

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 only been tested in the Australian courts 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 i.e. 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 sanction companies encouraging 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 medicines could be considered as promoting that product to members of the general public. 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 informational and not as 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 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.

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 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

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.

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 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.

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.

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.

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 be able to withstand community scrutiny.

The 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 accommodation costs if the accommodation 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 professionals scrutiny
- Conform to professional and community standards of ethics and good taste and
- Enhance the quality use of medicines.

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

Companies must ensure that there are no obligations to prescribe a product based on the sponsorship and that nothing should be offered or provided which would interfere with the independence of a 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 substantial sponsorship of philanthropic, cultural, educational, sporting and artistic activities or charities.

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 that they are 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 the work being undertaken. It is not appropriate to substitute this remuneration via a chance to win a prize.

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 information need of members of the general public regarding prescription medicines and the requirement for the industry to meet those needs in a responsible and appropriate manner. Section 9.2 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 only been tested in the Australian courts 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 as their primary purpose hospitality
- 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 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. It should also be held in a venue and location which would enhance this educational purpose.

"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, 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.

