertiser is not a sponsor, the advertiser should have access to this evidence.

For advertising claims for therapeutic use, the sponsor / advertiser must hold information or evidence to substantiate any indication for use. Depending on the class of the products, this evidence must either have been evaluated by the Agency or subject to self-certification by the sponsor as part of product licensing requirements.

Other advertising claims, such as product presentation, marketing or commercial claims, also must be valid and have been substantiated.

The term 'valid' embraces the concepts of safe and effective use of medicines. It can apply in the broader context to any marketing claim contained within an advertisement.

The term 'balance' embraces the overall balance within an advertisement of representations, risks and benefits.

Any therapeutic indication referred to in unbranded or generic advertising must have been substantiated. In this case, Requirements 3(a) and 3(b) are not relevant.

If a sponsor ceases to supply/import/manufacture or export particular medicines, that sponsor may request that the product licence be cancelled. Subject to relevant Australian government legislation, New Zealand government legislation and Australian state/territory legislation, where the cancelled product can continue to be lawfully

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supplied by a retailer (who is not also the sponsor) directly to consumers, the product may be advertised for supply subject to compliance with the Code.

Requirement 4

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

- (a) mislead or deceive, or be likely to mislead or deceive; or**
- (b) abuse trust, or exploit lack of knowledge; or**
- (c) exploit the superstitious or, without justifiable reason, play on fear or cause distress.**

The protection of public health and safety, in terms of quality, safety and efficacy of the advertised product (including performance claims) is the focus of this Requirement. The Australian Competition and Consumer Commission (Australia) and Commerce Commission (NZ) also have responsibility for laws prohibiting misleading or deceptive conduct and false and misleading representations (including advertising). These agencies deal with broader matters through the administration of relevant trade practices legislation. The Agency will liaise with the Australian Competition and Consumer Commission and the Commerce Commission in New Zealand where there is any potential regulatory overlap.

R4.1 An advertisement must not:

- i) contain any claim, statement or implication that the product is safe or that its use cannot cause harm or that it has no side effects or risks associated with its use;
- ii) contain any claim, statement or implication that the product is effective in all cases of a condition;
- iii) contain any claim, statement or implication that it is infallible, unailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- iv) contain any matter which is likely to lead persons to believe that;
 - they are suffering from a serious ailment, or
 - harmful consequences may result from the therapeutic product not being used.

Claims as described in iv) may be restricted representations. Where appropriate, and if claims made in an advertisement are consistent with public health messages, an exemption from iv) may be granted. Approval for the use of a restricted representation, as per Requirement 8 of the Code, may need to be sought. An example of a product category that meets the public interest criteria to allow approval for restricted representations is sunscreen preparations for skin cancer prevention.

R4.2 Comparative advertising

Comparative advertising must be balanced and must not be misleading, or likely to be misleading, either about the product advertised or any therapeutic products, or classes of therapeutic products, with which comparison is made.

Comparative advertisements must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence.

Where medicines whose market entry indications are compared with other medicines whose market entry indications have been evaluated by the Agency, the advertiser must, upon request, be able to produce evidence to substantiate the comparison.

In comparing products, advertisements must not discourage consumers from taking medicines prescribed by a healthcare practitioner.

R4.3 Scientific information

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

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Using complex scientific terminology in advertisements is likely to exploit the average consumer's lack of scientific knowledge to understand the true meaning of what is being said in the advertisement.

Extracts from scientific studies must not be ambiguous or mislead as to the content or results of the study or the performance of the medicine. Inserting selected abstracts from scientific papers or medical reports, which do not accurately reflect the results of the study or report, into an advertisement, has the potential to be ambiguous and may mislead by omission or implication. Titles of publications, or parts thereof, must not contravene the Code.

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, where that sponsor directly, or indirectly, has commercial interest in the medicine or its ingredients.

Requirement 5

Advertisements must not unduly glamorise products or services, or prey on the vulnerability of particular audiences.

Examples of potentially vulnerable audiences include, but are not limited to:

- *minors (people under 18 years of age)*
- *older people*
- *people with mental health problems*
- *people with impaired hearing/vision*
- *people with chronic or serious illness or long term or permanent disability*
- *people for whom English is a second language*

In considering the compliance of an advertisement directed to any of the potentially vulnerable groups listed above, the public interest criteria (refer Section A4.1) will be applied.

Requirement 6

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and is not presented as an endorsement of a product.

Unless prohibited by endorsed sector codes, advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the name of the endorser and acknowledgement of any valuable consideration.

Examples which would be taken to represent an endorsement by a government agency and therefore are prohibited include:

- *“approved by the Trans Tasman Therapeutic Products Agency” (or any other terminology in the trans Tasman legislation which implies approval)*
- *“recommended by the Australian Sports Commission”*
- *“supported by the National Science and Technology Centre”*

Examples of statements which would not be considered to imply an endorsement include:

- *Entered into the trans-Tasman database of therapeutic products*
- *Manufactured in a GMP licensed premise*
- *Manufacturing Licence No. (****)*

Examples which would be taken to represent an endorsement by a healthcare practitioner (as defined under Part A4 of the Code) and would be permitted subject to certain disclosure requirements include:

- *pictorial images of healthcare practitioners promoting a medicine,*
- *using the name of a healthcare practitioner to promote the medicine, or*
- *stating or implying that a healthcare practitioner, uses, recommends or was involved in the testing or development of a medicine.*

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Note: An approvals officer may request provision of a statutory declaration as authentication of an endorsement by an individual healthcare practitioner.

Hospitals or other facilities providing healthcare services

Facilities that provide health care or healthcare services include centres that are delivering healthcare services on a commercial or public health basis. For example hospitals, general practice, dentistry, community-based office practices, day-surgery centres, domiciliary nursing services, other healthcare providers, and other community services such as needle exchanges, ambulance services and mobile medical services.

Examples of an endorsement by a healthcare facility or service include:

- *advertising to consumers that a healthcare facility or service has a contract to use a specific medicine,*
- *promoting sponsorship of healthcare facilities or services by a brand name medicine,*
- *suggesting a healthcare facility or service prefers a particular brand of medicine, or*
- *suggesting a healthcare facility or service was involved in the development, testing or manufacture of the medicine being advertised.*

Requirement 7

Testimonials in advertisements, where not prohibited by law, must comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable consideration.

The use of testimonials in advertisements to promote medicines is acceptable, other than for prescription products directed to consumers (New Zealand), provided the testimonial:

- *is genuine;*
- *complies with the Code;*
- *is current;*
- *has been authenticated;*
- *presents the typical case, not the exceptional; and*
- *contains an acknowledgement of any valuable consideration.*

The advertising approval officer, at the time of assessing an advertisement for approval for publication, will request evidence of the above, including that it is typical, and is entitled to require a signed statutory declaration, and/or a copy of the signed testimonial, from the person making the testimony. If the substance of the testimonial in the advertisement has been altered from the original testimony, the advertisement may not be approved for publication.

“Current” means that the content of a testimonial must be up to date and hold true at the time of the publication of the advertisement.

“Typical” means that which reflects the characteristics of a group. i.e. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

Requirement 8

Advertisements directed to consumers must not refer directly or by implication to serious diseases, conditions, ailments or defects without approval from the Trans Tasman Therapeutic Products Agency.

Unless prior approval has been obtained (refer Part A4.2) advertisements directed to consumers must not contain a restricted representation. This means that they must not (either expressly or by implication) refer to the self-diagnosis of, or the treatment, management, prevention or cure of, serious forms of diseases, conditions, ailments or defects which are those diseases, conditions, ailments or defects (or symptoms of the aforementioned) which are generally accepted as not being suitable for treatment, management, prevention or cure by consumers.

PROHIBITIONS

1. *In Australia, it is prohibited to advertise directly to consumers, prescription medicines (i.e. containing Schedule 4 or 8 substances), and non-prescription medicines containing Schedule 3 substances that do not appear in Appendix H to the Standard for Uniform Scheduling of Drugs and Poisons, (as amended from time to time), including medical devices which contain those substances. The prohibition does not apply where the Australian Commonwealth, States and Territories governments include information about specific products in public health education initiatives such as vaccination campaigns.*
2. *In New Zealand, advertisements for Class A, Class B and Class C controlled drugs which are not exempted or partially exempted controlled drugs, as defined in the Misuse of Drugs Act 1975, may only be directed to healthcare practitioners and in appropriate media.*

PART B2

ADVERTISING MEDICAL DEVICES TO CONSUMERS

Requirement 1

Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.

Advertisements must not encourage consumers to purchase or use quantities of a medical device that may exceed, or be inappropriate for, their needs.

There is a range of ways in which advertisements for medical devices could encourage excessive or inappropriate use. One such example would be the encouraging of prolonged self-administration of a medical device, which could result in delay of persons seeking advice from a health care practitioner and/or mask the symptoms of a more serious disease; for example, an advertisement that encourages repeated and/or prolonged use of a peripheral nerve stimulator for pain relief.

In determining whether or not an advertisement is likely to encourage a consumer to use medical devices inappropriately or excessively, all circumstances relating to the advertisement will be taken into account, including the target audience and, where appropriate, the following factors:

- *the nature of the advertisement;*
- *the nature and quantity of therapeutic products:*
 - *offered as part of a price promotion;*
 - *offered as samples or giveaways; or*
 - *required to be purchased as a condition of entry to a competition;*
- *prizes offered in association with therapeutic products;*
- *the risk of the therapeutic products advertised;*
- *the design/conditions and promotion of any competition;*
- *the instructions for use, or advice, regarding the appropriate use of a medical device.*

Requirement 2

Advertisements must contain the mandatory information to encourage responsible use.

Any advertisement for medical devices must include all of the required statements in paragraphs (a) to (e), other than where:

- the advertisement does not contain a therapeutic claim or intended purpose for use and displays only the brand/name/picture of the medical device and/or the price and/or point of sale; or
- the advertisement is an unbranded, or a reminder, or a sponsorship advertisement.

All required statements in paragraph (a) must be prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood.

(a) Advertisements to consumers for medical devices must contain the following statements:

- the trade name;
- the intended purpose consistent with that included in the database of therapeutic products maintained by the Agency. [Until 2007, where there is no intended purpose on the database, the purpose must be consistent with the manufacturer's intended purpose for use]; and
- the following mandatory statement (except where the advertisement is for a health service or treatment program that includes a reference to the use or administration of a particular device as part of that service or treatment):

ALWAYS READ THE LABEL

and/or, where appropriate,

FOLLOW THE INSTRUCTIONS (or words to that effect)

If the medical device has contraindications or specific warnings that may affect the safe use of the device, which are reflected in the regulatory requirements for the product label or in the patient information, an appropriate warning must be given (where a warning includes a reference to a restricted medical device as part of the regulatory requirements for the label, approval to reference that restricted medical device is not required).

For example, if:

- *an electronic medical device is likely to interfere with a cardiac pacemaker; and/or*
 - *the use of a particular medical device is contraindicated for specific medical conditions;*
- then these warnings should appear in the advertisement for the devices.*

Requirement 3

To assist consumers to make informed decisions, advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated and:

- a) for medical devices – must be consistent with the manufacturer’s intended purposes included on the database for therapeutic products maintained by the Trans Tasman Therapeutic Products Agency; and**
- b) for exempt therapeutic products – must be compliant with the Code.**

Sponsors / advertisers are required to hold appropriate, balanced, comprehensive and credible evidence to support advertised claims. That is, when the claim is considered in the overall context of all information available at the time of advertising, it is, on balance, substantiated. Substantiation means that, before the claim has been advertised, the advertiser has sufficient evidence to support the claim or is satisfied, on reasonable grounds, that there is sufficient evidence to support the claim.

Evidence may be requested to verify any claim included in an advertisement. Where the advertiser is not a sponsor, the advertiser should have access to this evidence. That is, the sponsor / advertiser must hold information or evidence to substantiate any intended purpose included on the database for therapeutic products. Depending on the class of the products, this evidence will either have been evaluated by the Agency or have been subject to self-certification by the sponsor as part of product licensing requirements.

Other advertising claims, such as product presentation, marketing or commercial claims, also must be valid and have been substantiated.

The term ‘valid’ embraces the concepts of responsible and judicious use of products. It can apply in the broader context to any marketing claim contained within an advertisement.

The term ‘balance’ embraces the overall balance within an advertisement of representations, risks and benefits.

Any purpose of use referred to in unbranded or generic advertising must be consistent with the manufacturer’s purpose for use and have been substantiated. In this case, Advertising Requirements 3(a) and 3(b) are not relevant.

If a sponsor ceases to supply/import/manufacture or export particular medical devices, that sponsor may request that the product licence be cancelled. Subject to relevant Australian government legislation, New Zealand government legislation and Australian state/territory legislation, where the cancelled product can continue to be lawfully supplied by a retailer (who is not also the sponsor) directly to consumers, the product may be advertised for supply subject to compliance with the Code. Healthcare practitioners may continue to advertise the use (but not supply) of a cancelled medical device to consumers in relation to the health service being promoted.

If a medical device has not been evaluated by the Agency (eg class I, class IIa and some class IIb devices), the advertising approval officer may require the sponsor / advertiser to produce evidence to show how the therapeutic claims made in the advertisement fit in with the manufacturer’s purpose of use (as reflected in the therapeutic product database, where applicable), prior to approving an advertisement for publication.

Requirement 4

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

- (a) mislead or deceive, or be likely to mislead or deceive; or**
- (b) abuse trust, or exploit lack of knowledge; or**
- (c) exploit the superstitious or, without justifiable reason, play on fear or cause distress.**

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The protection of public health and safety, in terms of quality, safety and efficacy of the advertised product (including performance claims), is the focus of this Requirement. The Australian Competition and Consumer Commission (Australia) and Commerce Commission (NZ) also have responsibility for laws prohibiting misleading or deceptive conduct and false and misleading representations (including advertising). These agencies deal with broader matters through the administration of relevant trade practices legislation. The Agency will liaise with the Australian Competition and Consumer Commission and the Commerce Commission in New Zealand where there is any potential regulatory overlap.

R4.1 An advertisement must not:

- i) contain any claim, statement or implication that the product is safe or that it cannot cause harm or that it has no side effects or risks associated with its use;
- ii) contain any claim, statement or implication that the product is effective in all cases of a condition;
- iii) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- iv) contain any matter which is likely to lead persons to believe that;
 - they are suffering from a serious ailment, or
 - harmful consequences may result from the therapeutic product not being used.

Claims as described in iv) may be restricted representations. Where appropriate, and if claims made in an advertisement are consistent with public health messages, an exemption from iv) may be granted. Approval for the use of a restricted representation, as per Advertising Requirement 8 of the Code, may need to be sought. An example of a product category that meets the public interest criteria to allow approval for restricted representations is condoms for the reduction of the risk of transmission of sexually transmitted diseases.

R4.2 Comparative advertising

Comparative advertising must be balanced and must not be misleading, or likely to be misleading, either about the product advertised or any therapeutic products, or classes of therapeutic products, with which comparison is made.

Comparative advertisements must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence.

Where therapeutic products whose market entry indications, or purpose of use, are compared with other therapeutic products whose market entry indications have been evaluated by the Agency, the advertiser must, upon request, be able to produce evidence to substantiate the comparison.

In comparing products, advertisements for medical devices must only make comparisons between products with a similar intended purpose of use.

R4.3 Scientific information

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

Using complex scientific terminology in advertisements is likely to exploit the average consumer's lack of scientific knowledge to understand the true meaning of what is being said in the advertisement.

Extracts from scientific studies must not be ambiguous or mislead as to the content or results of the study or the performance of the medical device. Inserting selected abstracts from scientific papers or medical reports, which do not accurately reflect the results of the study or report, into an advertisement, has the potential to be ambiguous and may mislead by omission or implication. Titles of publications, or parts thereof, must not contravene the Code.

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, where that sponsor directly, or indirectly, has a commercial interest in the medical device or its components.

Requirement 5

Advertisements must not unduly glamorise products or services, or prey on the vulnerability of particular audiences.

Examples of potentially vulnerable audiences include, but are not limited to:

- *minors (people under 18 years of age)*
- *older people*
- *people with mental health problems*
- *people with impaired hearing/vision*
- *people with chronic or serious illness or long term or permanent disability*
- *people for whom English is a second language*

In considering the compliance of an advertisement directed to any of the potentially vulnerable groups listed above, the public interest criteria (refer A4.1) will be applied.

Medical devices that are considered to meet the public interest criteria for advertising to minors (ie people under 18 years of age) include:

- *tampons*
- *condoms and personal lubricants*
- *bandages and dressings*
- *devices for management of chronic conditions under medical supervision (where reference to these chronic conditions includes a reference to a restricted representation additional requirements apply - see Advertising Requirement 8).*

Requirement 6

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and is not presented as an endorsement of a product.

Unless prohibited by endorsed sector codes, advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the name of the endorser and acknowledgement of any valuable consideration.

Examples which would be taken to represent an endorsement by a government agency, and therefore are prohibited, include:

- *“approved by, the Trans Tasman Therapeutic Products Agency” (or any other terminology in the trans Tasman legislation which implies approval)*
- *“recommended by the Australian Sports Commission”*
- *“supported by the National Science and Technology Centre”*

Examples of statements which would not be considered to imply an endorsement, and therefore are permitted, include:

- *Entered into the trans-Tasman database of therapeutic products*
- *Manufactured in a GMP licensed premise*
- *Manufacturing Licence No. (****)*
- *Product is CE marked*

Examples which would be taken to represent an endorsement by a healthcare practitioner (as defined under Part A4 of the Code), and are permitted subject to certain disclosure requirements, include:

- *pictorial images of healthcare practitioners promoting a medical device,*
- *using the name of a healthcare practitioner to promote the medical device, or*
- *stating or implying that a healthcare practitioner, uses, recommends or was involved in the testing or development of a medical device.*

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Note: An approvals officer may request provision of a statutory declaration as authentication of an endorsement by an individual healthcare practitioner.

Hospitals or other facilities providing healthcare services

Facilities that provide health care or healthcare services include centres that are delivering healthcare services on a commercial or public health basis. For example hospitals, general practice, dentistry, community-based office practices, day-surgery centres, domiciliary nursing services, alternative health providers, and other community services such as needle exchanges, ambulance services and mobile medical services.

Examples of an endorsement by a healthcare facility or service which would be prohibited include:

- *advertising to consumers that a healthcare facility or service has a contract to use a specific medical device,*
- *promoting sponsorship of healthcare facilities or services by a brand name medical device,*
- *suggesting a healthcare facility or service prefers a particular brand of medical device, or*
- *suggesting a healthcare facility or service was involved in the development, testing or manufacture of the medical device being advertised.*

Requirement 7

Testimonials in advertisements, where not prohibited by law, must comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable consideration.

The use of testimonials in advertisements to promote medical devices is acceptable provided the testimonial:

- *is genuine;*
- *complies with the Code;*
- *is current;*
- *has been authenticated;*
- *presents the typical case, not the exceptional; and*
- *contains an acknowledgement of any valuable consideration.*

The advertising approval officer, at the time of assessing an advertisement for approval for publication, will request evidence of the above, including that it is typical and is entitled to require a signed statutory declaration, and/or a copy of the signed testimonial, from the person making the testimony. If the substance of the testimonial in the advertisement has been altered from the original testimony, the advertisement may not be approved for publication.

“Current” means that the content of a testimonial must be up to date and hold true at the time of the publication of the advertisement.

“Typical” means that which reflects the characteristics of a group. i.e. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

Requirement 8

Advertisements directed to consumers must not refer directly or by implication to medical devices, or procedures involving medical devices, that are intended to be used and/or administered solely by healthcare practitioners, without approval from the Trans Tasman Therapeutic Products Agency.

Medical devices that can be administered or used only by healthcare practitioners (“restricted medical devices”) are prohibited from being advertised to consumers unless:

- the advertisement does not specifically reference a particular branded product; or
- prior approval has been obtained (refer Section A4.2).

For example:

- *advertising to consumers of a brand named active implantable drug infusion device, which is implanted into the patient by a surgeon for relief of chronic pain, is prohibited.*

An application for an exemption to advertise direct to consumers, a medical device, or procedure using a medical device that is used and/or administered by a healthcare practitioner should address the public interest criteria outlined in Section A4.1.

PART B3

ADVERTISING THERAPEUTIC PRODUCTS TO HEALTHCARE PRACTITIONERS

Preface

The Advertising Principles and relevant Advertising Requirements included in this part of the Code apply specifically to advertisements for therapeutic products that are directed solely to healthcare practitioners.

PART A of the Code applies to the advertising of therapeutic products directed both to consumers and to healthcare practitioners.

All advertising directed to healthcare practitioners must encourage the responsible and quality use of therapeutic products. Because healthcare practitioners have expert and professional knowledge in their relevant fields, and are able to discriminate between information of value and advertising hyperbole, not all of the Advertising Requirements in Sections B1 and B2 (i.e. advertising directed to consumers) apply. There is no requirement for pre-approval or notification of advertisements directed to healthcare practitioners.

The following requirements for advertising to healthcare practitioners have been developed jointly by the relevant industry associations in Australia and New Zealand with reference to their existing codes of practice. These requirements will continue to be reflected in the industry association codes. Where applicable, the requirements are the same as those for advertising to consumers.

While the Australia New Zealand Therapeutic Products Advertising Code sets the minimum standard for advertising requirements, additional requirements may be applied to particular industry sectors through the industry association codes. These additional requirements can be found in the individual industry association codes, which also provide additional guidance on the application of these requirements.

NOTE: Some requirements that are applicable to advertising directed to consumers do not apply to advertising directed to healthcare practitioners. To retain the consistency of numbering, these parts have been noted as being intentionally blank.

Requirement 1

Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.

Requirement 2

Advertisements must contain the mandatory information to ensure responsible use.

Each industry code details how compliance with Advertising Requirements 2 and 3 is achieved. For example, sections 2 and 3 of the Medicines Australia Code of Conduct and section 6.2 of the Researched Medicines Industry Association of New Zealand Code of Practice cover the requirements for prescription medicines advertisements directed to health care practitioners.

In the Australian Self-Medication Industry Code of Practice, section 5.5 identifies the specific information that must be included in advertisements directed to healthcare practitioners.

Requirement 3

Advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated, and:

a) for medicines:

must be consistent with the approved Product Information, or other substantiation of efficacy provided by the sponsor to the Trans Tasman Therapeutic Products Agency;

b) for medical devices:
must be consistent with the manufacturer's intended purposes, included on the database for therapeutic products maintained by the Trans Tasman Therapeutic Products Agency; and

c) for exempt therapeutic products:
must be compliant with the Australia New Zealand Therapeutic Products Advertising Code.

Industry association codes provide guidance and examples on how to comply with this Advertising Requirement.

For example, for prescription medicines promoted to healthcare practitioners, all claims must be balanced, accurate, correct, fully supported by the Product Information (PI), literature or Data on File, or an appropriate industry source, where these do not conflict with the Product Information (refer section 1 of the Medicines Australia Code and section 4.3 of the Researched Medicines Industry Association of New Zealand Code of Practice).

For non-prescription therapeutic products, information and therapeutic claims must be current, accurate, balanced and must not mislead either directly, by implication, or by omission (refer section 5 of the ASMI Code, Principle 2 of the NZSMI Code of Practice and section 7.3 of the CHC Code of Practice).

Requirement 4

Advertisements must not directly nor by implication, omission, ambiguity or comparison mislead or deceive, or be likely to mislead or deceive.

Claims and representations made in advertisements must be truthful and have been substantiated.

R4.1 An advertisement must not:

- i) contain any claim, statement or implication that the product is safe or that its use cannot cause harm or that it has no side effects or risks associated with its use;
- ii) contain any claim, statement or implication that it is effective in all cases of a condition;
- iii) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;

R4.2 Comparative advertising

Comparative advertising must be balanced and must not be misleading, or likely to be misleading, either about the product advertised or any therapeutic products, or classes of therapeutic products, with which comparison is made.

Comparative advertisements must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence.

Where therapeutic products whose market entry indications, or purpose of use, are compared with other therapeutic products whose market entry indications have been evaluated by the Agency, the advertiser must, upon request, be able to produce evidence to substantiate the comparison.

R4.3 Scientific information

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

Extracts from scientific studies must not be ambiguous or mislead as to the content or results of the study or the performance of the therapeutic product. Inserting selected abstracts from scientific papers or medical reports, which do not accurately reflect the results of the study or report, into an advertisement, has the potential to be ambiguous and may mislead by omission or implication. Titles of publications, or parts thereof, must not contravene the Code.

Publication of research results in an advertisement must identify the researcher and the financial sponsor of the research, where that sponsor directly, or indirectly, has a commercial interest in the product or its ingredients or components .

R4.4 Substantiating Data

Any information used to support a claim must include sufficient detail, and be of adequate quality, to allow evaluation of the validity of results and hence of the claim.

Requirement 5

Advertisements must not unduly glamorize products or services.

Requirement 6

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and cannot be misconstrued as an endorsement of a product.

Advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not in any way imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the name of the endorser and acknowledgement of any valuable consideration.

Exclusions from this requirement are:

- *reference to the conduct of clinical trials and any funded research; and*
- *any statement about listing on the Australian Pharmaceutical Benefits Scheme (PBS), or by the New Zealand Pharmaceutical Management Agency (PHARMAC), or other government health funding body.*

Examples of an endorsement by a government agency which would be prohibited include:

- *“approved by the Trans Tasman Therapeutic Products Agency”*
- *“recommended by the Australian Sports Commission”*
- *“supported by the National Science and Technology Centre”*

Healthcare practitioners:

Examples which would be taken to represent an endorsement by a healthcare practitioner (as defined under Part A4 of the Code) and permitted subject to certain disclosure requirements, include:

- *pictorial images of healthcare practitioners promoting a therapeutic product,*
- *using the name of a healthcare practitioner to promote the therapeutic product, or*
- *stating or implying that a healthcare practitioner, uses, recommends or was involved in the testing or development of a therapeutic product.*

Hospitals or other facilities providing healthcare services

Facilities that provide health care or healthcare services include centres that are delivering healthcare services on a commercial or public health basis.

For example hospitals, general practice, dental services, community-based office practices, day-surgery centres, domiciliary nursing services, alternative health practices or centres, and other community services such as needle exchanges, ambulance services and mobile medical services.

Industry codes of practice address appropriate transparency requirements in relation to the funding of research by sponsors.

Requirement 7

Testimonials in advertisements, where not prohibited by law, must comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable consideration.

The use of testimonials in advertisements to promote therapeutic products is acceptable, provided the testimonial:

- is genuine;*
- complies with the Code;*
- is current;*
- has been authenticated; and*
- presents the typical case, not the exceptional.*

The advertising approval officer in New Zealand, at the time of assessing an advertisement for approval for publication, will request evidence of the above, including that it is typical and is entitled to require a signed statutory declaration, and/or a copy of the signed testimonial, from the person making the testimony. If the substance of the testimonial in the advertisement has been altered from the original testimony, the advertisement may not be approved for publication.

“Current” means that the content of a testimonial must be up to date and hold true at the time of the publication of the advertisement. “Typical” means that which reflects the characteristics of a group. i.e. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

Requirement 8 – this part is intentionally blank

The following requirement is applicable only to the advertising of therapeutic products directed to healthcare practitioners

Requirement 9 (medicines)

All communications made by company representatives must comply with the Code. Where the product being advertised is a finished product, therapeutic claims for unlicensed products and unapproved indications must not be made, unless the product is exempt from product licensing.

Whenever a therapeutic claim is made for a product for which the sponsor is required to hold a product licence, a company representative must offer the approved Product Information, or other data used by the sponsor as the basis for obtaining the product licence for the product.

**Whenever a therapeutic claim is made for:
an active ingredient that may be used in the manufacture of therapeutic products; or
a product which is exempt from product licensing;
the data used by the supplier to verify the claim must be offered by the company representative.**

Advertisements directed to healthcare practitioners for extemporaneously compounded therapeutic products (as finished goods which are exempt from product licensing) are required to comply with the Code.

Active ingredients are exempt from product licensing but may be advertised to healthcare practitioners to be used in extemporaneous compounding of finished products. Any factual new information on the benefits of a particular active ingredient can be provided as educational material or bona fide research, which is exempt from the Code (refer Section A3.1).

Requirement 9 (devices)

The representation of medical devices/diagnostics included on the database for therapeutic products maintained by the Trans Tasman Therapeutic Products Agency must be consistent with the manufacturer’s intended purposes and be consistent with the essential principles for the product.

When requested, the representative must be able to supply a copy of the sponsor’s product information consistent with the manufacturer’s intended purpose and essential principles. Claims outside the manufacturer’s intended purpose and essential principles must not be made.

For non-therapeutic claims the sponsor must hold substantiating data to support the claims.