

Code of Conduct

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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.

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

The format of these Guidelines is to present the text of the Section and its Explanatory Notes (in italics), then to provide guidance as to the section's interpretation and compliance with the section.

For convenience, the Sections dealing with PBS information disclosure have been grouped together. They set out the requirements for the provision of this information in various media.

Section 1.2 – Substantiating Data

Section

1.2 **Substantiating Data**

1.2.1 **Provision of Substantiating Data**

Further to the information supplied or generally available, a company will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets, including company information.

Data in support of a claim, including “data on file” or “in press” must be made available without delay upon reasonable request.

Where this material is not available through standard library services, it must be made available without delay.

1.2.2 **Level of Substantiating Data**

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

*Such substantiating information must not rely **solely** on data on file.*

Explanatory Notes

- 1.2.1 (a) *All data to substantiate claims must be easily retrievable so that they could be supplied on request within 10 working days.*
- (b) *Evaluated data* contained in an application for marketing in accordance with the current or previous Therapeutic Goods Administration guidelines for the registration of products may be used to substantiate claims. Such data must be made available when requested to substantiate a claim. A statement that the data are “Confidential” will not be accepted.*
- (c) *If the information on which a claim is based may not be released, eg an “in press” article which is subject to confidentiality provisions, then that information may not be used to substantiate a claim for the purposes of satisfying this section. Papers cited as “in press” must have been accepted for publication and be available as a final approved manuscript or in proof form. Papers submitted for publication and not yet accepted by a journal may be identified only as “unpublished data”, “personal communication”, “unrefereed data” or in similar terms.*
- (d) *Data relating to the cost effectiveness of a product may be used to substantiate promotional claims, however these data must conform with Sections 1.1, 1.2, 1.3, 1.5 and 1.7 of this Code.*
- 1.2.2 *In determining whether sufficient evidence is available to support a claim, companies should have regard to issues such as, but not limited to, the study design, the number of patients, the location of any trial or study, its primary purpose and end points, the results, the reputation and qualifications of the people involved*

in the study or trial, its consistency in the current body of evidence and where (eg peer reviewed journal or pay journal) or if it has been published.

For example, to satisfy the requirements of this section the evidence to support any major claim that will have a significant impact on the prescribing of a product, must be unequivocal and the highest quality. It should not rely upon evidence from sources such as poster presentations or abstracts that do not provide sufficient information to assess the veracity of the claim. Used appropriately these information sources may be used to support lesser or minor claims.

For further guidance regarding the application of this section please refer to the current Guidelines to the Code of Conduct.

Guidelines

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 health care 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 last 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, in general, 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 PI 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 ASCEPT and the other health care 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

Section

1.3 **False or Misleading Claims**

All information, claims and graphical representations provided to health care professionals and members of the general public must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

Claims must be referenced where there is a possibility that a reader may be misled if the source of the reference is not disclosed.

1.3.1 **Unapproved products and indications**

Products that have not been approved for registration by the Department of Health and Ageing must not be promoted. However, samples of unapproved products may be displayed and educational material made available at International Congresses* and Australasian Congresses in accordance with Section 6. This restriction also applies to unapproved indications for registered products.*

Explanatory Notes

1.3 *The majority of breaches of the Code found concern this section. The following are examples of situations where material may breach the Code. This list is not all inclusive and is based on the experience of the Code of Conduct Committee.*

- (a) *Literature references or quotations derived from a study or studies and citations of individual opinions which are significantly more favourable or unfavourable than has been demonstrated either within the study, or more likely from the body of clinical evidence or experience. It is unreasonable to cite the results of an excessively favourable (or excessively unfavourable to a comparative product) study in a manner which misleadingly suggests that those results are typical.*
- (b) *Information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions.*
- (c) *Citation of data previously valid but made obsolete or false by the evaluation of new data.*
- (d) *Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information not approved by the Commonwealth Department of Health and Ageing.*
- (e) *Shortening an approved indication (eg in a by-line) so as to remove a qualification or limitation to the indication.*
- (f) *Use of animal or laboratory data as sole evidence to support a promotional claim. It should be noted that if animal or laboratory data are used a prominent statement identifying this type of data and acknowledging that such data does not necessarily predict clinical effects must be made on the same page and within reasonable proximity to the data in a manner that is not obscured by other material.*
- (g) *Presentation of information in such a manner eg type size* and layout, which, to the casual reader could produce an incorrect perspective. The type size used for*

qualifying statements must not be less than 2mm. The qualifying statement must not be included with other reference material but must be situated on the same page as the original statement. The original statement and the qualifying statement must be linked by use of a readily identifiable asterisk or a similar symbol.

- (h) Statements made about a competitive product, particularly negative statements, not balanced with corresponding information about the product being promoted.*
- (i) Shortening the title of graphical representations reproduced from literature which alters the original author's meaning.*
- (j) Use of overseas Product Information to support a claim where that information is inconsistent with the Australian Approved Product Information.*
- (k) Literal or implied claims that a parameter, - contraindication, cautionary statement, adverse reaction or limitation on a claim in the Product Information, is not cause for concern.*
- (l) Lack of substantiation of claims not of a medical or scientific nature. It includes information or claims relating to marketing factors such as pricing and market share. Care should be taken when extrapolating prescribing practices from sales data.*

1.3.1 *Where a company has been formally advised by the Department of Health and Ageing that a product has been approved and its Product Information has been finalised, it is considered approved for registration for the purpose of this Code.*

Guidelines

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 health care professionals and members of the general public. This includes tag lines in promotional material provided to health care professionals.

To ensure that all material complies with this section, the following tests should be applied. All information provided to health care 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 this section 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 this section and Sections 1.1 and 1.2 also cover tag lines. 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

Section

1.7 **Comparative Statements**

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. “Hanging” comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc must not be used.

“Data on file” when used to substantiate comparative statements must comply with the requirement of Section 1.2.

Explanatory Notes

1.7 *Pharmaceutical advertising commonly contains comparisons with other products and such comparisons are usually made to show an advantage of the advertised product over its competitor(s). Provided that such comparisons with other products are factual, fair and can be substantiated, they are acceptable under the Code.*

The intention of this clause is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.

Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of Product Information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Australian as well as overseas Product Information documents.

Claims of comparative efficacy or safety should be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.

The accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used, such data must comply with the following conditions:

- the lack of significance must be stated explicitly; it is insufficient to state the p value*
- the data must not be used to generalise or to indicate superiority or inferiority*

The statement that the claim is not statistically significant needs to be linked in some manner to the original claim, made on the same page and within a reasonable proximity of the original claim in a manner that is not obscured by other material using a type size of not less than 2mm.

Care should be taken to distinguish between mathematically determined statistical significance on the one hand and clinical significance on the other.

Guidelines

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 health care 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.

Section 3.1.1 Primary Advertisements

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.

1. General Requirements:-

These requirements apply to advertisements and printed promotional material:

1. The PBS disclosure information should be contained within a text box that has a white background and is outlined in black.
2. 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.)
3. The text should appear in solid black with no half tones.
4. 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.
5. The text size should reasonably fill the text box with the minimum size to be not less than 2mm.
6. 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.

2. Wording

1. 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

2. 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.**

3. 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

4. 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

5. 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.**

6. 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**

3. Size

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

Primary Advertisements

1. 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”.

2. 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”.

3. 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".

Secondary and Short Advertisements

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

Reference Manual Advertising

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 health care professionals of the location of the PBS information within the Reference Manual.

Printed Promotional Material (Section 3.3.1)

The size requirements applying to full 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.

Medicines Australia has discussed compliance with this section of the Code with organisations such as Princeton Printers which are responsible for the printing of promotional documents such as medi-messages and has agreed upon the following requirements for these documents:

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.

If a desk calendar/wall planner contains a number of small items of printed promotional material a reference should be made to the PBS disclosure information in a similar manner to the medi-message pads or a reference to the PBS information which can be found elsewhere in the desk calendar eg. under the desk calendar flap. Medicines Australia has worked with organizations such as Princeton Publishers to identify how this disclosure should occur.

Audiovisual Promotional Material (Section 3.3.2)

Computer Based Promotional Material (Section 3.3.5)

Television Advertising (Section 3.4)

Advertising in Electronic Prescribing Software Packages (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 Commissioned Articles (Section 3.1.4)

Company commissioned articles that contain a reference to any specific product must comply with the PBS disclosure requirements of the Code and its Guidelines.

Congress Reports (Section 3.1.4)

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.

Medical Representatives (Section 4.8)

This section of the Code requires that medical 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 medical representative to

verbally advise a health care 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 minimize 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 10.3)

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 3.3.3 - Brand name reminders

Section

3.3.3.1 *Brand Name Reminders must include the following information:*

- (a) *The brand name of the product*
- (b) *The Australian Approved Name(s) of the active ingredient(s)*
- (c) *Where applicable, the notation “See Warning” or “See Boxed Warning” drawing attention to the boxed warning in the Product Information.*

Brand Name Reminders may also include:-

- (d) *a non-promotional logo, device or graph*
- (e) *a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the product*

3.3.3.2 *Brand Name Reminders are not to contain any promotional claims including promotional tag lines and or statements.*

3.3.3.3 *Brand Name Reminders will only be acceptable if it is possible to clearly and legibly display the product’s brand name. Where the nature of a Brand Name Reminder is such that it is demonstrably and obviously impractical to display the Australian Approved Name(s) of the active ingredient(s) as required in Section 3.3.3.1, the Brand Name Reminder must be accompanied by a document containing the information specified in Section 3.3.3.1.*

3.3.3.4 *Where the nature of a Brand Name Reminder is such that it is demonstrably and obviously impractical to display legibly the notation “See Warning” or “See Boxed Warning” as required in Section 3.3.3.1, a Brand Name Reminder must not be used for that product.*

Explanatory Notes

3.3.3 *An individual Brand Name Reminder should only be of token value, should not bring discredit to the industry and should be chosen on the basis that the item is clearly a Brand Name Reminder and not any other promotional material such as printed promotional material. The nature of any Brand Name Reminder or its packaging must not have the capacity to be confused with a therapeutic good.*

3.3.3.1 (b) *The Australian Approved Name should appear adjacent to the most prominent presentation of the trade name.*

Guidelines

A brand name reminder is an item of low monetary value which is intended to remind health care 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.

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

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

In a Code of Conduct complaint, a company argued that a tissue box which had promotional claims and the product information printed upon it was an item of printed promotional material rather than a brand name reminder and was therefore in breach of the Code. As this complaint was brought before amendments to the Code adopted in December 2002, this item was not found in breach of the Code. However, such items would be in breach of Edition 14 of the Code; tissue boxes are accepted as items used commonly as brand name reminders and should not be used as a printed promotional vehicle. In this complaint, concerns were also expressed that this tissue box containing promotional claims may have been viewed by members of the general public.

The section provides that brand name reminders must 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. Edition 14 of the Code introduces the possibility of including other information on a brand name reminder. It is now possible to include a non-promotional logo, device or graph and/or a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the product. If you choose to include these items on a brand name reminder their inclusion must not be promotional.

If a brand name reminder is not relevant to the working environment of a healthcare professional the value should not be greater than \$10.00 per item (exclusive of GST). The AUS \$10.00 limit per item is the cost to the company for the item. If the brand name reminder is relevant to the working environment of a healthcare professional the value should not be greater than \$20.00 per item (exclusive of GST). The AUS \$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."

Section 3.3.4 - Medical literature/reprints

Section

- 3.3.4.1** *The general interpretation and conclusions of any reprints of journal articles, proceedings of symposia* or summaries of literature used in promotion must be consistent with the Product Information for both:-*
- a) *the sponsor's products and*
 - b) *any competitor's products with which a comparison is being made.*
- 3.3.4.2** *Quotations from medical literature or from personal communications must accurately reflect the meaning of the author and significance of the study.*
- 3.3.4.3** *Any reports from congresses, symposia or other medical meetings, sponsored by a member of the pharmaceutical industry must be a balanced, true and accurate reflection of the findings of that meeting.*

Explanatory notes

- 3.3.4** *Healthcare professionals may request literature on subjects not covered by the Product Information such as non-approved indications. While it is not acceptable to routinely disseminate such literature where unsolicited, it is acceptable to provide such information on individual request, provided that the literature or accompanying communication clearly identifies that it refers to a product or indication not approved in Australia. If the product is approved in Australia it must be accompanied by the Australian Approved Product Information.*

Reprints themselves do not need to be accompanied by Product Information, but Product Information must be included with any accompanying material (eg letter) or presentation made which make promotional claims.

Quotations relating to medical products taken from public broadcasts or private occasions such as medical conferences or symposia, should not be reproduced without the written permission of the speaker unless subsequently published. Care should also be taken to avoid ascribing unpublished claims or views relating to prescription products to authors when such claims or views no longer represent, or may not represent, the current view of the author concerned.

- 3.3.4.3** *In addition to those reports prepared by a company, this section applies to reports prepared by individuals on behalf of companies*

Guidelines

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.tg.com.au/home/pol.html>.

Section 3.5 Mailings*

Section

- 3.5.1** *Mailings must comply with all relevant provisions of Section 1 of this Code and Australia's Privacy Legislation.*
- 3.5.2** *The Full Disclosure or Abridged disclosure Product Information as applicable must be included in all mailings where promotional claims are made.*
- 3.5.3** *The use of full disclosure Product Information is mandatory for promotion of all new chemical entities for 24 months from the date of first advertising, or longer at the discretion of the Company. Abridged disclosure Product Information may be used subsequent to that period.*
- 3.5.4** *Mailings should only be sent to those categories of health professionals that have indicated or can reasonably be assumed to have a need for, or interest in, the particular information. Requests by health care professionals to be removed from promotional mailing lists must be complied with promptly and no name restored except at specific request or with written permission.*
- 3.5.5** *Mailing lists should be kept up-to-date.*
- 3.5.6** *Exposed mailings including postcards, envelopes or wrappers must not carry matter which might be regarded as promotion to the general public or which could be considered unsuitable for public view.*
- 3.5.7** *Any accompanying material sent with a Mailing must comply with the requirements of the Code of Conduct as a stand-alone item.*
- 3.5.8** *All PBS listings, including any restrictions, as required in the preamble to Section 3 should be included in all mailings where product promotional claims are made.*

Explanatory notes

- 3.5.** *Statements on envelopes implying urgent attention should be restricted to matters relating to product recalls or important safety information.*

Envelopes should not be used for dispatch of promotional material if they bear words implying that the contents are non-promotional.

Unsolicited reprints of journal articles must be consistent with the Product Information, and any covering letter should comply with Section 1.
- 3.5.6** *The display of a product's brand name or Australian Approved Name alone on mailings directed towards health care professionals is not considered as promotion to the general public in this context.*
- 3.5.7** *For example a brand name reminder may be included with a mailing but must comply with the requirements of Section 3.3.3. as a stand-alone item in order to satisfy this Section.*
- 3.5.8** *See preamble to Section 3 and its Explanatory Notes.*

Guidelines

This section of the Code covers the requirements for promotional 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 3.7 - Competitions

Section

3.7.1 *Competitions must fulfil all of the following criteria:*

- (i) The competition is based entirely on medical knowledge or the acquisition of medical knowledge.*
- (ii) The prize is directly relevant to the practice of medicine or pharmacy.*
- (iii) Individual prizes offered are to be of low monetary value or be an item of educational material.*

3.7.2 *Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.*

3.7.3 *The conduct of competitions shall comply in all respects with relevant State and Federal regulations.*

Explanatory Notes

3.7 *The value of prizes permitted to be used in competitions is difficult to define and needs to be assessed on an individual basis. For further explanation regarding the application of this Section please refer to the current edition of the Guidelines to the Code of Conduct.*

Prizes which might be useful in the practice of medicine but are not specific to medicine or pharmacy must not be offered.

Guidelines

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 PI 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 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. With the availability of new technology the Committee has considered whether a PDA loaded with medical software satisfies the requirements for competition prizes. The Committee considered that a PDA with MIMS or other medical software would be directly relevant to the practice of medicine and would be a valuable clinical tool for doctors. The Committee considered that the PDA loaded with medical software may be considered an item of medical education and therefore comply with the provisions of the Code. Items such as a USB drive loaded with medical educational material may also be appropriate as a competition prize. Other items of computer or office equipment eg computers, fax machines; telephone systems or software updates do not comply with the provisions of the Code and must not be offered as competition prizes.

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.

The value of an individual prize should be no greater than **\$500 (exclusive of GST)**. The AUS \$500.00 limit per item is the cost to the company for the item. If a complaint is received in relation to the value of a competition prize, the company should be able to produce documentary evidence of the cost to the company. Where State or Territory laws require that a company include the recommended retail price on the competition entry form, it is recognised that this retail price could be over the \$500.00 limit per item.

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 maximum value of any educational item offered as a competition prize should be no more 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).

Section 3.8 – Gifts/Offers

Section

No items or offers shall be offered or given to healthcare professionals, their families or employees unless they are items or activities sanctioned by the following sections of this Code:-

- a) *Section 3.3.3 Brand Name Reminders,*
- b) *Section 3.7 Competitions,*
- c) *Section 6 Involvement in Educational Symposia, Congresses and Satellite Meetings*
- d) *Section 7 Sponsorship*
- e) *Section 10.2 Hospitality or*
- f) *Section 10.3 Medical Educational Material*

Explanatory Notes

- 3.8** *For further explanation regarding the application of this Section please refer to the current edition of the Guidelines to the Code of Conduct.*

Guidelines

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

- | | | |
|----|---------------|--|
| a) | Section 3.3.3 | Brand name reminder |
| b) | Section 3.7 | Prize for a complying competition |
| c) | Sections 6 | Involvement in Educational Symposia, Congresses and Satellite Meetings |
| d) | Section 7 | Sponsorship |
| e) | Section 10.2 | Hospitality; or |
| f) | Section 10.3 | 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 health care professionals.

Section 3.9 – The Use of the Internet for Pharmaceutical Information

Section

Medicines Australia supports the right of Companies to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner for the benefit of both patients and health care professionals. However, the promotion of products covered by the Code of Conduct to the general public via the Internet would breach Section 9.4 of the Code and various therapeutic goods legislation which stipulate that prescription medicines must not be promoted to the public.

An advertisement is defined as any statement which is intended (directly or indirectly) to promote the use or supply of a medicine. In providing information to members of the general public, companies must ensure that the intent of this action is informational and not promotional. Care needs to be taken by companies to ensure that material published is of the kind that it is reasonable to conclude that no intention of promotion exists.

The following provisions are applicable to information generated for use via Australian Internet sites.

3.9.1 Information available to the General Public

The purpose of this section is to identify how current, accurate and balanced information regarding prescription medicines available in Australia can be provided via this medium to members of the general public. The intent of the provision of this information must be educational and must never be promotional if it can be accessed by members of the general public.

The following information may be provided to members of the general public:-

3.9.1.1 *A brief non-promotional summary of the company's products available in Australia. This information should be current, accurate and balanced and must not be promotional. It must contain information about the product's precautions, adverse reactions, warnings and contraindications and interactions and may contain information about current research or clinical data that would assist members of the general public understand how this product works, its uses and compliance advice.*

All information provided to members of the general public about prescription medicines must be in accord with the product's current Approved Product Information.

3.9.1.2 *A copy of the product's Consumer Medicines Information (CMI). CMIs must appear in their entirety. They must not be amended, abridged or displayed in a promotional manner.*

3.9.1.3 *Reference or linkages to other reputable information sources that provide valuable educational material that would enhance a member of the general public's understanding of a disease area. When making such a reference or linkage a clear screen displaying the following statements must appear before the information can be accessed:-*

- that the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should refer to the CMI for products to fully understand the terms of a product's registration in Australia*
- that the intent of providing this material is informational and not as advice*

- any information provided by this source should be discussed with the reader's health care professional and does not replace their advice

3.9.2 Promotion to and the provision of Information to Health Care Professionals

3.9.2.1 *Promotional material on products covered by this Code must be accessible only to health care professionals.*

3.9.2.2 *Promotional information provided on the Internet to health care professionals must be accessible only via a secure system that is designed to prevent access by members of the general public.*

3.9.2.3 *Any promotional material provided to health care professionals via this medium must comply with the requirements of Sections 1 and 3 of the Code of Conduct.*

3.9.2.4 *Any references or linkages to other reputable information sources must be to sources which provide valuable educational material that would enhance the quality use of medicines in Australia. When making such a reference or linkage a clear screen displaying the following statement must appear before the reference material is accessed:-*

- *The information a reader is about to be referred to may not comply with the Australian regulatory requirements and that further information relevant to the Australian environment is available from the company or via the Approved Product Information.*

3.9.3 General

3.9.3.1 *Where an Internet site includes information regarding a product, the address and identity of the Company should be provided.*

3.9.3.2 *The intended audience should be readily apparent on the site.*

3.9.3.3 *It should be made clear when the reader is leaving the site or being directed to a site that the Company has not developed.*

3.9.3.4 *It is appropriate for Companies to link their sites to the text of the Code of Conduct on the Medicines Australia's website. Such a linkage must not be used to imply that Medicines Australia endorses any part of the content of the Company's site but to provide information to members of the general public and health care professionals on the Code of Conduct and the standards it sets.*

Explanatory Notes

3.9.1.1. *See Guidelines for examples of the application of this Section.*

3.9.1.3 *To determine whether an information source is appropriate companies must thoroughly and regularly review any information source and must be satisfied that it contains valuable educational material that can be readily understood by members of the general public and would enhance their knowledge of products available in Australia.*

3.9.2.3 *Where reference to other sources or Internet sites are made, Companies must take all reasonable steps to ensure that these information sources and Internet sites are appropriate and will enhance the appropriate prescribing, dispensing and usage of medicines in Australia.*

Guidelines

3.9.1 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 recognizes 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 3.9 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 3.9.1 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 health care 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.

3.9.2 Health Care Professionals

A company may wish to provide promotional and educational material to health care professionals via a website. If this site contains promotional material it must be a secure site that is designed to limit access to health care 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 health care 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 4 Medical Representatives

Section

- 4.4 Medical Representatives should at all times maintain a high standard of ethical conduct and professionalism in the discharge of their duties.*

- 4.9 Under no circumstances shall representatives pay a fee, in cash or kind, in order to gain access to a healthcare professional.*

Guidelines

One aspect of complying with this section of the Code is that medical representatives need to be aware of their environment when discussing prescription medicines. It may not be appropriate for a medical 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. Medical Representatives are encouraged to provide this information in an environment in which direct communication can be enjoyed with a health care professional.

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

Section 4.9 of Edition 14 of the Code of Conduct (which received authorisation from the ACCC in November 2003) 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 is 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. Whist 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.

Section 5.4 Supply of Starter Packs

Section 8.2 Product Familiarisation Programmes (PFP)

The maximum quantity of Starter Packs to be supplied to a medical practitioner, dentist or hospital pharmacist must be at these health care professional's discretion, should reflect their needs until the next visit by their representative and should conform to any relevant Federal or State regulations. The medical practitioner, dentist or hospital pharmacist must write the quantity requested and sign the request/receipt form as required by Federal and State Legislation.

Guidelines

The Code does not stipulate a maximum number of starter packs that can be provided to various health care professionals but does refer to the needs of those health care 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 health care 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 PI, 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.

Section 6 Involvement in Educational Symposia, Congresses and Satellite Meetings

General Principle

This section covers:-

- *Congresses which are events sponsored and organised by a society, college, university or other non-company entity,*
- *Symposia which are scientific meetings sponsored by a company as an independent event or as a satellite to a congress and*
- *Satellite meetings which are meetings held in conjunction with international or Australasian congresses and are under the auspices of the society, college or other non-company entity*

Educational meetings are important for the dissemination of knowledge and experience to health care professionals. Companies involved in these events must have the primary objective of the enhancement of medical knowledge and the quality use of medicines in Australia.

6.1 Trade Displays

- 6.1.1** *Trade Displays must be directed only to health care professionals.*
- 6.1.2** *A Trade Display must include, in a prominent position, the name of the sponsoring company.*
- 6.1.3** *Exhibitors must comply with all requirements of the sponsoring organisation when setting up and conducting a Trade Display.*
- 6.1.4** *Product Information for products being promoted must be available from the Trade Display stand.*
- 6.1.5** *Starter Packs must not be made available for collection from unattended Trade Display stands, nor be supplied to unauthorised or non-qualified persons.*
- 6.1.6** *Competitions that are held as part of a Trade Display must be consistent with the requirements of Section 3.7 of this Code.*
- 6.1.7** *All promotional materials used at Trade Displays must be consistent with the requirements of Sections 1.3.1 and 3.3 of this Code.*
- 6.1.8** *To encourage health care professionals to attend a Trade Display a Company may offer Brand Name Reminders (Section 3.3.3), involvement in complying competitions (Section 3.7), an item of Medical Educational Material (Section 10.2) or hospitality in accord with Section 6.2.*
- 6.1.9** *Any activities of a company in relation to its Trade Display must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste.*

6.2 Hospitality*

6.2.1 Any hospitality provided by Companies either directly or by sponsorship or assistance to the meeting organisers of educational meetings, must be secondary to the educational purpose

6.2.2 For Educational Meetings directly organised by, and the responsibility of companies, all hospitality must be simple and modest and no entertainment should be provided.

6.3 Behaviour

The behaviour of company representatives at Educational Meetings must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. The behaviour of company representative must be beyond reproach and must not bring discredit upon the industry.

6.4. Sponsorship or Involvement in Australasian Congresses

Companies may assist and make financial contributions to educational meetings organised by third parties and may sponsor the attendance of health care professionals at these meetings, if:-

- the primary objective of the meeting is the enhancement of medical knowledge and the quality use of medicines in Australia
- any assistance or sponsorship provided will be used for activities that further that objective, which would not bring discredit upon the industry and are able to successfully withstand public and professional and community scrutiny and conform to professional and community standards of ethics and good taste

6.5 Sponsorship of Health Care Professionals

The selection criteria for sponsorship to allow health care professionals to attend Educational Meetings must be based solely on their interest in the area of medicines being discussed and their ability to communicate any relevant information to Australian health care professionals to enhance the quality use of medicines.

6.6 Venue Selection

Educational Meetings organised by or the responsibility of companies must be held in venues suitable for the attainment of the primary objective of enhancing medical knowledge and the quality use of medicines in Australia. The choice of venue must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.

6.7 Reporting

Any reports generated from these meetings must comply with the requirements of Section 3.3.4.4.

6.8 Travel

The following applies to Companies sponsoring delegates travelling to, from and within Australia to symposia and/or congresses:

- Travel may be subsidised provided the meeting is directly related to the health care professional's area of expertise.
- Travel within Australia should be by Economy class unless there are circumstances where Business Class travel may be appropriate. For international travel, only Economy or Business class should be used.
- A reasonable level of accommodation expenses may be covered.
- Travel costs and expenses for family or travelling companion(s) must not be paid for or subsidised by the sponsoring Company.

Explanatory Notes

6. Refer to the current Code of Conduct Guidelines for assistance or contact Medicines Australia for advice.

- 6.1 All promotional material used at Trade Displays must be consistent with the requirements of Section 3.3.

In the case of international congresses held in Australia, it may be acceptable to display or supply educational material for a product not approved for registration in Australia or a non approved indication of a product registered in Australia, provided that any display material or educational material used clearly identifies that it refers to a product or indication not approved in Australia, and that the product or indication, as appropriate, is approved overseas.

An appropriately worded label, prominently located, would be sufficient to satisfy this Section. This label must state that the product or indication is unapproved in Australia.

In the case of Australasian congresses held in Australia, it is acceptable to display or supply educational material for products not approved for registration in Australia or a non approved indication of a product registered in Australia, if that product or indication has received registration or approval in New Zealand.

Information regarding products not approved for registration in Australia or non-approved indications of a product registered in Australia must be consistent with the approved Product Information in the country where the product is registered. Such Product Information must be available and distributed in accordance with this Code of Conduct.

Products not approved for registration in Australia must be approved for marketing in an overseas country from which there are delegates registered at the conference.

Please also refer to the Explanatory Note to Section 1.3.1 that discusses Australian unapproved products and indications.

- 6.1.2 Companies must ensure that any overseas affiliates sponsoring or involved in such meetings are made aware of and comply with the Code.

- 6.1.5 See also Section 5.

Starter Packs for products not approved for marketing in Australia must not be provided either at local or international congresses.

- 6.1.6 See also Section 3.7

- 6.1.8 Gifts, cash payments and/or donations to charities or societies must not be offered to health care professionals to visit Trade Display stands.

- 6.4 Companies may work with organisers and provide sponsorship to ensure third party educational meetings are a success and provide a forum for the dissemination of information that enhances the quality use of medicines. However companies should be fully cognisant of the activities that their sponsorship is supporting and must critically examine these activities to ensure they:-

- enhance medical knowledge,
- enhance the quality use of medicines

- do not bring discredit on the industry,
- could successfully withstand public, professional and community scrutiny
- conform to professional and community standards

Companies must critically examine any hospitality or entertainment provided at third party educational meetings to determine whether their involvement would meet the standards set by this Section. For example, a breach of this Section would be found if a company provided sponsorship for a lavish conference dinner that included significant entertainment even if the company was not involved in the planning or conduct of the event. A Company may however provide sponsorship for a modest conference dinner at which a medically related keynote address is given.

- 6.6** *Appropriate venues for congresses, symposia or press conferences would be conference centres or meeting facilities in city or suburban hotels or a country centre equivalent. The choice of venues in locations emphasising leisure and sporting facilities is prohibited.*

A venue for a company sponsored or organised meeting would be considered acceptable if held at the same or similar venue as the congress which is being organised by a society, college, university or other non-company entity. If challenged on the choice of a venue, it would be required that the Company substantiate this choice.

Companies considering whether to provide sponsorship for health care professionals to attend a third party meeting must critically examine the venue for the meeting to ensure it is an appropriate venue as defined by the Code.

For advice on the application of this Section please refer to the current Guidelines to the Code of Conduct.

- 6.8** *This provision covers the sponsorship of delegates as distinct from speakers at symposia and congresses.*

For advice on the application of this Section please refer to the current Guide to the Code of Conduct.

Guidelines

This section of the Code covers the behaviour of companies when they interact with health care 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 or prescription-like medicines.

This may result in OTC, diagnostic and device representatives being able to see health care 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 health care professionals by a number of means including the holding of educational meetings, the sponsorship of such meetings or the involvement in educational meetings.

The following information provides an insight into the discussions of various Medicines Australia working groups that have been responsible for revisions to Section 6 contained in the 14th Edition of the Code. This discussion is intended to assist companies regarding how they can comply with the requirements of this section.

It should be noted that Section 6 applies specifically to members of the health care professions. It is not intended to apply to health care professionals that have a direct relationship with companies via arrangements such as membership of advisory boards or who are undertaking activities on behalf of the company such as research projects or clinical trials. However the general principles contained in the preamble to Section 10 of the Code would apply to all dealings with health care professionals.

Trade Displays

This section of the Code recognises the ability of companies to provide or display educational 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 educational 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 Australasian congresses, it is also possible to display or supply educational 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 listed 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 health care professionals. This could be done in a separate document that compares the two PIs 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 health care 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.

Hospitality

If a company is holding its own educational meeting it should ensure that any hospitality that is offered is simple and modest. 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. For example, open sandwiches, rolls and quiches would be appropriate for lunch. Lavish hospitality such as lobster and caviar would not be appropriate.

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. However, guidance should also be provided to representatives regarding to 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 health care 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 non-controversial entertainment such as a string quartet.

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 Health Care Professionals

This section applies when companies sponsor health care professionals to attend either domestic or international educational meetings. The choice of a health care 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 health care professional colleagues of the information they acquire at these meetings.

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.

Travel

The Code sets out the appropriate levels of travel that should be offered to health care professionals when they are being sponsored to attend an educational meeting. This provision does not apply to educational speakers who are commonly covered by other contractual arrangements.

It is possible to subsidise the cost of travel to educational 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 health care professionals, but should not be extravagant and they must be able to withstand community scrutiny.

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 health care professional at the company's expense. Companions and family members are welcome to join health care 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 health care 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 7 Sponsorship

Section

The Code of Conduct recognises the significant contribution of the pharmaceutical industry to the quality use of medicines in Australia through sponsorship of health care professional organisations and activities involving health care professionals.

The provisions of this Section cover the sponsorship of any activities involving health care professionals by a company, including the attendance at international scientific and educational meetings.

- 7.1.1** *Where Companies undertake the sponsorship of any health care professional activity such support must:-*
- *be able to successfully withstand public and professional scrutiny,*
 - *conform to professional and community standards of ethics and good taste; and*
 - *enhance the quality use of medicines*
- 7.1.2** *No sponsorship should be conditional upon any obligation to prescribe a particular product. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional's prescribing or dispensing practices.*
- 7.1.3** *Clear guidelines for the awarding of sponsorship must be developed and which are capable of being publicly disclosed if required. These guidelines must reflect the requirements of Section 7.1.1.*
- 7.1.4** *Sponsorship of educational meetings and sponsorship of health care professionals to attend these meetings must comply with the requirements of Section 6.*

Explanatory Notes

- 7.** *Companies must be fully aware of the activities that any sponsorship will support and be satisfied that they meet the standards established in this section. Sponsorship must not be used to avoid the requirements of Section 6, 7 and 10.*

Sponsorship can be provided to organisations that support cultural, educational, philanthropic, sporting and artistic activities or charities but companies must ensure that this association is not undertaken for promotional reasons or used for promotional purposes.

Guidelines

This section of the Code recognises the valuable contribution the pharmaceutical industry makes to the health care 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 health care professional activity, the sponsorship must:

- Be able to successfully withstand public and professional 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 health care professional's prescribing or dispensing practices.

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 health care 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 amendments to Edition 14 of the Code of Conduct are not designed to prohibit the sponsorship of charitable or philanthropic events as identified in the Explanatory Notes to Section 7. 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 health care professions as this would contravene the requirement of the Code that prohibits the provision of entertainment to health care 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 health care professionals. If, however, the entertainment was modest and there was a bona fide educational component to the dinner it might be acceptable to invite health care 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 8.3 Market Research

Section

The sole purpose of these activities must be to collect data and not a means to promote to and/or reward healthcare professionals

- 8.3.1. Market Research studies must be clearly identified as such when the initial approach is made.*
- 8.3.2. Any payment must be kept to a minimum and should not exceed a level commensurate with the work involved.*
- 8.3.3. Promotion should not be represented as Market Research or research of any type.*
- 8.3.4 Market Research should not be able to be confused with a competition and should be a genuine initiative to collect relevant and useful information to enhance the quality use of medicines.*

Explanatory Notes

- 8. This section does not apply to evaluations being carried out under the approval of the Drug Committees in hospitals.*

When selecting individuals or organisations to undertake any research activities companies may wish to refer to the Market Research Society of Australia - Code of Professional Behaviour.

Guidelines

An amendment to Section 8.3 has been made in Edition 14 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

See also Section 3.7 dealing with competitions.

Section 9.2 – Product Specific Media Statements

Section

9.2.1 *The purpose of a media releases is to provide current, accurate and balanced information about medicines available in Australia and therefore must include information about the product's precautions, adverse reactions, warnings, contraindications and interactions. The intent of such media releases must be educational and not to promote particular treatments to the general public.*

A media release issued directly, or through conferences for the lay media to announce a new product or major indication approval to the public, will be allowed if the product has been registered for use in Australia and the medical profession has been supplied with the appropriate information.

The media release may include the product's trade name, the Australian Approved Name of the product, its approved indications, therapeutic class, launch date and a balanced and accurate discussion of the product's method of action.

The media release must indicate any PBS listings and restrictions or a notation if the product is not listed on the PBS. It must also be accompanied by a copy of the product's current Consumer Medicine Information or the direct website of information.

The media release must be in language that reflects current community standards and must not include any material that could be considered promotional or comparisons with other products.

9.2.2 *No other media releases relating to a specific medicine are permitted however it is acceptable to respond to both media inquiries and inquiries from members of the general public.*

9.2.3 *Media releases should not be accompanied by any material which encourages or is designed to encourage the use of any prescription medicines. Its purpose should be solely educational and informative.*

9.2.4 *Companies are always responsible for all material prepared for the media by the agencies engaged by them.*

Explanatory Notes

9.2 *Companies are encouraged to seek the advice of the Medicines Australia Chief Executive Officer or delegate prior to arranging press statements or media conferences.*

Companies should ensure that any sponsored experts be fully briefed on the provisions of the Code where it may be expected that the expert may have direct contact with the general public or lay media.

No statements or comments should be initiated by a company regarding any products that are not approved for marketing in Australia but are available in overseas countries.

This provision does not restrict companies from responding to key international developments such as landmark clinical trials but any response must be current, accurate

and balanced and must not be promotional. The intent of this communication must be educational.

9.2.2 *Companies must ensure that their response to any public inquiry should not be promotional.*

9.2.4 *Conduct by agencies engaged by Companies in relation to media releases and product launches will always be treated as conduct authorised by the Company.*

Guidelines

As with Section 3.9 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.

Section 9.8 Discredit to, and Reduction of, Confidence in, the Industry

Activities with, or materials provided to members of the general public must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. Such activities would be seen as a Severe Breach of the Code of Conduct.

Section 10.5 Discredit to, and Reduction of, Confidence in, the Industry

Activities engaged in by Companies with health care professionals or materials provided to health care professionals must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. A breach of this requirement is a Severe Breach of the Code of Conduct.

Explanatory Notes

10.5 *Examples of activities that would be seen to bring the industry into disrepute could include*

- *activities such the provision of personal services or products to gain access to health care professionals*
- *activities where no medical education is delivered and an inducement such as a meal is offered for attendance*

For other examples please refer to the Guidelines to the Code of Conduct.

Guidelines

These two sections are new to Edition 14 of the Code.

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 health care professionals, e.g. car washes, facials, etc.
- “Educational” meetings that have hospitality as their primary purpose
- Providing entertainment to health care 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 health care professionals
- The provision of promotional material to members of the general public
- Financial inducements to health care 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

Section

Companies may choose to support, initiate or become involved in activities with healthcare professionals. Such involvement either by financial or other means must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and of good taste.

Financial or material benefits must not be offered to healthcare professionals to influence them in their prescribing or dispensing of pharmaceutical products.

Interactions with health care professionals must have the primary objective of enhancing medical knowledge and the quality use of medicines in Australia.

This section is relevant to, but is not limited to, activities such as independent educational meetings organised by medical representatives or companies.

10.1 Entertainment*

Interactions between Companies and health care professional must not include entertainment.

An exception to this requirement is that educational meetings of two or more days duration may include a modest opportunity for unstructured and individual recreational activities at the delegate's own expense.

10.2 Hospitality

Any hospitality offered by Companies to health care professionals should be simple, modest, secondary to the educational content and provided in an environment that enhances education and learning. The venue and location at which a company provides hospitality to health care professionals must be conducive to education and learning and must not be chosen for its leisure or recreational facilities.

A Company must not subsidise or pay for the costs of family or companions of attendees at educational meetings.

Explanatory Notes

- 10.1** *In relation to Educational meetings of two or more days' duration, Companies may provide a period of time for unstructured, individual sporting or recreational activities at the delegates own expense. This period of time should be no longer than a half day. This period of time should not be the focal point of the educational meeting and should not be promoted as the primary focus of the meeting.*

The organising of educational meetings to coincide with any recreational events or entertainment would be a breach of this section. The primary purpose and reasons for attendance for any interaction with health care professionals is to increase medical knowledge and enhance the quality use of medicines in Australia.

- 10.2** *The choice of venues in locations emphasising leisure and sporting facilities is prohibited. The choice of venues primarily used for sporting, cultural or artistic activities should be carefully scrutinised to ensure no entertainment is being provided either directly or indirectly.*

Meals or any other hospitality provided by companies at an educational meeting should not differ to that expected at any professional business meeting and should reflect the professional standing of the audience. Examples of activities that would be seen as acceptable include:-

- *Medical education in conjunction with a simple lunch meeting in a surgery at which the catering could include the provision of sandwiches or takeaway food or what the health care professional would normally consume at a working lunch*
- *Medical education given in conjunction with a meal outside a practice consistent with the quality expected by a professional attending a business meeting.*

In relation to companions and family members it is unacceptable for a Company to pay for, subsidise or reimburse a health care professional for any costs, including but not limited to:

- *Travel costs to and from any meeting*
- *Their accommodation costs at the meeting; or*
- *Any meals or hospitality they may consume at the meeting*

Guidelines

This section utilises the same tests seen in Section 6 and 7 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 health care 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

Entertainment

A primary restriction of this section is that no entertainment should be provided to health care 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 health care 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 health care 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 organize rounds of golf for the participating health care professionals. The organisation of the golf should not be the

responsibility of the company and the company should not sponsor or subsidise the costs.

Hospitality

If during any interactions with health care professionals, such as a surgery meeting by a medical representative, hospitality is offered, it must be simple and modest and secondary to the educational intent of the meeting. 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 simple and modest and at the level of a normal business meeting.

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 health care 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.

If necessary, medical representatives can provide hospitality for surgery meetings but it should be simple and modest. As a general rule the type of hospitality seen at business functions should be used. Sandwiches and quiches are therefore appropriate for these types of meetings. The provision of lavish catering, such as seafood platters, is not appropriate.

Section 12.3 Abuse of the Code

Section

If, in the Code of Conduct Committee's view, a complaint by a company is considered frivolous or vexatious the Committee may request the complainant company to show cause why the Committee should not impose a fine of a maximum of \$200,000 for abuse of the Code of Conduct.

Explanatory Notes

12.3 *A Company may be found to breach this Section if a single complaint is considered to be frivolous or vexatious or, following a series of complaints against a single or number of competitors within a therapeutic class by a single complainant.*

A complaint or series of complaints may be found to be frivolous or vexatious regardless of whether or not the complaint or complaints are sustained.

For further information regarding the application of this section please refer to the Guidelines to the Code of Conduct.

Guidelines

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.