



MEDICINES

Australia

CODE OF CONDUCT GUIDELINES

**To be read in conjunction with
Code of Conduct Edition 15**



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Introduction

These Guidelines have been written to provide assistance to companies in complying with the provisions of the Medicines Australia Code of Conduct. The Guidelines provide insight both into the experiences of the Code of Conduct and Monitoring Committees and the deliberations of Medicines Australia and its members when developing amendments to the Code of Conduct.

These Guidelines are a living document and will be augmented as issues arise or where requested by the Code of Conduct Committee or the Medicines Australia membership.

In addition to these Guidelines, the Code, through its Explanatory Notes, provides assistance on understanding the Code and compliance with the Code.

These Guidelines do not cover all sections of the Code. However, if you would like any further assistance regarding the Code, its interpretation or operation, please contact Medicines Australia on (02) 6282 6888 or email secretarycodecommittee@medicinesaustralia.com.au.

To gain a first hand experience of how the Committee considers the sections of the Code, companies are encouraged to accept when offered invitations to attend Code of Conduct meetings as either Committee members or observers.

Format

For convenience, some sections of the Code have been grouped together. eg all provisions dealing with PBS information disclosure. They set out the requirements for the provision of this information in various media.

Section 1 Nature and Availability of Information and Claims**Section 1.2 Substantiating Data**

The purpose of this section is twofold. First, it affirms that in response to a reasonable request, supporting evidence must be made available to both healthcare professionals and members of the industry in a timely manner. In all but exceptional circumstances the provision of this data should take place within ten working days of the request. This requirement covers any “data on file” or “in press” material that a company may reference in support of claims.

Companies should be aware that by referencing “data on file” or “in press” material they commit to honouring a request to supply it under the requirements of this section.

The second requirement of the section relates to the level of substantiating data needed to support medical or promotional claims. Note that these provisions are in addition to those of Section 1.1, which requires that all medical and promotional claims are fully supported by the Product Information, literature, data on file or appropriate industry source where the latter documents do not conflict with the Product Information.

The Explanatory Notes to this Section describe the types of issues companies should consider when assessing whether the evidence they have is sufficient to meet the requirements of this Section.

The Code of Conduct Committee, when it considers complaints against medical or promotional claims, uses a hierarchy of evidence to determine whether the substantiating data provided meets the requirements of this section.

Useful guides to understanding this hierarchy of evidence are two NHMRC publications entitled “*A guide to the development, implementation and evaluation of clinical practice guidelines*” and “*How to use the evidence assessment and application of scientific evidence*”. These guidelines describe levels of evidence ranging from Level 1 evidence (obtained from a systematic review of all relevant randomised controlled trials) to Level IV evidence (obtained from case series, either post-test or pre-test/post-test). The Committee uses the principles in these documents to determine the quality of the evidence provided to it in support of medical and promotional claims made.

These publications can be accessed from the NHMRC website at www.health.gov.au/nhmrc/publications/pdf/cp69.pdf

The Code of Conduct Committee considers that any claim which will significantly influence how a medicine is prescribed or dispensed should be supported by the highest level of evidence available. For example, a comparative claim stating that one product is more efficacious or better tolerated than another must be supported by evidence that would not leave the reader in any doubt regarding the superiority of the product. The quality of the data to support this claim is therefore critical to ensure that readers can be assured that such claims are based on appropriate evidence.

Comparative advertising must always meet all the requirements of the Code set out in Sections 1.3 and 1.7.

For the reasons given above, the Committee considers that in general, abstracts and poster presentations that have not undergone significant peer review and/or have not been accepted for publication in recognised major journals are insufficient as the sole supporting evidence for a promotional claim. This does not mean that these data sources cannot be used at all. However, they cannot be relied on as the sole support for claims which will have a significant influence on how a medicine is prescribed or dispensed.

Where a clinical study has undergone peer review through evaluation by the TGA and been included in the Product Information, but has not yet been published other than as an abstract or poster, is an example of where it may be acceptable to use the abstract or poster as the basis for a promotional claim. Alternatively, if the data presented in the abstract or poster is consistent with other published peer-reviewed papers, further extends or supplements other observations and no contradictory evidence had been identified, this would further support the acceptability of the use of the abstract or poster. Companies should make it clear that the claim is referenced to a poster or abstract. Companies should use the primary reference or approved Product Information in addition to the referenced abstract or poster.

The Committee also considers that companies should ensure that they are not selectively using papers to support their claims or making generalisations to clinical outcomes from surrogate measures.

The Code of Conduct Committee has determined that all claims must be current, accurate and balanced and able to be substantiated with appropriate supporting data at the time of publication of the claims. That is, publication of a supporting study in a peer reviewed journal at some time after publication of the claim is not a defense for use of the relevant poster or abstract to support the claim. Companies have a responsibility to update their promotional and educational materials to reflect the availability of new data or emerging evidence while remaining consistent with the approved PI.

Type size for references must be not less than 1.5mm as measured by the font's lower case "e".

The Committee has expressed concern at the use of statements such as "Clinical efficacy not yet established" as this infers that a clinical effect will be established. The issue relates to the implication or link between invitro data and clinical effect that companies are using in promotional materials. It may be more appropriate to use a statement such as "*Laboratory/invitro/animal data does not necessarily predict human clinical effect*". Companies are encouraged to refrain from having animal data and clinical claims in close proximity or in some circumstances on the same page as this is potentially misleading.

The various Medicines Australia Committees have also cautioned companies in relation to the use of statistically non-significant p-values in promotional material.

Where a table or graph has been adapted from other sources, companies are encouraged to ensure that the adaptation does not alter the conclusions of the original paper and that the graph or table is clearly identified as being adapted from another source. The adapted table or graph should be an accurate reflection of the original findings and should be clear and not confusing to the reader or intended to disguise the results.

Where a tabulated or graphical representation of data based on different kinds of analyses is presented in a comparative manner, the different methods of analysis must be clear to the reader. For example, where results from an intention to treat analysis are compared with a retrospective sub-group analysis it must be clear to a reader that the analyses are based on different methodologies and interpreted on that basis.

As the Explanatory Notes to this Section describe, companies should look to issues such as:

- The study design
- The number of patients
- The location of the study
- Its primary purpose and end points
- The results
- The reputation and qualifications of the trialists
- The studies place within the current body of evidence, and
- Whether and where the results from the study have been published

when assessing whether the evidence they have is sufficient to meet the requirements of this Section.

The Code of Conduct Committee also has a preference for being told when a company has made a financial contribution to a study which is relied on as substantiating data.

The Code of Conduct Committee, when considering a complaint, requires that any substantiating data is provided to it and will rigorously review this data to ensure that it is of sufficient quality and weight to support the claims being made. The addition of a member of Australian Society for Clinical, Experimental Pharmacologists and Toxicologists (ASCEPT) and the other healthcare professionals who are not from the pharmaceutical industry as permanent members of the Code of Conduct Committee greatly assists the Committee in its determination on whether the evidence provided is sufficient to support the claims made.

The Committee will not necessarily find any substantiating data itself in breach of the Code. Rather, a breach may be found through inappropriate reliance on certain substantiating data.

Section 1.3 False and Misleading Claims

The purpose of this section of the Code is to ensure that claims and statements made by the industry are current, accurate, balanced and not misleading.

The section relates not only to promotional and medical claims, but to all information and graphical representations provided both to healthcare professionals and members of the general public. This includes tag lines in promotional material provided to healthcare professionals.

To ensure that all material complies with this section, the following tests should be applied. All information provided to healthcare professionals and members of the general public must be:

- Current
- Accurate
- Balanced, and
- Must not mislead, either directly, by implication or by omission

The Explanatory Notes to Section 1.3 provide significant guidance on how companies can comply with this section. However, the following may provide further assistance.

When comparative claims are made, the Code of Conduct Committee require unequivocal evidence that the comparison meets the requirements of this section. Care should therefore be taken to ensure that any comparative claims are both supported by appropriate evidence and reported accurately. Given the possible significant impact of comparative claims on prescribing practices, the Code requires a higher level of evidence to support such claims. See also Section 1.7 Comparative Statements.

Care should also be taken when using animal data (Explanatory Note [f]). The Code requires that if animal or laboratory data are being used, they are clearly identified. In the past, linkage by means of a small asterisk or similar symbol to statements in small font sizes has been found inadequate and to have breached the Code. The Code of Conduct Committee prefers to see such statements adjacent to any claim based on animal studies and in a sufficient size (not less than 2 mm) to ensure that the reader is aware of the source of the claim or data. It is important that there must be no suggestion, either intentionally or by omission, that would lead a reader to infer some clinical benefit. Again, this should be acknowledged in a prominent and clearly worded statement.

The Explanatory Note to Section 1.3 (f) should not be read as prohibiting the use of animal or laboratory data as substantiation for claims that cannot be proven by any other mechanism. These characteristics, with any limitations, would also be reflected in the approved Product Information for these products.

Companies should note that tag lines are covered by all provisions of Section 1. The test will be whether the tag line makes an implicit or explicit claim and, if it does, whether there is sufficient evidence to support such a claim.

In relation to the currency of substantiating data, it should be noted that companies may use data to support claims with data that are not referred to in a product's Product Information. However these data must not conflict with the Product Information. The Code of Conduct Committee expects that where there is new evidence about a product that may not be consistent with its Product Information, (eg through suggesting a significantly higher level of efficacy or tending to deny the basis for a contraindication or precaution) such data should not be used to support promotional claims. The Committee would expect that a company would submit the new data for evaluation in support of an application to update its Product Information following which the new data could be relied on for promotional purposes.

Section 1.7 Comparative Statements

The intention of this provision is to prohibit unjustified comparisons in which the product or activities of a competitor are unfairly denigrated.

It is important to remember that if you are making comparative claims you need unequivocal supporting evidence. If a comparative claim comes before the Code Committee it will carefully scrutinise the evidence provided to ensure it is sufficient to support the comparison being made. This will include a review of the type of evidence provided, for example, an examination of issues such as the protocols of any studies relied on, the primary and secondary results of these studies, the authors, and if/where the study was published (see also Section 1.2 for further information on supporting evidence).

The intent of any comparison should be that it provides valuable and accurate information comparing products for the benefit of healthcare professionals and their patients. Care should also, therefore, be taken in the way a comparative claim is presented. It is critical that the depiction of any comparison is accurate. Care should be taken, for example, to ensure that any graphical or visual comparisons between products are accurate and appropriate.

For example, a breach of the Code has been found by the use of unequal width bars in a bar graph comparing the efficacy of two products, which implied that the results of the comparison were more meaningful for one product than another. Such a graph was considered unfair and misleading and found to be in breach of Section 1.7.

The Code Committee has determined that promotional taglines come under the auspice of Section 1 as does any other promotional claim. A company must make a decision as to the promotional nature of the tagline and ensure that it is appropriately referenced and qualified.

PBS Disclosure Requirements

Background

In the lead up to the 2002 Federal Budget, Medicines Australia discussed with the government ways in which PBS expenditure could be reduced by ensuring prescribers were provided with information regarding the PBS status of medicines. In an effort to assist the government, Medicines Australia agreed to make amendments to its Code of Conduct to require the disclosure of this information in promotional material and by its medical representatives. The amendments to the Code adopted in September 2002 reflect this agreement with government. The Guidelines do not distinguish between Section 85 and Section 100 drugs. All advertised prescription medicines must comply with this requirement.

The following discussion sets out the requirements of how this information should be disclosed.

Journal Advertising Section 3.1

Primary Advertisements (Section 3.1.1) and Secondary Advertisements (Section 3.1.2)

This section requires that various promotional materials include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (PBS) listing and restriction. The following guidelines identify the minimum requirements for the content and layout of this disclosure in promotional material.

A. General Requirements

These requirements apply to advertisements and printed promotional material:

- (i) The PBS disclosure information should be contained within a text box that has a white background and is outlined in black.
- (ii) The font used should be either Arial or Universal (not condensed forms) or a similar clear “sans” face. (NB fonts corresponding to these may go under different names, e.g. Helvetica.)
- (iii) The text should appear in solid black with no half tones.
- (iv) The spacing within the text box must make conventional use of upper and lower case type and contain adequate space between any lines and words to ensure easy readability.
- (v) The text size should reasonably fill the text box with the minimum size to be not less than 2mm.
- (vi) The text box must contain only the PBS disclosure information. No embellishments or other material should be included in this box including pack size, dosage forms, presentations, quantities, number of repeats etc.

B. Wording

- (i) For products listed on the PBS without any restrictions, the following wording should appear in the text box: “PBS Information: This product(s) is listed on the PBS as a *(insert the product type of product as identified in the Schedule)*”.

e.g

PBS Information: This product is listed on the PBS as a drug for obstructive airway diseases

- (ii) For products with differing formulations and the promotional item covers all formulations all information about those formulations should be included in the text box. Where only one formulation is being promoted the PBS Box need only include information pertaining to that formulation.

e.g

**PBS Information: "Formulation X. Authority required for the treatment of Y.
Formulation Z. This product is not listed on the PBS.**

- (iii) For products listed on the PBS as a restricted benefit or where an authority is required, and this information is no longer than three lines as they appear in the PBS Schedule, the following wording should appear in the text box: "PBS Information: Restricted Benefit *or* Authority Required. *Insert wording of the restriction or authority requirement*".

e.g

PBS Information: Restricted benefit. Symptomatic treatment of osteoarthritis

- (iv) For products listed on the PBS as a restricted benefit or where an authority is required, and this information is longer than three lines as they appear in the PBS Schedule, the following wording should appear in the text box: "PBS Information: Restricted Benefit *or* Authority Required. *Either the statement "Refer to PBS Schedule for full information" or an accurate paraphrase or précis of the PBS restriction*". This information also applies to Section 100 products.

e.g

PBS Information: Restricted benefit. Refer to PBS Schedule for full restricted benefit information.

e.g

PBS Information: Restricted benefit. For use in patients that meet the criteria set out in the General Statement for Lipid Lowering Drugs

- (v) For products not listed on the PBS, the following wording should appear in the text box: "PBS Information: This product(s) is not listed on the PBS".

e.g

PBS Information: This product is not listed on the PBS.

- (vi) For products not listed on the PBS but listed on the RPBS, the following wording should appear in the text box: "PBS Information: This product is not listed on the PBS. For RPBS information refer to the PBS Schedule."

e.g

**PBS Information: This product is not listed on the PBS.
For RPBS Information refer to PBS Schedule**

C. Size

Sizes set out below are the smallest permitted. If need be, the box must be enlarged to accommodate the required text.

Note that a Secondary advertisement can only appear in a publication which also contains a Primary advertisement.

Both Primary and Secondary advertisements must include PBS information included in a text box as described below:

- (i) Full or double Page advertisements (such as appear in medical journals e.g. Australian Doctor or Medical Observer) or advertisements of A4 size or greater.

The text box must be no smaller than 18 cm² and must allow text of no smaller than 2mm. For example, a text box could measure 12cm x 1.5cm, 6cm x 3cm, 18cm x 1 cm or 9cm x 2cm.

The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

- (ii) Half page advertisements (such as appear in medical journals e.g. Australian Doctor or Medical Observer) or advertisements of size A5 up to A4

The text box must be no smaller than 15 cm² and must allow text of no smaller than 2mm. For example, a text box could measure 15cm x 1cm, 5cm x 3cm, 7.5cm x 2 cm or 10cm x 1.5cm.

The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

- (iii) Quarter page advertisements (such as appear in medical journals e.g. Australian Doctor or Medical Observer) or advertisements less than A5 size

The text box must be no smaller than 10 cm² and must allow text of no smaller than 2mm. For example, a text box could measure 10cm x 1cm, 5cm x 2cm, 7.5cm x 1.33 cm or 8cm x 1.25cm.

The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

Short Advertisements (Section 3.1.3)

If a Short advertisement appears by itself within one publication, the size requirements for the PBS disclosure information relating to Primary and Secondary advertisements apply. If a Short advertisement appears in a publication in which a Primary advertisement for the same product also appears, the following text must appear in the Short advertisement in a type size of not less than 2mm "For PBS information refer to Primary advertisement".

Company Commissioned Articles (Section 3.1.4)

It is recognised that the distinction between Company commissioned articles and advertisements can be blurred. Through the use of statements from an independent expert in combination with promotional claims on behalf of the company, the material becomes an advertisement - whether published in a journal or other form such as a newsletter distributed to healthcare professionals by a company representative. Company commissioned articles that contain a promotional claim must comply with the PBS disclosure requirements of the Code and its Guidelines and inclusion of Product Information as required by Section 3.1.1 or Section 3.1.2.

Congress Reports (Sections 3.1.4 and Section 10.5)

Congress reports are not normally considered as Commissioned Articles provided they do not contain promotional claims. While no PBS disclosure statement is required a statement to the effect “Please review Australian Product Information before prescribing any product in this report” should be included if the report discusses a product approved for use in Australia. If there is a reference to a product not registered in Australia, or an unregistered use of a product registered in Australia, a statement to the effect “Some products/uses of Product X discussed in this publication are not registered in Australia. Please review the Australian Product Information” should be included.

Reference Manual Advertising (Section 3.2)

For all reference manual advertising in publications such as the MIMS Bi-monthly, which is greater than a third of a page as measured by the Reference Manual, a text box must appear containing the statement “For PBS Information refer to Section *insert relevant reference manual section*”. The size of the font must be not less than 2mm measured by the font’s letter “e”.

e.g

For PBS Information refer to Section 2(f)

For advertising which is a third of a page or less, companies are encouraged to include a statement advising healthcare professionals of the location of the PBS information within the Reference Manual.

Printed Promotional Material (Section 3.3)

The size requirements for the PBS disclosure information applying to Primary advertisements also apply to printed promotional material and text which complies with these requirements should appear at least once in each item of printed promotional material.

For small promotional documents the following requirements apply:

Medi-message telephone message pads

Each promotional message slip must carry the wording “For PBS Status See PBS Book”. This text should be clearly distinguishable from any other text and contained within a white box.

Doctors’ Desk sets

If a Doctors’ Desk set contains a number of small items of printed promotional material a reference should be made to the PBS disclosure information. The Desk set should include the statement “For PBS information, refer to the PBS information (include the location of the PBS information such as on the PBS card under the flap)”. This statement should appear once in a clear and prominent position on the desk set. It is not required to be placed within each advertisement included in the desk set.

Diaries/Calendars

Each advertisement must include the PBS disclosure information. Where the diary is of sufficient size the PBS requirements for a Primary advertisement apply. Where the diary/calendar is of a pocket size, the advertisement must carry the wording "For PBS Status see PBS Book". The text should be clearly distinguishable from any other text and contained within a white box.

Audiovisual Promotional Material (Section 3.6)

Company Computer Based Promotional Material (Section 3.7)

Advertising in Electronic Prescribing Software Packages (Section 3.9)

Restricted Access Television Advertising (Section 3.10)

All PBS listing information as required in the general requirements must be displayed in these promotional media in a manner that allows the audience to read and understand the information provided. The type size used in these media must be such that allows easy and clear legibility and should be contained in a text box that commences with the statement "PBS information".

Company Representatives (Section 4.10)

This section of the Code requires that company representatives either provide prescribers with information regarding all PBS listings and restrictions, or make reference to this material in printed form when they are making promotional claims regarding a prescription product. It is sufficient for a company representative to verbally advise a healthcare professional of this information, to offer them this information in written form or to refer to a printed source of this information.

The disclosure should be clear and distinct with no attempt to minimise or limit this important information.

Trade Displays (Section 6.1)

To comply with the PBS disclosure requirements for trade displays a prominent statement regarding the PBS status of products being promoted at a trade display must be incorporated on the trade display. This information must be of an appropriate size such that is easily viewed by the prescriber when visiting the trade display. The PBS information may be on the trade display material, attached (eg with Velcro®) to the trade display material or free standing.

Medical Education Material (Section 10.4)

Material supplied for medical education must not contain promotional claims and accordingly does not require a PBS disclosure box. Any material supplied with educational material and containing a promotional claim must comply with all provisions of the Code in relation to printed promotional material.

Section 3 Promotional Material

Section 3.1 Journal Advertising

Section 3.1.1 Primary Advertisement

Edition 15 of the Code emphasises the requirement that the Product Information, Abridged Product Information or the Minimum Product Information must appear in the body of the advertisement.

Section 3.1.3 Secondary Advertisement

The use of a Secondary advertisement in any issue of a publication that does not also contain a Primary advertisement is not permitted.

Section 3.1.3 Short Advertisement

Short advertisements are required to include PBS information. For details on how to include this information, see PBS Disclosure Requirements in these Guidelines on page 12.

Section 3.3 Printed Promotional Material

With Edition 15 of the Code it is a requirement that the Minimum Product Information is printed within the body of all items of printed promotional material. This is to ensure that sufficient prescribing information is available to healthcare professionals when reviewing an item of promotional material. This applies to items such as leave behinds, detail aids used for demonstration by a medical representative, retained sales aids, leaflets, posters or other display materials to be given to healthcare professionals or other display material such as posters which are intended to be provided to a healthcare professional.

In addition, a copy of the Product Information must also be offered to healthcare professionals or included with mailed printed promotional material for the first 24 months from the date of first advertising. After 24 months, the Abridged Product Information may be offered or included with mailings.

It is not required to include the Minimum Product Information on items of printed promotional material for display purposes such as trade display banners, light boxes, panels or posters. However, such materials must include the following statement:

“Please review Product Information before prescribing. Product Information is available from the trade display.”

For further information on the requirements for Product Information please refer to the Checklists in Appendix 1.

For small promotional documents the following requirements apply:

Medi-message telephone message books

Primary advertisements within these items are not required to include the Minimum Product Information within the body of the advertisement. The Minimum Product Information for all advertised products must be included in the message book and must form a fixed part of the message book.

A clear and prominent statement must be included within the body of each advertisement:

“Please review Product Information before prescribing. Product Information can be found in the back of this medi-message book.”

Doctors’ Desk sets

Primary advertisements within these items are not required to include the Minimum Product Information within the body of the advertisement. A clear and prominent statement to the effect: *“Please review Product Information before prescribing. Product Information can be found... (for example: in the Product Information booklet in the back pocket).”*

Any item included with the Doctors’ desk set that is detachable from the desk set and includes a brand name must comply with the requirements for a Brand Name Reminder. These items, such as sticky note pads or message note pads, should not include promotional claims.

Diaries

Primary advertisements within these items are not required to include the Minimum Product Information within the body of the advertisement. The Minimum Product Information must be included and form a fixed part of the diary. Each advertisement must include a clear and prominent statement to the effect:

“Please review Product Information before prescribing. Product Information can be found... (for example in the professional section in this diary.)”

Calendars

Primary advertisements within these items are not required to include the Minimum Product Information within the body of the advertisement. A clear and prominent statement to the effect: *“Please review Product Information before prescribing. Product Information can be found... (for example, in the back of the calendar or adjacent to the conference planner.)”*

Section 3.4 Mailings

This section of the Code covers the requirements for promotional material and patient education material designed for distribution through the postal system or by private means.

Exposed mailings such as business reply cards must not include any statements, promotional taglines, pictures or graphics that might be interpreted as promoting a particular prescription medicine to the general public. The use of a product brand name or Australian Approved Name by itself is not considered to be promoting the medicine to the general public.

Section 3.9 Advertising in Electronic Prescribing Software

The Therapeutic Goods Act and Regulations prohibit advertising of prescription medicines to the general public. This principle is recognised in the Code of Conduct.

Companies should particularly consider the following when developing advertisements for inclusion in electronic prescribing software:

- Any advertisement that includes a promotional claim, including a promotional tagline is classified as a Primary advertisement. Advertisements in strip or banner format that include a promotional claim are classified as Primary advertisements.
- Primary advertisements in electronic prescribing software are not required to include Minimum Product Information as there must be access to the Product Information by a hyperlink or similar mechanism embedded within the advertisement or through a button linking to a database of Product Information within the software.
- No advertisement (Primary or Short) may be included in a screen that displays Consumer Medicine Information (CMI) or patient education materials.
- No advertisements may be included in a clinical tool* that is designed or intended to be used by a healthcare professional in consultation or discussion with a patient. In determining whether a clinical tool may be used by a healthcare professional directly in consultation with a patient, a company should consider whether the language used in the tool is directed to the patient or to the healthcare professional, and the content of the material - whether this is intended for a consumer or for the healthcare professional. Companies should consider preparing an internal rationale and justification for placing advertisements in clinical tools.

**meaning a dialogue box that opens within the prescribing software with diagnostic or medical information used to evaluate a patient.*

- Advertisements may be included in clinical tools that are intended for use by, and directed to, a healthcare professional.
- Companies must ensure that the Australian Approved Name and all other text included in an advertisement are easily and clearly legible. Attention should be given to the size of the text, contrast between the text colour and background colour, and the resolution of computer screens likely to be used by healthcare professionals. It is recommended that companies consider the “worst case” screen resolution that may be used by doctors
- Companies must ensure that all advertisements are reviewed in the computer environment in which medical profession will view the advertisement prior to approving an advertisement for inclusion in electronic prescribing software.

It is acceptable to include an advertisement that only includes the company name and logo in prescribing software

Section 3.11 Gifts/Offers

This section recognises the industry's primary role in providing current, accurate and balanced information on its products to healthcare professionals. It is not the role of the industry to provide healthcare professionals with gifts or offers. However the Code does recognise that the following items or opportunities are acceptable and are dealt with in the following specific sections of the Code:

- | | | |
|-------|--------------|---|
| (i) | Section 3.12 | Brand Name Reminder |
| (ii) | Section 3.13 | Prize for a complying competition |
| (iii) | Sections 6 | Involvement in Educational Symposia, Congresses and
Satellite Meetings |
| (iv) | Section 7 | Sponsorship |
| (v) | Section 10.2 | Hospitality; or |
| (vi) | Section 10.4 | Medical Educational Material |

This section therefore prohibits the provisions of all gifts and offers that do not conform to these sections.

No gifts or offers should be provided to the families or employees of healthcare professionals.

Section 3.12 Brand Name Reminders

A brand name reminder is an item of low monetary value which is intended to remind healthcare professionals of the existence of a product. Items such as mugs, pens, mouse pads and boxes of tissues are examples of acceptable brand name reminders.

Only items that are relevant to the working environment of a healthcare professional are acceptable as brand name reminders. Items such as sporting equipment (golf balls, tennis balls), umbrellas, car sun-shades, beach towels, magazines, picnic rugs, luggage tags and clothing are not considered appropriate.

Tissue boxes are accepted as items used commonly as brand name reminders and should not be used as a printed promotional vehicle.

Brand name reminders are not intended to be used by the healthcare professional's friends or family. Items such as gift vouchers, tickets to sporting/cultural events, cash or cash equivalents are not considered appropriate.

When choosing items to be used as brand name reminders, it is important that the items can clearly be recognised as a brand name reminder and not any other type of promotional item.

Brand name reminders should not be items that may bring the industry into disrepute.

An item of medical education (medical journals, textbooks etc in both hard copy and electronic form) that includes a product brand name printed on the outside of the text or media is regarded as both a brand name reminder and medical education and must conform with all requirements of Sections 3.12 and 10.4 for such an item, **excepting** the monetary limit. No promotional claims may be included - either printed on the item of medical education or included within an electronic medium. If a brand name is included on an item of medical education, it should appear on the cover or frontispiece and not on every page of the book.

This section provides that brand name reminders must only contain the brand name of the product, the Australian Approved Name of the active ingredient and any boxed warning or a statement drawing attention to a boxed warning.

The value of a brand name reminder should not be greater than \$20.00 per item (exclusive of GST). The AUD \$20.00 limit per item is the cost to the company for the item. If a complaint is received in relation to the value of a brand name reminder, the company may be required to produce documentary evidence of the cost to the company.

An item with corporate branding for provision to a healthcare professional becomes a gift and therefore must comply with Section 3.11. Corporate sponsorship of a sporting, cultural or community activity can be provided but must not be undertaken for product promotional reasons or used for product promotional purposes.

Section 3.13 Competitions

To comply with the requirements of this Section it is critical that all questions are a true test of medical knowledge. While a competition involves an element of chance the actual conditions under which a healthcare professional enters must be based entirely on medical knowledge or the acquisition of medical knowledge. For example, questions based on the information contained in a product's Product Information may be appropriate, whereas questions about a company's postal address or telephone number would not satisfy this section, as the Code of Conduct Committee found in one complaint it considered. All questions must satisfy this requirement.

Questions should be of appropriate quality, quantity and educational rigour and there should be clear and unambiguous answers. The Committee considers that a competition question should be referenced to enable a healthcare professional to find the answers in accompanying material or the Product Information.

Companies should ensure that requests for market research information, starter packs or which products are prescribed are separate and distinguishable from competitions. It is preferable that competition and market research questions appear on different pages or be sufficiently separated that they cannot be confused.

Prizes offered by a competition must be relevant and specific to the practice of medicine or pharmacy. Examples of appropriate prizes might be an item of medical equipment such as a stethoscope or blood pressure monitor. Items such as PDA, MP3 players, even if loaded with medical software are considered to be inappropriate competition prizes as they are not specific to the practice of medicine or pharmacy. A digital camera is also considered to be an inappropriate competition prize as it is not directly relevant to the practice of medicine or pharmacy. Other items of computer or office equipment eg computers, fax machines, mobile telephones, telephone systems, DVD players or software updates do not comply with the provisions of the Code and must not be offered as competition prizes.

It is acceptable to include a product brand name or company logo in a discreet location and size on a competition prize.

The degree of difficulty and/or number of competition questions should be proportional to the value of the prize offered. For example, a prize valued at the permitted upper limit is expected to be offered for answering more difficult, complex or challenging competition questions.

A competition prize can be delivered by a medical representative but it should not be as a requirement of making an appointment.

Medical educational material may also be provided. An example of an appropriate prize may be a recognised authoritative medical text or attendance at a reputable and educationally valuable scientific meeting. Should companies consider offering the latter type of prize, they should take care to ensure the educational event complies with the requirements of Sections 6, 7 and 10.

It would not be appropriate to provide a prize including an international airfare, accommodation expenses and registration to an international educational meeting. However, an economy class flight, a reasonable level of accommodation costs and the registration fee for an Australasian educational meeting may be appropriate. If considering offering this type of prize, companies should refer also to Section 6 to make sure the standards discussed in that section can be complied with when offering this type of prize.

- The value of an individual prize should be no greater than \$500 (exclusive of GST).
- The value of an educational item offered as a competition [prize should be no greater than \$5,000 (exclusive of GST).

- Multiple competition prizes may be offered but the total value of these prizes should not exceed \$5,000 (exclusive of GST).
- The total value of the prize pool for competitions associated with particular products is limited to AUD \$50,000 per product per calendar year.

Use of the Internet for Pharmaceutical Information

Section 3.8 Healthcare Professionals

A company may wish to provide promotional and educational material to healthcare professionals via a website. If this site contains promotional material it must be a secure site that is designed to limit access to healthcare professionals. A mechanism such as a password protected site has been considered to comply with the requirements of this section.

All material contained on a website directed to healthcare professionals must also comply with the provisions of Sections 1 and 3. This means that the standards applying to items such as advertising and printed promotional material apply to material included on a company sponsored website.

Companies should take care when including references or links to other information sites. References to any sites that may put the company at risk of being found in breach of the Code should be removed without delay.

Section 9.6 Information to the General Public

The Therapeutic Goods Act prohibits the advertising of prescription medicines to members of the general public. The Act defines advertisement:

“advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended whether directly or indirectly, to promote the use or supply of the goods.”

The Code reflects this legislative requirement that prohibits the promotion of prescription medicines to members of the general public. The Code also recognises the information need of members of the general public regarding prescription medicines and the requirement for the industry to meet those needs in a responsible and appropriate manner. Section 9.6 is designed to set a framework in which this information can be provided to members of the general public on the internet in a non-promotional and educational manner.

Companies considering providing this type of information to members of the general public should be aware of the legal advice received by Medicines Australia when these provisions of the Code were being drafted. Although the Therapeutic Goods Act definition of advertisement has been tested in the Australian courts only to a limited extent, there have been a number of cases that look at the issue of advertising. These cases have led to the legal advice that the definition of advertising would therefore capture information published on the internet or a media release, if, when objectively assessed, the material is intended directly or indirectly to promote the use or supply of a particular product.

Thus, the test under the legislation is whether the information, when objectively assessed, is intended directly or indirectly to promote the use or supply of a particular product. Companies must therefore be aware that, if information published by them about their products can be accessed by consumers, there is always a risk that the publication could be said to promote the use or supply of a particular product.

In developing a website or source of information under Section 9.6 it is envisaged that a company should be able to develop a brief non-promotional summary of its prescription medicines. The format of the information contained in MIMS Bimonthly is suggested as an appropriate template, given that it includes a balanced description of the key aspects of a product and is based on the approved Product Information.

The wording and terms used in this summary must, however, reflect the audience to which it is targeted, which may not enjoy the same level of medical or technical knowledge as readers of MIMS Bi-monthly.

In addition, companies are encouraged to include a copy of the Consumer Medicine Information on their websites. Again, this information has been designed specifically for consumers and is in a format that provides valuable information regarding prescription medicines. The CMI should be published in its entirety, suitably identified as a CMI document, and must not be embellished e.g by including logo or promotional devices.

This section of the Code is designed to meet the information needs of members of the general public when they seek information on prescription medicines available in Australia. Given the current legislative framework that prohibits the promotion of prescription medicines to members of the general public, companies need to be careful when making information about their products available via the internet so as not to be considered as promoting their products.

The Code does not allow companies to encourage members of the general public to seek out or access information regarding specific prescription medicines, since this may be considered as promotion. For example, a disease awareness campaign that makes no mention of specific prescription treatments but includes a website address that contains the name of a specific prescription medicine could be considered as promoting that product to members of the general public. In recent rulings the Code Committee has determined that it is a breach of the Code for a product name to appear on a disease state website thereby linking a disease to a specific prescription medicine. In respect to any box containing "Enter here if you have been prescribed X" the Committee considered that any reference to the product should be removed because it may be considered to be promoting that product to members of the general public.

While the Committee did not find the listing of product names which may interact with this therapeutic class in breach of the Code, they were of the view that there was the potential for more harm than good and recommended that this type of information should not be included on a disease state website. Members were of the view that a general statement such as "if you are on any other drug therapy please discuss this with your doctor or pharmacist" or "some medications may cause xx problems. Please discuss this with your doctor" would be more appropriate.

A disease state website should however contain a statement that it is provided by a particular (named) pharmaceutical company as required by the Code.

However, the development of a website that contains a product name in its address and contains its CMI, for example, may be appropriate if it is not linked to other activities that may fail the test of intent. Companies should carefully consider the tests identified by Medicines Australia's legal advisers when developing internet sites that can be accessed by members of the general public.

The section also allows linkages to other reputable information sources that will enhance a member of the general public's understanding of a disease area. For example, this could be a linkage to a patient support group or a site that is devoted to non-promotional information on a particular disease state.

Companies are advised to take particular care when including references or links to other information sources and ensure they are aware of the information in those other internet sites and that they keep informed of any changes to that information. If the information accessible through the reference or link when objectively accessed is intended directly or indirectly to promote the use or supply of a company's products, the reference or link should not be made.

The Code also requires that when making these references and linkages a clear screen should be displayed showing certain specified disclaimers:

- That the information the reader is about to access may not comply with the Australian regulatory environment and that readers should refer to the CMI to fully understand the Australian regulatory approval, and
- That the intent of providing this material is to inform and not to offer advice, and
- Any information provided should be discussed with the reader's healthcare professional and does not replace their advice

Companies should note that these disclaimers may not protect a company from breaching the Therapeutic Goods Act if the linked site includes material which is found to constitute an advertisement for the company's product.

Medicines Australia encourages any company considering making information about its products available to the general public under the provisions of this section to contact Medicines Australia to discuss these activities, or to seek their own legal advice.

Section 4 Company Representatives

One aspect of complying with this section of the Code is that company representatives need to be aware of their environment when discussing prescription medicines.

Section 4.5 Hospital policies and operating theatre procedures

In addition to the requirements of the Code of Conduct, companies should ensure that all company representatives are aware of other protocols that may relate to their interactions with healthcare professionals. Some examples of other protocols relevant to the activities of company representatives include:

- NSW Therapeutic Advisory Group Inc Position Paper
“Pharmaceutical Representative and Hospital Staff Liaison in Public Hospitals”
- ACORN Standards S27 Visitors to the Perioperative Environment
Standard Statements 5 and 6 refer to Medical Company and commercial representatives
- Australian Society of Anaesthetists position statement “Guidelines for Visitors to the Operating Theatre”

Company representatives and companies should also ensure that in any interaction with a healthcare professional where a patient may be present ie hospital ward or operating theatre they are acting in compliance with all hospital policies including patient confidentiality arrangements. This includes company training programs in hospitals or clinics and preceptorships.

In any interaction with a healthcare professional the company representative should ensure that the frequency, timing and duration of appointment, together with the manner in which they are made, are such as not to cause inconvenience to the healthcare professional. The wishes of an individual healthcare professional or the arrangements in force at any particular practice must be observed by Company Representatives.

Section 4.8

It would not be appropriate for a company representative to discuss a product, for example, in the waiting room of a surgery when this information could be overheard by members of the general public. Company representatives are encouraged to provide this information in an environment in which direct communication can be enjoyed with a healthcare professional.

A competition prize can be delivered by a company representative but it should not be as a requirement of making an appointment.

Section 4.11

Section 4.11 of Edition 15 of the Code of Conduct states “Under no circumstances shall a representative pay a fee in cash or in kind, in order to gain access to a healthcare professional.” As a Secretariat Medicines Australia is unable to interpret any section of the Code. Any complaint received by Medicines Australia in relation to an alleged breach of the Code will be referred to the Code of Conduct Committee for their review and decision.

In 2000 the ACCC provided advice to APMA that it may be a breach of the Trade Practices Act to preclude members from dealing with organisations that operate medical appointment making systems. Whilst not agreeing with this view APMA issued a statement in February 2000 to the effect “Members should in no way feel constrained by the provisions of the Code of Conduct from entering into arrangements with third parties in relation to proposals for medical representatives or companies to access general practitioners.”

The intention of 4.14 is that all company representatives who are directly involved with the development, review and approval of promotional material for healthcare professionals and educational material for use by consumers and personnel who are directly interacting with healthcare professionals for the purpose of promoting the company’s products must complete the Code of Conduct component of the currently endorsed Medicines Australia education program within 12 months of commencement in employment in that role.

The requirement for company representatives who are directly involved with the development, review and approval of promotional material to complete the Code of Conduct component of the endorsed Medicines Australia education program only applies to company employees or agents (including agents working under a contract to the company but not directly employed by the company). It does not apply to third party contractors etc such as advertising agencies, although these personnel are encouraged to also undertake the Code of Conduct component of the endorsed Medicines Australia education program.

This doesn’t include Managing Director, Clinical Research Associates, Medical Information, Corporate Affairs personnel unless these personnel are also responsible for the development, review and approval of promotional material and patient education material. However, all company personnel should be aware that the Code of Conduct applies to all company interactions with healthcare professionals.

As of 6 December 2006, any person newly employed in a role (whether a new employee or a transfer from another position) where their primary employment is the development, review and approval of promotional materials for prescription medicines or the review of promotional materials must have completed the Code of Conduct component of the endorsed Medicines Australia education program within 12 months. If staff transferring to a new company were previously in this role (development, review and approval of materials) there is no requirement to complete the Code of Conduct component of the currently endorsed Medicines Australia education program. However if the company representative was not employed in this role previously they must complete the Code of Conduct component of the endorsed Medicines Australia education program within 12 months of commencing employment in this role. If a company takes the decision to require additional training to that referred to in the Code eg require all staff to complete the Code of Conduct component of the endorsed Medicines Australia education program that is at the company’s discretion.

Section 5 Product Starter Packs

Section 5.1 Supply of Starter Packs

From 1 July 2006, the States and Territories will amend the relevant legislation so that:

- it will be a condition of licence that manufacturers and wholesalers comply with the Medicines Australia Code of Conduct for the Supply of Starter Packs; and
- authorised representatives of manufacturers and wholesalers will be exempted from requirements in medicines and poisons legislation that would otherwise make it an offence for them to supply scheduled medicines, provided they do so in compliance with the Medicines Australia Code of Conduct for the Supply of Starter Packs.

For manufacturers and wholesalers, compliance with the Code will be a condition of the wholesaler's or distributor's licence. For authorised company representatives (including agents working under a contract to the company but not directly employed by the company), a reverse licence will apply. A reverse licence is a general permission given under the legislation for a person to undertake an activity that would otherwise be prohibited.

All companies should ensure that representatives supplying Starter Packs understand these provisions and develop and maintain appropriate recording systems so that compliance by authorised representatives (including "third party" agents) can be demonstrated.

Starter Packs should only be supplied to healthcare professionals appropriate to their legal authority to prescribe and dispense such products. For example, it would not be appropriate to supply to a nurse practitioner starter packs for medicines that a nurse practitioner is not permitted to prescribe.

Labeling

In relation to the labeling of starter packs, Section 5.8 states that companies should supply adhesive labels pre-printed with fields for the prescriber to complete or alternatively pre-print these details on the primary packaging. This is not a mandatory requirement; however, companies are encouraged to supply adhesive labels or, alternatively, to have the fields printed on the packaging where it is practical to do so. It is recognised that it may take companies a period of time to develop and supply adhesive labels or to change printed packaging materials if companies elect to print the recommended fields on the packaging.

Number of Starter Packs

The Code does not stipulate a maximum number of starter packs that can be provided to various healthcare professionals but does refer to the needs of those healthcare professionals when determining how many starter packs can be provided. In the recent past the Code of Conduct Committee has considered complaints where a number of starter packs have been packaged together and provided to healthcare professionals for use by their patients. This practice has caused some concerns within the Code Committee as it was seen as a means of circumventing both the size and quantity requirements of the Code. Where a starter pack of one third the trade pack size would only take a patient midway through the necessary titration period as required in the approved Product Information, the Code Committee has expressed the view that if it was in the best interest of patients this could be justification for providing sufficient tablets in the starter kit to achieve a quality use of medicine outcome.

Should a company undertake this bundling of starter packs it must be in a situation to prove to the satisfaction of the Code Committee that this practice was not an attempt to circumvent the requirements of the Code, was undertaken in the best interests of the patients, supported the quality use of medicines and complied with the provisions of the Code.

Where electronic requests for starter packs are received by a company or agent acting on behalf of a company, either an electronic or hard copy of the request and the record of the supply must be retained.

Requirement for signature when requesting or receiving starter packs

The intention is to ensure that a healthcare professional is actually requesting the samples and that when starter packs are supplied there is record kept of the supply to ensure security of the starter packs.

For a healthcare professional to receive samples, the healthcare professional's signature must appear at either the request for the starter packs or on receipt of the starter packs. This is intended to allow for e-mailed requests for starter packs. If an e-mail request is received, the healthcare professional's signature must be obtained upon delivery of the starter packs. Another option might be for a secure password protected mechanism for a specific doctor to request starter packs which would take the place of a signature.

Section 6 Involvement in Educational Symposia, Congresses and Satellite Meetings

This section of the Code covers the behaviour of companies when they interact with healthcare professionals regarding prescription or prescription like medicines. In the case of multi-divisional companies it has been understood that there are differing rules that apply to these sections of the market and that the Medicines Australia Code of Conduct covers the activities of those representatives only when they are involved with prescription medicines.

This may result in OTC, diagnostic and device representatives being able to see healthcare professionals and provide them with entertainment that would be contrary to the provisions of the Medicines Australia Code. Medicines Australia encourages members with multiple divisions to consider this issue carefully to ensure the positive reputation and image of the industry is upheld.

The purpose of this section is to detail how the industry should contribute to educational meetings and its behaviour at such meetings. The Code recognises that the industry plays a vital role in the provision of accurate and reliable information to healthcare professionals by a number of means including the holding of educational meetings, the sponsorship of such meetings or the involvement in educational meetings.

Trade Displays

Claims for products and indications approved in Australia must also comply with the requirements of Section 1. Any materials supplied for Australian-registered products must comply with all relevant provisions of the Code.

This section of the Code recognises the ability of companies to provide or display material for products or indications that are not approved in Australia at international and Australasian congresses as defined in the glossary of the Code of Conduct.

For international congresses, if a company wishes to display or have material available on a trade display regarding a non-Australian approved product or indication, this material must make it clear to a casual reader or passer-by that this product or indication is not approved in Australia. A statement on each piece of material to this effect and a prominent statement on the trade display where this material is being presented would satisfy this requirement.

For products that are not registered in Australia (or indications that are not approved in Australia) the specific requirements included in Section 3 of the Code with respect to promotional materials do not apply, such as required wording for PBS information, inclusion of the Minimum Product Information on printed promotional materials etc. However, all materials should include the name of the supplier and the city, town or locality of the registered office; a clear and unambiguous statement for prescribers to review the product information (or equivalent document) before prescribing and that this information is available from the Trade Display.

For Australasian congresses, it is also possible to display or supply material for products not approved for registration in Australia or non-Australian approved indications if that product or indication has received registration or approval in New Zealand.

When matters involving these activities have come before the Code Committee, it has been suggested that if a product is approved in Australia as well as internationally, it would be advantageous if any differences between the Australian indications and the international Product Information and the material being supplied at the trade display could be identified for the benefit of healthcare professionals. This could be done in a separate document that compares the two Product Information documents and highlights any differences.

Companies should remember that there are a number of activities or items in addition to educational material that can be made available at trade displays including brand name reminders, involvement in competitions, medical educational material or complying hospitality. Other gifts or incentives provided by a company to encourage a healthcare professional to visit its stand at a trade display are prohibited.

However, when discussing amendments to this section it was agreed by Medicines Australia members that should a company wish to be involved in a passport type activity, where participants at the educational meeting are encouraged to attend each trade display by the event's third party organisers in exchange for being entered in a competition to win a prize, this would be acceptable.

Companies should also recognise the requirement in Section 6.1.9 that all activities in relation to trade displays must successfully withstand public and professional scrutiny and conform to professional and community standards. This includes the appearance and behaviour of company representatives such as their attire and general demeanour. Although not subject to a specific complaint, the dressing of company representatives in pyjamas was not considered appropriate by a Code of Conduct Committee when it was considering a complaint regarding another aspect of a trade display.

Invitations to Company-Sponsored Educational Meetings

The following comments arose from the Monitoring Committee's review of invitations to company-sponsored educational meetings:

Length of meetings

Although the duration of the educational session was important, other factors should be taken into consideration such as the value of the educational content, the speakers and educational material provided etc.

The Committee advised that if a program did not have formal CPD points allocated, the company should ensure that the invitation described the educational content or meeting agenda in sufficient detail to allow a healthcare professional to be informed of the quality of the education to be provided. As any hospitality provided in association with the meeting should be secondary to the educational component, this would also provide evidence to support this requirement of the Code. While people often remain longer to network or ask further questions it would assist healthcare professionals in knowing a probable finish time.

Many educational events that enabled CPD points to be gained had been evaluated by the RACGP prior to the awarding of points. The Committee recommended that companies use the approved RACGP wording when indicating the number of CPD points.

Companies should use "Allocated total CPD points 4 (Group 2) in the RACGP QA&CPD Program"

The only alternative is "x CPD Points have been applied for" if the Provider is waiting on the adjudication outcome.

Use of a company template for educational meeting invitations would appear to offer good guidance on appropriate wording (refer to appendix). However, guidance should also be provided to representatives regarding the extent to which elements of the template may be altered. For example, the inclusion of images or graphics that emphasise hospitality elements (wine and food or venue photos) are not appropriate as these may give the impression that the provision of education is not the primary purpose of the meeting

Partner Payments

In relation to partner payments, the use of the words 'partner contribution' may imply that the cost of a partner's attendance is partly paid for by the company. It is preferable to use wording that emphasises that the partner payment is for the full cost of their attendance.

Venues

Photos of a venue should not be included on invitations as the venue should not be the primary attraction or focus of the meeting.

It is also acceptable to provide appropriate hospitality to attendees at a third party educational meeting, such as dinner for visiting healthcare professionals that may be attending a College annual conference. However this hospitality must be basic and simple and must not involve the provision of entertainment.

Sponsorship or Involvement in Australian Congresses and Satellite Meetings

This section covers the sponsorship of educational meetings that are organised by third parties such as a College or Society. The Code is not intended to apply the pharmaceutical industry's standards to such third party organisations, but it does require companies to ensure when they are making sponsorship decisions that they will maximise the enhancement of medical knowledge, improve the quality use of medicines and conform to community standards.

This section would apply, for example, if a company is invited to sponsor a conference dinner at an educational meeting. The company must ensure that it examines any hospitality or entertainment provided at that dinner and that the educational content of the meeting has merit and is the primary purpose of the meeting.

For example, a company could provide sponsorship of a conference dinner if it was not lavish, involved an educational speaker and there was incidental entertainment such as a string quartet in the background. The intention is that any entertainment included in a dinner that is sponsored by a company should not be a focal point during the dinner, such as a concert presentation, dance band etc. The test will be whether the entertainment detracts from the educational intent of the meeting in total and would be able to successfully withstand public and professional scrutiny. A useful test for companies may be whether they could support their choices if questioned by the media. This test applies to both domestic and international events.

Companies are strongly encouraged to support the educational content of such meetings rather than any related hospitality.

Sponsorship of Healthcare Professionals

This section applies when companies sponsor healthcare professionals to attend either domestic or international educational meetings. The choice of a healthcare professional must be based on the individual's interest in the area of medicine being discussed and their ability to communicate any relevant information gathered from these meetings with their Australian colleagues.

Companies should document their sponsorship criteria and the manner in which the sponsored individuals will inform their healthcare professional colleagues of the information they acquire at these meetings.

Section 7 Sponsorship

This section of the Code recognises the valuable contribution the pharmaceutical industry makes to the healthcare professions through the sponsorship of various activities. The Code sets out when such sponsorship is appropriate and uses the tests seen in Section 6.

These tests state that if a company wishes to sponsor a healthcare professional activity, the sponsorship must:

- Be able to successfully withstand public and professionals scrutiny
- Conform to professional and community standards of ethics and good taste, and
- Enhance the quality use of medicines

In this way the industry believes health care outcomes will be enhanced in a socially responsible manner.

Companies must ensure that there are no obligations to prescribe a product based on the sponsorship and that nothing should be offered or provided which would interfere with the independence of a healthcare professional's prescribing or dispensing practices.

Where a company provides support for medical practice activities, such programs must not be offered or provided conditional upon any obligation to prescribe a particular product, switch to a particular product or for the purpose of gaining exclusive access to a medical facility.

Companies should ensure they have documented how they award sponsorships and what the criteria they used are based on the requirements of this Code. They must also be fully aware of what their sponsorship dollar is buying to ensure that they can comply with the requirements set out in this section.

Sponsorship should not be used as a vehicle to avoid other requirements of the Code. For example, a College or Society should not be influenced to hold a sporting event for healthcare professionals that could be sponsored by a company and thereby avoid the requirements of Section 10 of the Code that prohibits such events.

This section does not cover the industry's substantial sponsorship of philanthropic, cultural, educational, sporting and artistic activities or charities.

The Code recognises the importance of the pharmaceutical industry's support of these worthwhile activities and encourages industry participation. However the Code does require companies to consider several issues when they are considering providing sponsorship for charitable or philanthropic organisations or events.

When considering sponsorship opportunities, of primary importance to companies is the test of being able to withstand public and professional scrutiny and the ability to conform to any relevant professional and community standards of ethics and good taste. In addition, involvement in these activities must not be undertaken for product promotional reasons or for promotional purposes. Other sections of the Code of Conduct will also need to be considered, particularly the prohibition of entertainment and the restrictions on any hospitality provided by the industry.

For example if a company is asked to sponsor a golf day which has been designed to raise funds for a hospital, it should begin by asking whether this is a bona fide charity, assuring itself that the reason for involvement is not promotional and that the activity could withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. The company would then have to examine any benefits it might derive from this sponsorship and whether these are acceptable under the Code. Discreet signage and recognition of the company name would be acceptable. However, for events that involve members of the general public the use of a product name would not be acceptable.

If the benefits from sponsorship involve a number of rounds of golf, these cannot be offered to members of the healthcare professions as this would contravene the requirement of the Code that prohibits the provision of entertainment to healthcare professionals.

If the event also involved a dinner that included entertainment and no educational component, similarly attendance at this event could not be offered to healthcare professionals. If, however, the entertainment was modest and there was a bona fide educational component to the dinner it might be acceptable to invite healthcare professionals to such an event.

A company may also sponsor a charitable event or organisation by providing a contribution (either cash or goods) towards a competition prize. In such instances the company should ensure the event and the prize are able to withstand public and professional scrutiny and the ability to conform to any relevant professional and community standards of ethics and good taste.

Section 8 Research

Section 8.2 Market Research

This section is primarily directed at Market Research conducted with healthcare professionals, but recognises that Market Research may also on occasion be undertaken with members of the general public.

Section 8.2 is intended to make it clear that market research and competitions should not be confused. On a number of occasions the Code of Conduct Committee has seen activities that are neither a complying competition nor a complying piece of market research. This may include some market research questions, such as seeking the number of patients presenting with a certain condition, followed by the opportunity to correctly answer another set of questions to be eligible to be entered into a prize draw.

Companies should take care to ensure that, if they are undertaking either activity each is run separately and that each activity complies with the relevant section of the Code. If market research data is being sought it is reasonable that some form of payment is made that is commensurate to a health professional's time and in accordance with business practice.

Section 8.2.2

The rationale for requiring that any voucher that is provided in lieu of cash must only be valid to obtain an item that is directly relevant to the practice of medicine or pharmacy is that companies should not be providing items of entertainment to healthcare professionals such as movie tickets, scratchies, lottery tickets etc. This relates to market research commissioned by a pharmaceutical company. It is not expected that companies would examine what payment was provided to a healthcare professional when purchasing an existing market research report produced by a third party that was not commissioned by a pharmaceutical company.

Any remuneration must be commensurate for the time spent.

The overarching principle of all provisions of the Code is that entertainment or an item of entertainment must not be provided to a healthcare professional when participating in any activity covered by the Code of Conduct.

A voucher to a healthcare professional must be valid only to obtain an item that is directly relevant to the practice of medicine or pharmacy.

These provisions relate to direct company market research and market research commissioned by a company to a third party.

Where a company purchases a market research report from externally commissioned or initiated research these provisions will not apply.

See also Section 3.13 dealing with competitions.

Section 9 Relationship with the General Public

Section 9.2 Product Specific Media Statements

As with Section 9.6 dealing with the provision of information on the Internet, Section 9.2 discusses how the pharmaceutical industry can act responsibly by meeting the information needs of the general public by the provision of current, accurate and balanced information about their prescription medicines available in Australia. However, the Therapeutic Goods Act prohibits the advertising of prescription medicines to members of the general public. The Act defines advertisement:-

“advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended whether directly or indirectly, to promote the use or supply of the goods.”

The Code reflects this legislative requirement that prohibits the promotion of prescription medicines to members of the general public. The Code also recognises the need of members of the general public for information regarding prescription medicines and the requirement for the industry to meet those needs in a responsible and appropriate manner. Section 9.2 is designed to set a framework in which this information can be provided to members of the general public in a non-promotional and educational manner by a media statement.

Companies considering the provision of this type of information to members of the general public should be aware of the legal advice received by Medicines Australia when these provisions of the Code were being drafted. Although the Therapeutic Goods Act definition of advertisement has been tested in the Australian courts only to a limited extent, there have been a number of cases that look at the issue of advertising. These cases have led to the legal advice that the definition of advertising would therefore capture information published on the internet or a media release, if, when objectively assessed, the material is intended directly or indirectly to promote the use or supply of a particular product.

Thus, the test under the legislation is whether the information, when objectively assessed, is intended directly or indirectly to promote the use or supply of a particular product. Companies must be aware that if information published by them about their products can be accessed by consumers, there is always a risk that the publication could be said to promote the use or supply of a particular product.

This will be the case even if the publication adopts a general and educative approach of the kind described in the Code.

Medicines Australia encourages companies considering making information about its products available to the general public under the provisions of this section to contact Medicines Australia to discuss these activities, or to seek their own legal advice.

Companies should not provide pack shots for publication/broadcast by the media. The TGA has previously provided advice to the Pharmacy Board of NSW that a brochure for consumers that includes pictorial representation of products is an advertisement.

Discredit to and Reduction of Confidence in the Industry

Section 9.10 General Public

Section 10.8 Healthcare Professionals

Examples of activities that may be considered as bringing the industry into disrepute include:

- The provision of personal services or products to gain access to healthcare professionals, e.g. car washes, facials, etc.
- “Educational” meetings that have hospitality as their primary purpose
- Providing entertainment to healthcare professionals such as theatre tickets, or opportunities to attend sporting or artistic events
- Activities such as “dine and dash” where opportunities are created to meet with healthcare professionals
- The provision of promotional material to members of the general public
- Financial inducements to healthcare professionals to prescribe or dispense prescription medicines

Activities that would bring discredit upon the industry or reduce confidence in the industry will be treated as severe breaches and may attract a fine up to \$200,000.

Section 10 Relationship with Healthcare Professionals

(Including educational meetings, individual healthcare professionals, consultants, Advisory board members, clinical trial investigators)

The same tests apply Section 6, 7 and 10 to determine whether the behaviour of the industry is appropriate in accordance with the Code. The introductory paragraphs to Section 10 apply as if it were a section of the Code and states that involvement in activities with healthcare professionals must:

- Successfully withstand public and professional scrutiny
- Conform to professional and community standards and
- Have the primary objective of enhancing medical knowledge and the quality use of medicines in Australia

Sections 6.2/10.2 Hospitality

If a company is holding its own educational meeting it should ensure that any hospitality that is offered is consistent with the professional standing of the delegates. Meals provided at an educational meeting should not be extravagant or exceed standards which would meet professional and community scrutiny. Companies should remember that hospitality must always be secondary to the educational purpose of the meeting. An appropriate level of hospitality would be what is expected in a normal business meeting.

If during any interactions with healthcare professionals, such as a surgery meeting by a medical representative, hospitality is offered, it must be secondary to the educational intent of the meeting and must not be extravagant. If the provision of this hospitality is undertaken outside the surgery, the venue should be such that would enhance the educational purpose of this meeting and again should be at the level of a normal business meeting but not extravagant.

In preference the provision of hospitality should not be offered to practice staff as the primary purpose of this interaction is to provide information regarding prescription medicine to healthcare professionals. However, should members of practice staff be provided incidentally with hospitality that has been provided for the benefit of healthcare professionals this may be appropriate in limited circumstances, but companies must not enter into any arrangement whereby access to the practice is on the basis of the provision of the hospitality.

“Dine and dash” type activities where offers are made to pick up take away food for a doctor in return for an opportunity to discuss a product with him or her is inappropriate and would be in breach of the Code.

Section 6.6 Venue Selection

For educational meetings organised by companies, the venues must be chosen on the basis of their ability to contribute to the enhancement of medical knowledge and the quality use of medicines.

Given the professional standing of the audience to which medical information is provided, it is reasonable to use venues that reflect this audience. For example, a five star hotel in a major city would be an appropriate venue if it had all the facilities which would enhance the imparting of medical knowledge, such as dedicated conference facilities, and could successfully withstand community scrutiny.

For meetings outside major cities, companies must take care to choose venues that do not emphasise leisure and or sporting facilities. For example, a regional meeting may be located at a golf course which provides limited conference facilities. It would be unlikely that this venue selection would meet the requirements of the Code. However, a venue that has a dedicated conference facility and can manage and supply the quality provision of education, but also has a golf course attached or located near it may be appropriate.

However, some hotels which have adequate conference facilities may not be suitable choices if in the public's mind they are promoted and/or perceived as luxury resorts where the emphasis is on leisure and recreation. Companies will need to consider the choice of these venues carefully and be able to support their choice particularly in relation to community standards.

In relation to educational meetings organised by third parties, the standard adopted by the pharmaceutical industry is not being imposed upon these organisations. However, companies should ensure that they are comfortable with the choice of venue and that the meeting's educational purpose is being enhanced by being held at a particular venue.

Sections 6.8 Travel

The Code sets out the appropriate levels of travel that should be offered to healthcare professionals when they are being sponsored to attend an educational meeting.

It is possible to subsidise the cost of travel to educational or other meetings. If the meeting is held within Australia, travel should be by economy class only. An exception for business class may be allowed for reasons such as medical conditions or where the length of travel exceeds four hours of air travel, but the general rule should be to use economy class travel. For international travel, either economy or business class can be used.

For both domestic and international educational events, accommodation costs may include an allowance for meals whilst travelling, and transfers. These allowances should reflect the professional standing of healthcare professionals, but should not be extravagant and they must be able to withstand community scrutiny.

Sections 10.1/10.6.9 Entertainment

A primary restriction is that no entertainment should be provided to healthcare professionals. This would include the provision of tickets to cultural, sporting or artistic events, the inclusion of a band as a featured attraction at a dinner meeting or the invitation to a corporate box at a sporting event.

The industry has agreed that its role is not to provide entertainment to healthcare professionals, but to be their partner in the enhancement of positive health outcomes by providing reliable and accurate information about its prescription medicines available in Australia.

An allowance has been made in relation to educational meetings of two days' duration or longer, where it is possible for a period of no longer than half a day to be allocated for healthcare professionals to undertake recreational or sporting activities. These activities must not be arranged or paid for by the companies involved.

For example, for a two day weekend meeting, Saturday afternoon could be dedicated to individual recreational time where the conference venue could organise rounds of golf for the participating healthcare professionals. The organisation of the golf should not be the responsibility of the company and the company should not sponsor or subsidise the costs.

Costs Incurred by Partners, Travelling Companions or Families of Healthcare Professionals

Any travel costs of companions or family members must not be paid for or subsidised by companies. Companies are encouraged to make arrangements so that airline tickets cannot be exchanged for multiple lower priced tickets that would allow a companion or family member to travel with a healthcare professional at the company's expense. Companions and family members are welcome to join healthcare professionals at educational meetings but any costs they incur must not be paid for or subsidised by the company. An estimate of the costs that are likely to be incurred by companions and family members should be advised to healthcare professionals considering taking a family member or companion to ensure they are aware of the costs that will be charged to those individuals. It is generally accepted that in most cases there will be no additional accommodation costs if a standard hotel room is shared by family members or companions.

Section 10.4 Medical Education and Section 10.5 Medical Literature/Reprints

Companies should be cognisant of the policies of other parties' concerning the reference to and use of their publications in pharmaceutical company promotional materials, including whether prior approval for the proposed use is required. For example, Therapeutic Guidelines Limited provides "*Conditions for the Use of Therapeutic Guidelines Publications in Pharmaceutical Industry Promotion.*" This policy may be found at <http://www.tga.com.au/home/pol.html>.

Companies can disseminate the full compilation of independent conference abstracts or posters etc to a healthcare professional even if such a compilation includes items about products that are not approved in Australia or unapproved indications. This is accepted as being equivalent to educational material prepared by a third party. However, a company cannot prepare and proactively disseminate (unsolicited) to healthcare professionals a compilation of a selection of posters and abstracts from a conference which includes items about unapproved products or indications relevant to their company's products. Companies can provide such a selection where each abstract or poster or other item relates to approved products or indications.

The same principles described above apply to dissemination of information from independent conferences at company-initiated meetings.

Section 10.6 Consultants and Advisory Boards

Companies should be cognisant that a document summarising the purpose, objectives, justification of the size/number of the Advisory Board/s must be publicly available for scrutiny by the Code of Conduct Committee and complainant should a complaint be lodged. It is not the intention of the Code that should a complaint be lodged that confidential and commercially sensitive information would be disclosed to a competitor or other parties.

In relation to the number of healthcare professionals identified as reasonably necessary to form an Advisory Board, it is recommended that 8-12 would be appropriate. Should a company require additional healthcare professionals the justification for the number should be outlined in the rationale for the Advisory Board.

Should a company consider that there is sufficient justification for forming more than one Advisory Board for an individual product the reasons must also be outlined in the rationale for the formation of the multiple boards.

Section 12 Sanctions

Section 12.3 Abuse of the Code

The purpose of this Section of the Code is ensure that every opportunity is given to the Code of Conduct Committee to consider valid and meaningful complaints by reducing the possibility of having to consider trivial or vexatious complaints.

To sustain an allegation that a single complaint is in breach of this section, the company complained about would have to demonstrate concerns such as:

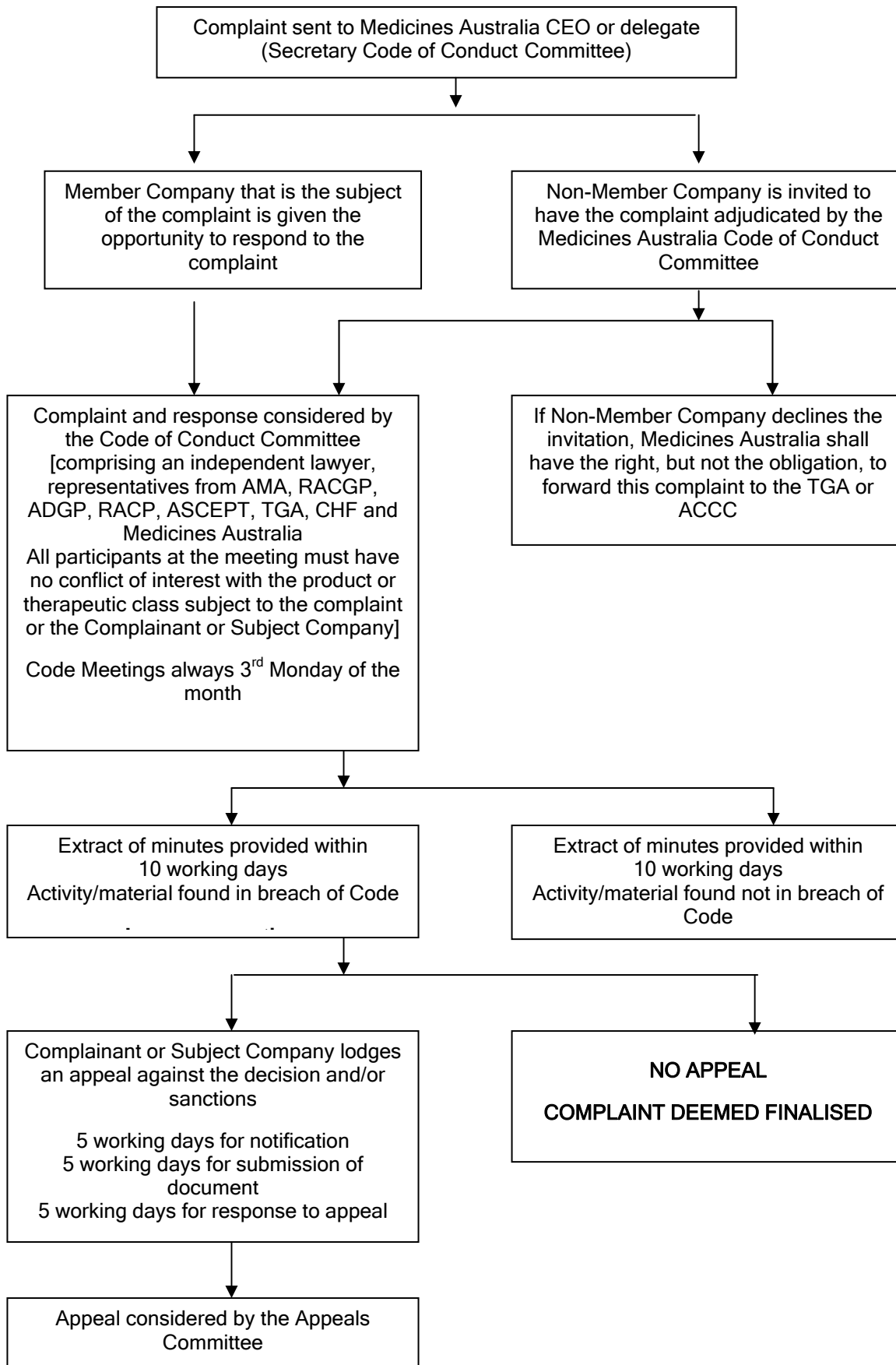
- the sole matter subject of the complaint is trivial,
- the matter could have been successfully dealt with via further intercompany dialogue pursuant to the Intercompany Dialogue Guidelines in Appendix 1 of the Code,
- there was no patient safety issue involved in the complaint,
- it involved only a competitive issue,
- even though a non-technical breach was found, the sanction imposed by the Committee did not go beyond what the respondent company had already undertaken in the course of intercompany dialogue, or
- even though it might be a technical breach of the Code (i.e. type size not complied with) it was not appropriate to bring this individual trivial matter to the Code of Conduct Committee when it could easily have been resolved by intercompany dialogue (see above).

A series of complaints against either a single company or a number of companies may breach this section for similar reasons to those raised above.

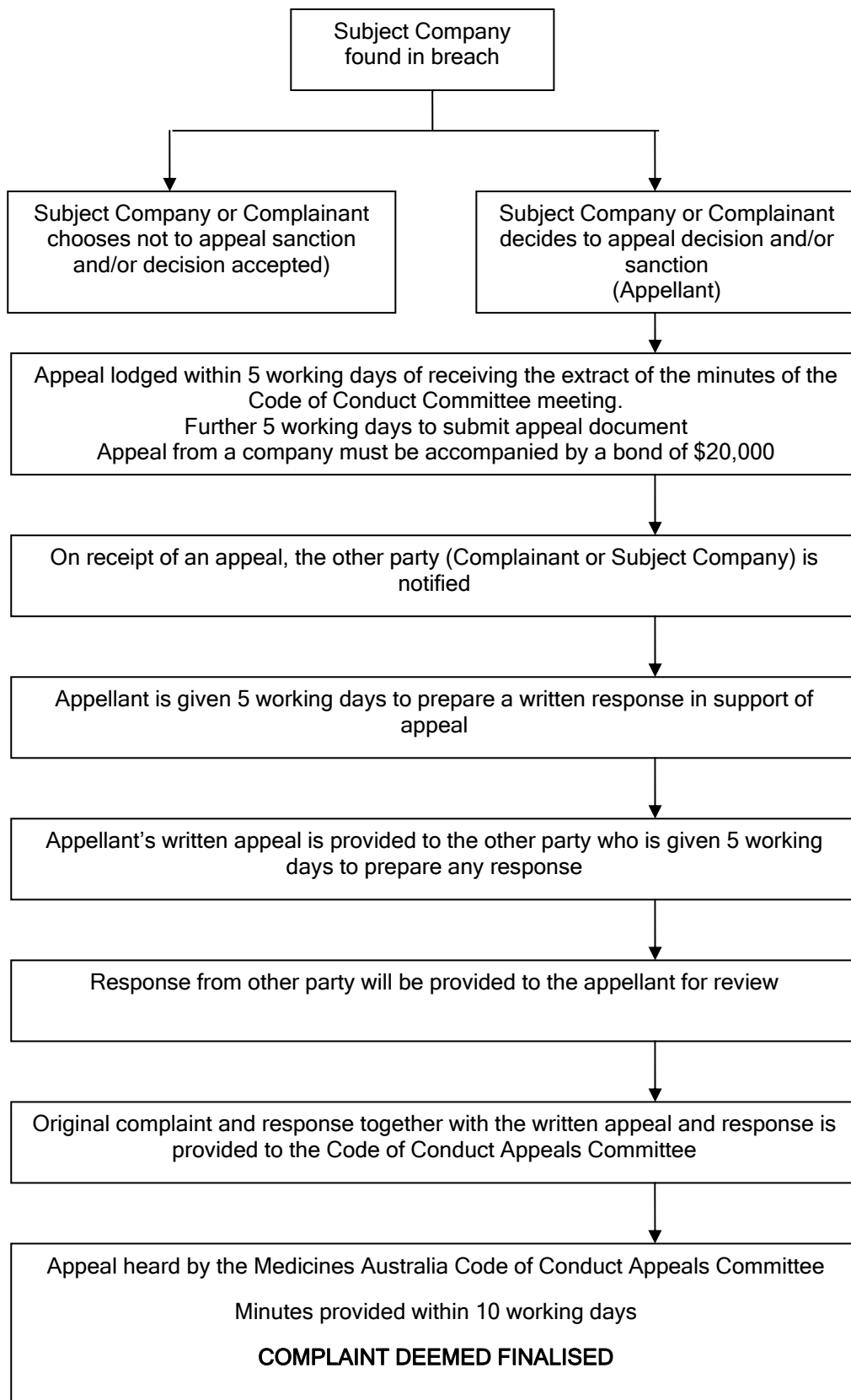
It is important for companies to understand that a finding of an abuse of the Code is not dependent upon whether a breach of the Code is found or not. Rather, it is about using the Code in an inappropriately trivial way that would preclude the Committee's consideration of other more meaningful complaints.

The Committee may, having considered a number of competitive inter-company complaints, ask that a mediation meeting be held with those two companies. During this mediation phase an agreement would be sought from the two companies that no further complaints be lodged until the finalisation of the mediation process. This mediation process has been successful in the past and will be recommended by the Committee should it consider that resolution between two companies may be achieved by such discussions.

Appendix 1 - Medicines Australia Complaints Handling Process



Appendix 2 - Code of Conduct Appeals Procedures



Appendix 3 - Code of Conduct and Appeal Summary

Industry Generated Complaint	Non-industry Generated Complaint
Complaint Submission Form completed and signed	Complaint Submission Form completed and signed
<p>Evidence of intercompany dialogue</p> <ul style="list-style-type: none"> • Letter sent to Subject Company (10 working days to respond) • Teleconference or face to face meeting (10 working days to arrange) • Additional meetings may be arranged if a resolution is possible 	<p>Complaint to Medicines Australia must include the following:</p> <ul style="list-style-type: none"> • Item subject to complaint • If possible a letter detailing concerns about the promotional item or activity
<p>Evidence of early involvement of the most senior executive responsible for the prescription medicines business (Managing Director, CEO, General Manager)</p>	<p>On receipt of the complaint Medicines Australia may refer the Complainant to an independent facilitator:</p> <ul style="list-style-type: none"> • Discuss details of the complaint to allow facilitator to ascertain which sections of the Code may be applicable • Facilitator may also act as an intermediary between the Complainant and Subject Company in an attempt to resolve the complaint (or reach a partial resolution) • Independent facilitator to provide Medicines Australia with agreed outcomes • If no resolution complaint submitted to the Code of Conduct Committee with sufficient information to allow the Subject Company to provide a full response
<p>Letter of complaint to Medicines Australia must be signed by the Association Representative or Alternative Association Representative (Non-member companies it would be the most senior executive responsible for the prescription medicines business)</p>	
<p>Complaint must contain the following information:</p> <ul style="list-style-type: none"> • Item subject to complaint • Detail of alleged breaches of the code including relevant sections • Supporting references (if applicable) <p>20 complete sets ready for use by the Code of Conduct Committee</p>	
<p>Complaint sent to Subject Company (10 working days to respond)</p>	<p>Complaint sent to Subject Company (10 working days to respond)</p>
<p>Response to complaint must include the following information:</p> <ul style="list-style-type: none"> • Item subject to complaint • Product Information • Response to Medicines Australia must be signed by the Association Representative or Alternative Association Representative (Non-member companies it would be the most senior executive responsible for the prescription medicines business) 	<p>Response to complaint must include the following information:</p> <ul style="list-style-type: none"> • Item subject to complaint • Product Information • Response to Medicines Australia must be signed by the Association Representative or Alternative Association Representative (Non-member companies it would be the most senior executive responsible for the prescription medicines business)

20 complete sets ready for use by the Code of Conduct Committee	20 complete sets ready for use by the Code of Conduct Committee
Code of Conduct Committee consider complaint - receive written complaint and response Code of Conduct Committee meetings held on 3 rd Monday of the month. Dates available on Medicines Australia website www.medicinesaustralia.com.au	Code of Conduct Committee consider complaint - receive written complaint and response Code of Conduct Committee meetings held on 3 rd Monday of the month. Dates available on Medicines Australia website www.medicinesaustralia.com.au
Committee ruling - brief statement provided via fax/email within 2 working days	Committee ruling - brief statement provided via fax/email within 2 working days
Extract of the minutes of the Code of Conduct Committee meeting provided 10 working days Minutes remain confidential until the complaint is deemed finalised ie until either the Complainant or Subject Company has notified Medicines Australia of their intention in relation to any appeal. If no appeal is lodged within the 5 working days complaint is deemed finalised. If one party lodges an appeal the complaint is not deemed finalised until the extract of the minutes of the appeals Committee meeting is distributed to both parties.	Extract of the minutes of the Code of Conduct Committee meeting provided 10 working days Minutes remain confidential until the complaint is deemed finalised ie until either the Complainant or Subject Company has notified Medicines Australia of their intention in relation to any appeal. If no appeal is lodged within the 5 working days complaint is deemed finalised. If one party lodges an appeal the complaint is not deemed finalised until the extract of the minutes of the Appeals Committee meeting is distributed to both parties.
Where notification of an appeal is received by Medicines Australia the appellant has a further 5 working days in which to submit their written appeal document 10 copies of the document must be provided to Medicines Australia There is no requirement to include materials that formed part of the original complaint or response to the complaint	Where notification of an appeal is received by Medicines Australia the appellant has a further 5 working days in which to submit their written appeal document 1 copy of the document must be provided to Medicines Australia There is no requirement to include materials that formed part of the original complaint or response to the complaint
Members of the Appeals Committee receive the following documents: <ul style="list-style-type: none"> • Original complaint • Response to the complaint • Extract of the minutes • Appeal document • Response to the appeal 	Members of the Appeals Committee receive the following documents: <ul style="list-style-type: none"> • Original complaint • Response to the complaint • Extract of the minutes • Appeal document • Response to the appeal
Appeal sent to other party (5 working days to respond)	Appeal sent to other party (5 working days to respond)
Extract of the minutes of the Appeals Committee meeting provided 10 working days	Extract of the minutes of the Appeals Committee meeting provided 10 working days

Appendix 4 - Journal and Reference Manual Advertising

Primary (Section 3.1.1)	Secondary (Section 3.1.2)	Short (Section 3.1.3)	Reference Manual (Australian Prescription Product Guide and MIMS) (Section 3.2)
<p>Use (Section 3.1.1.2) Primary advertisement is mandatory for advertising of all new chemical entities or the advertising of new indications</p> <ul style="list-style-type: none"> For 24 months from the first advertising of a new chemical entity For 12 months following a change of clinical significance made to the PI 	<p>Use (Sections 3.1.2.1) The use of a Secondary advertisement in any issue of a publication that does not also contain a Primary advertisement is not permitted.</p>	<p>Use (Section 3.1.3.1) The sole use of a Short advertisement in any issue of a publication that does not also contain a Primary advertisement is not permitted</p> <ul style="list-style-type: none"> For 24 months from the first advertising of a new chemical entity For 12 months following a change of clinical significance made to the PI 	<p>Use (Section 3.2) The Use of Primary, Secondary and Short advertisements must comply with the requirements of Sections 3.1.1, 3.1.2 and 3.1.3</p>
<p>Change in Clinical Significance Must be used for 12 months following a change in clinical significance</p> <ul style="list-style-type: none"> Where a change of clinical significance relating to product safety or the addition of a boxed warning is incorporated into the Product Information, it should be indicated in all representations of the Product Information for a period of 12 months from the date of change. Indicated by an asterisk(s) to a footnote Font size not less than 2mm as measured by the lower case 'e' Please note change(s) in Product Information <p>The full text of the changed section should be included in any abridged Product Information during this period</p>			
<p>After 24 Months After 24 months from first advertising or 12 months in the case of a change of clinical significance a Primary advertisement is not required however a company can choose to use a Primary advertisement at their discretion</p>	<p>After 24 Months The use of a Secondary advertisement in any issue of a publication that does not also contain a Primary advertisement is not permitted.</p>	<p>After 24 Months After 24 months from first advertising or 12 months in the case of a change of clinical significance a Short advertisement can be used in a journal without the requirement for a Primary advertisement to also be included</p>	
<p>Promotional Claims May contain promotional claims - must conform to provisions of Section 1</p>	<p>Promotional Claims May contain promotional claims - must conform to provisions of Section 1</p>	<p>Promotional Claims Must not contain any promotional claims</p>	
<p>Advertisement must contain the following (Section 3.1.1.3)</p>	<p>Advertisement must contain the following (Section 3.1.2.2)</p>	<p>Advertisement must contain the following (Section 3.1.3.2)</p>	<p>Primary, Secondary and Short advertisements must comply with the requirements of Sections 3.1.1, 3.1.2. and 3.1.3</p>
Brand Name of the product	Brand Name of the product	Brand Name of the product	Brand Name of the product
Australia Approved Name(s) of the active ingredient(s)	Australia Approved Name(s) of the active ingredient(s)	Australia Approved Name(s) of the active ingredient(s)	Australia Approved Name(s) of the active ingredient(s)
Name of supplier and the city, town, locality of the registered	Name of supplier and the city, town, locality of the registered	Name of supplier and the city, town, locality of the registered	Name of supplier and the city, town, locality of the registered

office	office	office	office
Clear and unambiguous statement for prescribers to review the PI before prescribing	Clear and unambiguous statement for prescribers to review the PI before prescribing	Statement to the effect that further information is available from the supplier	Statement to the effect that further information is available from the supplier
All PBS listings, including any restrictions	All PBS listings, including any restrictions	All PBS listings, including any restrictions	All PBS listings, including any restrictions
<p><u>The PI, Abridged PI or Minimum PI must appear in the body of the advertisement</u></p> <p><u>If the Minimum PI is printed within the body of the advertisement a company may also make reference to the PI or Abridged PI elsewhere in the journal.</u></p> <p>Product Information should form a fixed part of the journal</p> <p>Font Size - PI and Abridged PI not less than 1 mm as measured by the lower case 'e' Minimum PI not less than 1.5mm as measured by the lower case 'e'</p>	<p>A reference to the location of the Primary advertisement or the Product Information index or advertisers index</p> <p>Font Size - not less than 2mm as measured by the lower case 'e'</p>	<p>No PI, Abridged PI or Minimum PI is required for a Short advertisement however the following information may be included on the advertisement:</p> <p>(a) Up to 5 words describing the therapeutic class, but without the use of promotional phrases. (b) Graphics (non promotional) (c) A statement of available dosage forms. (d) A statement referring to the location of Product Information in a reference manual. (e) The website address of the company.</p> <p>No other material is permitted.</p>	<p>Reference to the Therapeutic Class Number or page on which the relevant PI is located</p>
<p><u>Abridged Product Information</u> Font Size - not less than 1mm as measured by the lower case 'e'</p> <p>The following shall appear:</p> <p>(a) Approved indications for use (b) Contraindications (c) Clinically significant warnings (d) Clinically significant precautions for use (e) Clinically significant adverse effects and interactions (f) Available dosage forms (g) Dosage regimens and routes of administration (h) Dependence potential of clinical significance (i) Reference to special groups of patients (including Australian pregnancy categorisation if issued). (j) boxed warnings</p>			
<p><u>Minimum Product Information</u> Font Size - not less than 1.5mm as measured by the lower case 'e'</p> <p>The following shall appear:</p> <p>(a) An approved indication or indications for use together with the dosage and method of use (b) A succinct statement of the contraindications, precautions and side effects, including any boxed warnings that may appear in the full Product Information (c) A clear and unambiguous statement for prescribers to review the Product Information before</p>			

<p>prescribing</p> <p>(d) A statement to the effect that full disclosure Product Information is available on request from the Company</p>			
<p>PBS Listing PBS Listing - as required in the preamble to Section 3</p> <ul style="list-style-type: none"> Text box with white background and black outline Font - clear "sans" font (not condensed) eg Arial, Universal, Helvetica Text must be black Text size not less than 2mm as measured by the lower case 'e' Text box must not include other information eg dosage, cost, repeats, pack size PBS Box Size 18cm² - A4 or greater 15cm² - A5 - A4 10cm² - less than A5 <p>Further information on the PBS listing can be found in the Guidelines to Edition 15</p>	<p>PBS Listing PBS Listing - as required in the preamble to Section 3</p> <ul style="list-style-type: none"> Text box with white background and black outline Font - clear "sans" font (not condensed) eg Arial, Universal, Helvetica Text must be black Text size not less than 2mm as measured by the lower case 'e' Text box must not include other information eg dosage, cost, repeats, pack size PBS Box Size 18cm² - A4 or greater 15cm² - A5 - A4 10cm² - less than A5 <p>Further information on the PBS listing can be found in the Guidelines to Edition 15</p>	<p>PBS Listing PBS Listing - as required in the preamble to Section 3</p> <ul style="list-style-type: none"> Text box with white background and black outline Font - clear "sans" font (not condensed) eg Arial, Universal, Helvetica Text must be black Text size not less than 2mm Text box must not include other information eg dosage, cost, repeats, pack size PBS Box Size 18cm² - A4 or greater 15cm² - A5 - A4 10cm² - less than A5 <p>Further information on the PBS listing can be found in the Guidelines to Edition 15</p>	<p>PBS Listing Primary Advertisements</p> <p>Example: For PBS Information: Refer to Section 2(a) or PBS Information: This product is listed on the PBS for</p> <p>Short Advertisements Before prescribing please review Product and PBS Information in Section 1(a)</p>
<p>PBS Dispensed Price PBS dispensed price must be included in the mandatory text. If only one indication must include price for that indication. If no specific indication is being promoted must include all presentations.</p>			
<p>Font/Text Size Summary</p> <ul style="list-style-type: none"> Font/type size refers to the lower case 'e' Product Information - 1mm Abridged PI - 1mm Minimum PI - 1.5mm Reference to PI if not in the body of the advertisement - 2mm Change of clinical significance - 2mm Mandatory text - 1.5mm Qualification - 2mm PBS Box - 2mm 			

Appendix 5 - Advertising in Electronic Prescribing Software

Primary Advertisement	Short Advertisement
May contain promotional claims	Must not contain promotional claims
No advertisements with patient education materials, consumer medicines information or in clinical tools which may be used by a prescriber for consultation or discussion with a patient	
Must contain the following (Section 3.9.3)	Must contain the following (Section 3.9.4)
Brand Name of the product	Brand Name of the product
Australia Approved Name(s) of the active ingredient(s)	Australia Approved Name(s) of the active ingredient(s)
Name of supplier and the city, town, locality of the registered office	
Clear and unambiguous statement for prescribers to review the PI before prescribing	Clear and unambiguous statement for prescribers to review the PI before prescribing
All PBS listings including any restrictions	All PBS listings including any restrictions
Identification and details of substantiating references within the body of the advertisement or accessible via a hyperlink or similar mechanism	
<p>The instruction to review the PI before prescribing may be displayed within the advertisement or immediately adjacent to it in the dialogue box in which the advertisement appears</p> <p>Primary advertisements in electronic prescribing software are not required to include Minimum Product Information</p> <p>Access to the PI may be provided through a hyperlink or similar mechanism embedded within the advertisement or through a button linking to a data base of PI documents within the software</p>	
A statement to the effect that further information is available on request from the sponsor	
Type size and graphics used must be such that allows easy and clear legibility having regard to sizes and resolutions standards of screens likely to be used and contrast between text and background	Type size and graphics used must be such that allows easy and clear legibility having regard to sizes and resolutions standards of screens likely to be used and contrast between text and background

Appendix 6 - Non - Paper Based Advertising

Audio Visual Promotional Material (Section 3.6)	Computer Based Promotional Material (Section 3.7)	Television Advertising - HCP Audience (Section 3.10)
Must contain the following (Section 3.6.1)	Must contain the following (Section 3.7)	Must contain the following (Section 3.10.1)
Brand Name of the product		Brand Name of the product
Australia Approved Name(s) of the active ingredient(s)		Australia Approved Name(s) of the active ingredient(s)
Name of supplier and the city, town, locality of the registered office		Name of supplier and the city, town, locality of the registered office
Clear and unambiguous statement for prescribers to review the PI before prescribing		Clear and unambiguous statement for prescribers to review the PI before prescribing
<u>PI or Abridged PI</u> After 24 months from first advertising or 12 months in the case of a change of clinical significance a company may use an Abridged PI	<u>PI or Abridged PI</u> After 24 months from first advertising or 12 months in the case of a change of clinical significance a company may use an Abridged PI	<u>PI or Abridged PI</u> After 24 months from first advertising or 12 months in the case of a change of clinical significance a company may use an Abridged PI
Where audiovisual item is demonstrated, on completion the PI must be offered to the individual or in a group situation to the audience	Where audiovisual item is demonstrated, on completion the PI must be offered to the individual or in a group situation to the audience Where the PI is included in an interactive data system instructions for accessing the PI must be clearly displayed	Statement to the effect that the PI and substantiating references can be obtained from (the company) or by phoning (Telecaster number)
<u>PBS Listing</u> PBS Listing - as required in the preamble to Section 3	<u>PBS Listing</u> PBS Listing - as required in the preamble to Section 3	<u>PBS Listing</u> PBS Listing - as required in the preamble to Section 3
<u>Promotional Claims</u> Claims included in any audio visual material must be referenced and the references made available to the individual or audience in a group situation	<u>Promotional Claims</u> Where promotional or medical claims are included in the computer based promotional material, details of the substantiating references must be readily accessible via the computer based promotional material	<u>Promotional Claims</u> Statement to the effect that the PI and substantiating references can be obtained from (the company) or by phoning (Telecaster number)
<u>Type Size</u> The type size and graphics used in all promotional material must be such that allows easy and clear legibility	<u>Type Size</u> The type size and graphics used in all promotional material must be such that allows easy and clear legibility	<u>Type Size</u> The type size and graphics used in all promotional material must be such that allows easy and clear legibility. Mandatory items must appear on screen for not less than 10 seconds unless the words are concurrently spoken at a clearly audible rate in a shorter time.

Appendix 7 - Checklist for Invitations to Company Sponsored Educational Meetings

Sections 6 and 10
Next page

WOMENS MENTAL HEALTH

Join us to hear from

Professor Kate Jones

Professor of Psychiatry
Giralang Hospital, Canberra

Education meeting topic -
should give information on
the educational
content/outcomes

Information on presenter -
title, position, expertise or
special interest

Professor Jones has specialised in Women's Mental Health with a special interest in areas of Post-Natal Depression and Premenstrual Dysphoric Disorder
The presentation will address treatment options for Post-Natal Depression
Chairperson: Dr Simone Smith (Deakin Hospital)

Date: Tuesday 26 October 2004

Venue: Lakeside Restaurant
2 Lake Street
Lakeside

Time: 6.45pm Registration (including pre dinner drinks)
7.15pm Opening Comments (followed by entrée)
7.30pm Presentation by Professor Jones
8.15pm Dinner followed by questions and discussion
9.30pm Close

Detail should indicate whether a meal is to be served, the duration of the educational component and an indication of the finishing time. Photos of venue or graphics of food/wine should not be included. Venue or hospitality should not be primary focus of the meeting

This activity has been approved by the RACGP QA&CPD Program.
Total points: 2 (Category 2)

Please reply by Tuesday 19 October 2004 to Heather or Pat
Phone: 02 6666 8888 or Fax on 02 6688 6688

Yes Thank you I would like to attend No Thank you I not b

Please note
correct wording for
the allocation of
points - please
check with
RACGP if unsure

Doctor's Name: _____

Surgery Address: _____

Phone No: _____ Fax No: _____

Special Meal Requests: _____

QA Number: _____

Please note: If your QA/CPD Number is not provided, you will not receive CPD points.

Company Name/Product Logo

If including any reference to partner costs please ensure that it reflects the full cost of the meal not a partner contribution with the company contributing to cover part of the cost.