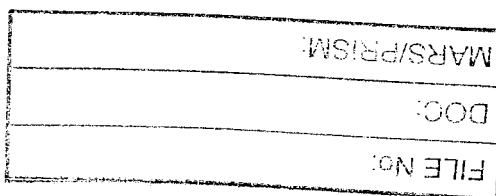


30 November 2005

Mr Scott Gregson  
General Manager, Adjudication  
Australian Competition and  
Consumer Commission  
470 Northbourne Avenue  
Dickson ACT 2602



ABN 47 702 595 758  
The Chifley Tower  
2 Chifley Square  
Sydney NSW 2000  
Australia  
Tel 61 2 9230 4000  
Fax 61 2 9230 5333  
Correspondence  
GPO Box 50  
Sydney NSW 2001  
DX 105 Sydney  
www.aar.com.au

Dear Mr Gregson

### Medicines Australia Code of Conduct - application for authorisation

We enclose, on behalf of Medicines Australia, an application for revocation of the authorisation in respect of Edition 14 of Medicines Australia's Code of Conduct and substitution of a replacement authorisation in respect of Edition 15 of the Code of Conduct (**the Code**) under s91C, s88(1), s88(8) and s 88(8AA) of the Trade Practices Act 1974 (Cth) (**the TPA**).

Medicines Australia requests that authorisation be granted for a period of 5 years.

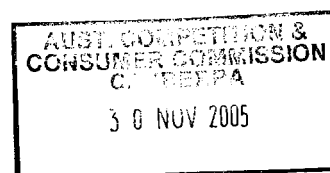
#### 1. Documents enclosed

We enclose the following documents in support of the application:

- completed Forms A, B and E;
- submission accompanying the application for revocation and substitution of the authorisation;
- enclosures to the submission as follows:
  - Annexure 1 – final draft of Edition 15 of the Code including the Explanatory Notes. A copy of the final form of Edition 15 will be forwarded to the Commission once it has been adopted by a special resolution of the Medicines Australia members, which is scheduled to occur on 6 December 2005;
  - Annexure 2 – Therapeutic Goods Administration's Marketing Approval Letter;
  - Annexure 3 – Background to the establishment of the Joint Therapeutics Agency of Australia and New Zealand;
  - Annexure 4 – Recommendation 12 of the Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review);

Our Ref CYOS: EXMS:201287744

exms S0111632096v2 201287744 30.11.2005



Sydney  
Melbourne  
Brisbane  
Perth  
Port Moresby  
Singapore  
Hong Kong  
Jakarta  
Shanghai  
Bangkok  
Phnom Penh

- Annexure 5 – a list of stakeholders consulted in relation to Recommendation 12 of the Galbally Review; and
- Annexure 6 – Medicines Australia Code of Conduct Guidelines to be read in conjunction with Edition 15 of the Code.

## 2. Interim authorisation

Medicines Australia also requests that the Commission grant interim authorisation so that Edition 15 can be implemented with effect from 1 January 2006. There are a number of reasons why Medicines Australia is keen for Edition 15 to be implemented on 1 January 2006, as set out below.

### (a) Review provisions and stakeholder consultation

The Code provides that Medicines Australia will carry out a review of the provisions of the Code of Conduct after seeking input from interested parties no later than every three years. As the Commission is aware, Edition 14 of the Code came into effect three years ago on 1 January 2003. Medicines Australia commenced its review of Edition 14 in January 2005. There has been extensive consultation in relation to the proposed amendments to the Code which will be included in Edition 15.

During the consultation process all major healthcare professional organisations were consulted on the content of the Code and possible new areas that should be encompassed. Medicines Australia directly invited written submissions to the Review of the Code of Conduct from the following stakeholders:

- Australian Medical Association (AMA)
- Royal Australian College of General Practitioners (RACGP)
- Australian Divisions of General Practice (ADGP)
- Royal Australasian College of Physicians (RACP)
- National Prescribing Service (NPS)
- Consumers' Health Forum of Australia (CHF)
- Therapeutic Goods Administration
- Pharmaceutical Benefits Branch of the Department of Health and Ageing
- Medical Publishers Association
- Advertising Federation of Australia
- Pharmaceutical Health and Rational Use of Medicines Committee
- Australian Pharmaceutical Advisory Council
- The Pharmacy Guild of Australia
- The Pharmaceutical Society of Australia
- Society of Hospital Pharmacists of Australia
- Generic Medicines Industry Association (GMiA)

- Medicines Australia membership
- Non-member companies (Alphapharm, AMRAD (now part of MSD), Arrow, Aspen, Baxter, Biochemie, Dentsply, Ferring, FH Faulding, Galderma, GenPharm, GenRx, Genzyme, Mayne, NovoNordisk (which recently applied for membership), Servier and Sigma. Some of these companies provided written responses and others attended seminars organised by Medicines Australia as described below).

In addition, Medicines Australia representatives offered face to face meetings with the major stakeholders to expand upon any comments made in written submissions, or simply to elicit comments.

All comments were considered by a Review Panel of 16 member company representatives, which was chaired by Medicines Australia Vice-Chairman, Ms Erica Mann.

Medicines Australia also conducted seminars in July 2005 to discuss the proposed amendments with member and non-member companies and again in October 2005 to communicate the final proposed changes. The latter seminars also included advertising agencies that provide services to the industry. In view of the large number of stakeholders consulted, the final draft of the Code was only prepared in November 2005.

**(b) Advertising cycles**

A number of amendments that have been included in Edition 15 impose additional requirements on companies in relation to the content of advertisements and promotional materials. Advertising cycles are typically planned on an annual basis within the industry, from the beginning of January to the end of December. Consequently, members have already had to begin preparing advertisements for the 2006 year in contemplation that the amended provisions of the Code will be in effect.

**(c) Amendments to regulation of starter packs**

Section 5 of Edition 15 has been extensively revised and expanded as a result of industry and stakeholder consultation and negotiation with the National Coordinating Committee on Therapeutic Goods following the Galbally Review. Recommendation 12 of the Galbally Review, which was supported by Medicines Australia, required that the States and Territories repeal provisions relating to the supply of samples of medicines and poisons within their drugs, poisons and controlled substances legislation and that APMA (now Medicines Australia) amend the Code to include standards for clinical samples (known as Starter Packs) with respect to certain matters, as set out in further detail in the attached submission.

As a consequence of the Galbally Review, and as a result of the agreement on changes to the Code, the States' and Territories' legislation relating to Starter Packs will be repealed by 1 July 2006. This will bring to an end the current significant differences that exist between States and Territories regarding their requirements for the supply of Starter Packs. The relevant requirements have been incorporated in Section 5 of the Medicines Australia Code of Conduct.

Medicines Australia's members will need sufficient time to implement changes to their internal procedures to comply with the revised provisions of the Code when the States' and Territories' legislation is repealed over the course of the next few months.

**(d) Establishment of the Joint Therapeutics Agency of Australia and New Zealand**

As the Commission will be aware, it is proposed that the TGA is to be replaced in mid 2006 by the Joint Therapeutics Agency of Australia and New Zealand (***Joint Therapeutics Agency***). The background to this is set out in Annexure 3 in the attached submission.

Whilst it is proposed under the new Therapeutic Products Advertising Code that advertising of prescription medicines to consumers will be permitted in New Zealand, direct to consumer advertising of prescription medicines will continue to be prohibited in Australia, both through the Joint Therapeutics Agency Rules and the Medicines Australia Code.

Edition 15 of the Code will include the three Advertising Principles from the new Therapeutic Products Advertising Code in the Preamble. Section 11.6 of the Code allows for the referral of complaints between Medicines Australia and the Central Complaints Panel to be established under the Therapeutic Products Advertising Code, as described in that Code.

The Code also includes provisions for the hearing of complaints about the conduct of non-members. If a non-member refuses to have the matter considered by the Medicines Australia Code of Conduct Committee, Medicines Australia reserves the right to refer such matters to the TGA, the Joint Therapeutics Agency (once it is established) and/or the Commission.

The Joint Therapeutics Agency will formally endorse all of the industry codes that are operating at the time of its formation. These codes will become part of the infrastructure for self-regulation and the management of complaints. The Medicines Australia Code is being used as a benchmark code for all sectors of the industry. Accordingly, it is important that the Code which is endorsed by the Joint Therapeutics Agency is Edition 15, the most up to date version of the Code which has undergone extensive industry consultation over the last year, as described in detail above.

As with the new provisions in section 5 of the Code, discussed above, Medicines Australia's members will need sufficient time to implement changes to their internal procedures to comply with the new legislation and Therapeutic Products Advertising Code in advance of the legislation coming into effect in mid-2006.

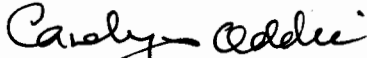
**(e) Amendments as a result of complaints made to the Code of Conduct Committee**

A number of other amendments have been included in Edition 15 as a result of complaints made to the Code of Conduct Committee and submissions received in the course of the review of the Code. Medicines Australia believes it is appropriate that these amendments are implemented as soon as possible to enhance compliance with the objectives of the Code. The objectives include that companies' activities have the primary objective of enhancing medical knowledge and ensuring quality use of medicines in Australia and should be such that they are able to withstand both public and professional scrutiny, and conform to professional and community standards of ethics and good taste.

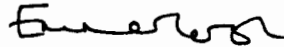
Representatives of Medicines Australia would welcome the opportunity to meet with the Commission to discuss the application for interim authorisation and any queries the Commission has in relation to the provisions of Edition 15 of the Code.

If you require any further information regarding any aspect of the application, please contact Carolyn Oddie or Emma Marsh on the numbers below.

Yours sincerely



**Carolyn Oddie**  
Partner  
Carolyn.Oddie@aar.com.au  
Tel 61 2 9230 4203



**Emma Marsh**  
Senior Associate  
Emma.Marsh@aar.com.au  
Tel 61 2 9230 4136

---

Form A  
Commonwealth of Australia  
*Trade Practices Act 1974 - Subsection 88(1)*  
Exclusionary Provisions:  
Application for Authorisation

To the Australian Competition and Consumer Commission:

Application is hereby made under subsection 88(1) of the *Trade Practices Act 1974* for an authorisation under that subsection

- to make a contract or arrangement, or arrive at an understanding, where a provision of the proposed contract, arrangement or understanding would be, or might be, an exclusionary provision within the meaning of section 45 of that Act
- to give effect to a provision of a contract, arrangement or understanding where the provision is or may be an exclusionary provision within the meaning of section 45 of that Act.

1.
  - (a) **Name of applicant**  
Medicines Australia Inc.
  - (b) **Short description of business carried on by applicant**  
Industry body representing prescription pharmaceutical suppliers in Australia
  - (c) **Address in Australia for service of documents on the applicant**  
Allens Arthur Robinson, GPO Box 50, Sydney NSW 2001
2.
  - (a) **Brief description of contract, arrangement or understanding and, where already made, its date**  
Medicines Australia Code of Conduct 15<sup>th</sup> edition
  - (b) **Brief description of those provisions of the contract arrangement or understanding that are, or would or might be, exclusionary provisions**  
See submission accompanying application
  - (c) **Names and addresses of other parties or proposed parties to contract, arrangement or understanding**  
Current and future members of Medicines Australia Inc.

- 
3. **Names and addresses (where known) of parties and other persons on whose behalf application is made**

Current and future members of Medicines Australia Inc.

---

4. (a) **Grounds for grant of authorisation**

See submission accompanying application

---

- (b) **Fact and contentions relied upon in support of those grounds**

See submission accompanying application

---

5. **This application for authorisation may be expressed to be made also in relation to other contracts, arrangements or understandings or proposed contracts, arrangements or understandings, that are or will be in similar terms to the abovementioned contract, arrangement or understanding**

- (a) **Is this application to be so expressed?**

No

---

- (b) **If so, the following information is to be furnished:**

- (i) **the names of the parties to each other contract, arrangement or understanding**
- 

- (ii) **the names of the parties to each other proposed contract, arrangement or understanding which names are known at the date of this application**
- 

6. (a) **Does this application deal with a matter relating to a joint venture?**

No

---

- (b) **If so, are any other applications being made simultaneously with this application in relation to that joint venture?**
- 

- (c) **If so, by whom or on whose behalf are those other applications being made?**
-

---

**7. Name and address of person authorised by the applicant to provide additional information in relation to this application**

Carolyn Oddie

Allens Arthur Robinson


GPO Box 50

Sydney NSW 2001

---

Date: 30 November 2005.

Signed ~~by~~ on behalf of the applicant

  
(Signature)

---

Carolyn Oddie

Solicitor for the applicant

---

Form B  
Commonwealth of Australia  
*Trade Practices Act 1974* - Subsection 88(1)  
Agreements Affecting Competition:  
Application for Authorisation

To the Australian Competition and Consumer Commission:

Application is hereby made under subsection 88(1) of the *Trade Practices Act 1974* for an authorisation under that subsection

- to make a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of that Act
- to give effect to a provision of a contract, arrangement or understanding which provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45 of that Act.

1. (a) **Name of applicant**

Medicines Australia Inc.

(b) **Short description of business carried on by applicant**

Industry body representing prescription pharmaceutical suppliers in Australia

(c) **Address in Australia for service of documents on the applicant**

Allens Arthur Robinson, GPO Box 50, Sydney NSW 2001

2. (a) **Brief description of contract, arrangement or understanding and, where already made, its date**

Medicines Australia Code of Conduct 15<sup>th</sup> edition

(b) **Names and addresses of other parties or proposed parties to contract, arrangement or understanding**

Current and future members of Medicines Australia Inc.

3. **Names and addresses (where known) of parties and other persons on whose behalf application is made**

Current and future members of Medicines Australia Inc.

4. (a) **Grounds for grant of authorisation**

See submission accompanying application

---

**(b) Facts and contentions relied upon in support of those grounds**

See submission accompanying authorisation

---

5. **This application for authorisation may be expressed to be made also in relation to other contracts, arrangements or understandings or proposed contracts, arrangements or understandings, that are or will be in similar terms to the abovementioned contract, arrangement or understanding.**

**(a) Is this application to be so expressed?**

No

---

**(b) If so, the following information is to be furnished:**

**(i) the names of the parties to each other contract, arrangement or understanding**

---

**(ii) the names of the parties to each other proposed contract, arrangement or understanding which names are known at the date of this application**

---

6. **(a) Does this application deal with a matter relating to a joint venture?**

No

---

- (b) If so, are any other applications being made simultaneously with this application in relation to that joint venture?**
- 

- (c) If so, by whom or on whose behalf are those other applications being made?**
- 

7. **Name and address of person authorised by the applicant to provide additional information in relation to this application**

Carolyn Oddie

Allens Arthur Robinson

GPO Box 50

Sydney NSW 2001

---

---

Date: 30 November 2005.

Signed ~~by~~ on behalf of the applicant

*C. Oddie*

(Signature)

---

Carolyn Oddie

Solicitor for the applicant

---

**Form E**  
**Commonwealth of Australia**  
***Trade Practices Act 1974* - Subsection 88(8)**  
**Exclusive dealing:**  
**Application for Authorisation**

To the Australian Competition and Consumer Commission:

Application is hereby made under subsection 88(8) of the *Trade Practices Act 1974* for an authorisation under that subsection to engage in conduct that constitutes or may constitute the practice of exclusive dealing.

**1. (a) Name of applicant**

Medicines Australia Inc.

**(b) Short description of business carried on by applicant**

Industry body representing prescription pharmaceutical suppliers in Australia

**(c) Address in Australia for service of documents on the applicant**

Allens Arthur Robinson, GPO Box 50, Sydney NSW 2001

**2. (a) Description of the goods or services in relation to the supply or acquisition of which this application relates**

See submission accompanying application

**(b) Description of the conduct that would or may constitute the practice of exclusive dealing**

Requirement of participation of certain persons in the education program endorsed by Medicines Australia Inc. from time to time as described in the submission accompanying the application

**3. (a) Class or classes of persons to which the conduct relates**

See submission accompanying application

**(b) Number of those persons**

**(i) At present time**

More than 50

**(ii) Estimated within the next year**

More than 50

- 
- (c) Where number of persons stated in item 3 (b)(i) is less than 50, their names and addresses

---

4. (a) Grounds for grant of authorisation

See submission accompanying application

---

(b) Facts and contentions relied upon in support of those grounds

See submission accompanying authorisation

---

5. (a) Does this application deal with a matter relating to a joint venture?

No

---

(b) If so, are any other applications being made simultaneously with this application in relation to that joint venture?

---

(c) If so, by whom or on whose behalf are those other applications being made?

---

6. Name and address of person authorised by the applicant to provide additional information in relation to this application

Carolyn Oddie

Allens Arthur Robinson

GPO Box 50

Sydney NSW 2001

---

Date: 30 November 2005.

Signed ~~by~~ on behalf of the applicant



(Signature)

---

Carolyn Oddie

Solicitor for the applicant



# Medicines Australia

## Submission accompanying application for authorisation of the 15th edition of the Medicines Australia Code of Conduct

### 30 November 2005

#### 1. Submission

Medicines Australia (**MA**) provides this submission in support of its application for revocation of the authorisation in respect of Edition 14 of the Code of Conduct and substitution of a replacement authorisation in respect of Edition 15 of the Code of Conduct (**the Code**) under s91C, s88(1), s88(8) and s88(8AA) of the Trade Practices Act 1974 (Cth) (**the TPA**). A copy of the final draft of Edition 15 of the Code is enclosed at Annexure 1. A copy of the final form of Edition 15 will be forwarded to the Commission once it has been adopted by a special resolution of the Medicines Australia members, which is scheduled to occur on 6 December 2005.

Edition 15 of the Code of Conduct includes some amendments as discussed in further detail below. The Code of Conduct sets the appropriate standard for the promotion of prescription medicines in Australia and the relationship between the industry and the general public. Representatives of MA would be pleased to meet with the Commission if required to discuss the authorisation application and the contents of this submission.

#### 2. Background to the application

As the Commission is aware, the Code of Conduct of the then Australian Pharmaceutical Manufacturers Association Inc (**APMA**) was first published in 1960 and since then it has been revised on a regular basis. In February 2001, APMA applied for revocation of Clearance C23698 and authorisation of the Code (since the Code had previously been the subject of an authorisation in 1977). This application and supporting submission was followed by a supplementary submission in September 2001. At that time, the Code was in its 13th edition, which had been adopted on 5 September 2000.

Edition 14 of the Code was adopted on 3 December 2002. MA requested that the Commission suspend its consideration of the 13th edition of the Code and substitute for that application an amended application for authorisation of the Code and the accompanying Explanatory Notes. The final determination in respect of Edition 14 of the Code was granted on 14 November 2003.

The Code sets out standards of conduct for marketing of prescription products to health professionals and the relationship between the industry and members of the general public. The purpose of the Code is to protect consumers and to maintain high ethical standards in the marketing of prescription products. As such, the Code complements and reinforces:

- the provisions in the Therapeutic Goods Act 1989 (Cth) (**TGAct**) including, in particular, the prohibition on the direct advertising of prescription products to members of the public; and
- the prohibitions on misleading and deceptive conduct and making false representations in ss52 and 53 of the TPA.

### 3. Terms of substitute authorisation sought

---

Application is made under ss88(1), 88(8), 88(8AA) and 91C of the TPA, as appropriate, for a substitute authorisation:

- to make a contract or arrangement, or arrive at an understanding, where a provision of the proposed contract, arrangement or understanding would be, or might be, an exclusionary provision within the meaning of s45 of the TPA;
- to give effect to a provision of a contract, arrangement or understanding where the provision is, or may be, an exclusionary provision within the meaning of s45 of the TPA;
- to make a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of s45 of the TPA; and
- to give effect to a provision of a contract, arrangement or understanding which provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of s45 of the TPA; and
- to engage in conduct that constitutes or may constitute the practice of exclusive dealing within the meaning of s47 of the TPA.

### 4. Arrangement for which authorisation is sought and public benefits resulting from the specific provisions of the arrangement

---

#### 4.1 Background

Members of MA are required to comply with the Code as a condition of membership. In addition, the Therapeutic Goods Administration (**TGA**) through its marketing approval letter requires that promotional material for prescription medicines on the Australian Register of Therapeutic Goods (**ARTG**) must comply with the requirements of the Code. A copy of the TGA's marketing approval letter is enclosed as Annexure 2.

As the Commission will be aware, it is proposed that the TGA is to be replaced in mid 2006 by the Joint Therapeutics Agency of Australia and New Zealand (**Joint Therapeutics Agency**). The background to this is set out in Annexure 3.

Whilst it is proposed under the new Therapeutic Products Advertising Code that advertising of prescription medicines to consumers will be permitted in New Zealand, direct to consumer advertising of prescription medicines will continue to be prohibited in Australia, both through the Joint Therapeutics Agency Rules and the MA Code.

Edition 15 of the Code will include the three Advertising Principles from the new Therapeutic Products Advertising Code in the Preamble. Section 11.6 of the Code allows for the referral of

complaints between Medicines Australia and the Central Complaints Panel to be established under the Therapeutic Products Advertising Code, as described in that Code.

The Code also includes provisions for the hearing of complaints about the conduct of non-members. If a non-member refuses to have the matter considered by the MA Code of Conduct Committee, MA reserves the right to refer such matters to the TGA, the Joint Therapeutics Agency (once it is established) and/or the Commission.

There is an argument that the arrangement, which amounts to an agreement between the members of MA, could raise issues under s45(2)(a)(i) or (ii) of the TPA. However, MA submits that even if this is the case, none of the provisions of the Code has the purpose or has or is likely to have the effect of substantially lessening competition in any relevant market, and in any event, the public benefit of the arrangement outweighs any anti-competitive detriment.

The various sections of the Code are discussed below.

#### **4.2 Nature & availability of information & claims**

Section 1 provides that it is the responsibility of companies to ensure that all promotional and medical claims are balanced, accurate, correct and able to be substantiated. It emphasises the need for all claims to be consistent with the product information approved by the Therapeutic Goods Administration. Specific provisions deal with:

- the responsibility of members to provide substantiating data on request;
- the level of substantiating data to be provided. The Explanatory Notes to section 1.2.2 have been amended to clarify that substantiating data should not solely rely upon evidence from sources such as poster presentations or abstracts, but that these sources can be used as secondary references to support claims;
- the obligation of members not to make false or misleading claims, including an obligation to reference claims where there is a possibility that a reader may be misled if the source of the reference is not disclosed;
- the limited circumstances in which information about unapproved products may be displayed;
- the requirement that promotional material be in good taste, taking into consideration prevailing community standards;
- prohibition on the use of unqualified superlatives;
- limitations on the use of the word "new" to describe a product;
- guidelines for comparative statements;
- prohibition on imitation of promotional material used by other manufacturers in a way that is likely to mislead or confuse;
- prohibition on the use of doctors' names or photographs in a way that is contrary to medical ethics; and
- the requirement that promotional material must be clearly distinguishable as such.

The above provisions, together with the Explanatory Notes which accompany them, complement and encourage compliance with s52 of the TPA. The provisions support responsible prescribing practices and protect consumers.

#### **4.3 Product Information**

Certain types of promotional material (as set out in section 3 of the Code) must be accompanied by Product Information, Abridged Product Information or Minimum Product Information, which are described in section 2 of the Code and/or by details of changes in the Product Information or boxed warnings. All promotional claims must be supported by or be consistent with the Product Information which is reviewed and approved by the TGA as part of the process for approving and registering medicines in Australia.

These requirements in section 2 encourage rational prescribing practices and help to protect consumers by providing essential information about products.

#### **4.4 Promotional material**

Section 3 sets out certain standards to which promotional material such as advertisements, audio visual material and articles must conform.

Section 3 has been amended in a number of ways. The main amendments include:

- clarification that Primary advertisements in journals must contain in the body of the advertisement either the Product Information, the Abridged Product Information or the Minimum Product Information (section 3.1.1.3);
- clarification that if the Minimum Product Information is included in the body of a Primary advertisement, the company may also print the Product Information or Abridged Product Information if it so chooses (section 3.1.1.4)
- new provision – use of a Secondary advertisement in any issue of a publication that does not also contain a Primary advertisement is not permitted (section 3.1.2.1);
- an additional Explanatory Note that promotional taglines may not be used in a Short advertisement (Explanatory Note to section 3.1.3.1);
- new provision – where promotional claims are made in company commissioned articles (advertorials), the article must also comply with the requirements for a Primary or Secondary advertisement (section 3.1.4.5);
- new provision – printed promotional material must contain Minimum Product Information within the body of the item (section 3.3.1(e)). There is an exception to this requirement for trade display materials, but such materials must direct prescribers to review the Product Information and Product Information must be available from the display (section 3.3.4);
- new provision – companies must ensure that no advertisements are placed in electronic prescribing software packages with clinical tools or patient education materials which may be used by a prescriber for consultation or discussion with a patient (section 3.9.1). The provision has been included in Edition 15 following a complaint to the MA Code of Conduct Committee that advertisements in prescribing software did not comply with the Code and other submissions to the Review of the Code of Conduct criticising the practice of including

such advertisements in parts of prescribing software that might be seen by patients. The provision is designed to replace section 3.10.10 of Edition 14 of the Code which provides:

As prescribing software packages may include information which could be shared with patients by prescribers, the content of any advertisements, particularly graphics, must be such as to not cause any offence, alarm or concern or give rise to unrealistic expectations of benefit when viewed by members of the general public, including children.

Advertisements should also not be designed to stimulate a patient's demand for the prescription of a particular product.

This new provision may have some effect on the activities of current or potential providers of electronic prescribing software that contains advertising capability. However, it is not intended that companies be prevented from advertising prescription medicines in such software entirely. Advertising of prescription medicines will still be permitted in those parts of the software that are used only by healthcare professionals. In addition, parts of the software that may currently be seen by patients include advertisements for over the counter medicines, the PBS, HIC, GP's surgeries etc. Advertisements of this kind will still be permitted. The purpose of the new provision is to assist companies to comply with their obligations under the TGAct;

- new provision – in relation to brand name reminders, only items that are relevant to the working environment of a healthcare professional are suitable (section 3.12). The value of a Brand Name Reminder must not exceed \$20 (section 3.12 and Guidelines).
- new provision – if multiple competitions are to be conducted within a calendar year for the same product, the total volume of prizes for the competitions must not exceed \$50,000 (Explanatory Note to section 3.13 and Guidelines).

These provisions as amended help to ensure that claims are not misleading or deceptive, encourage rational prescribing practices and help to protect consumers.

#### **4.5 Company representatives**

Section 4 sets out standards of conduct and knowledge for 'company representatives'. It requires them to possess sufficient medical and technical knowledge to present product information accurately and be aware of all the provisions of the Code.

Medical representatives who have been employed in the prescription pharmaceutical industry since April 1983 are required to have completed or be currently undertaking an endorsed MA education program for medical representatives. Medical representatives entering the pharmaceutical industry for the first time must enrol in the Code of Conduct component of the endorsed MA education program within the first six months of employment and complete the full program within two years from commencement. It is proposed that the MA endorsed education program for 2006 will be run by the University of Queensland.

The Code also contains a new provision which requires any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public, or who has direct interaction with healthcare professionals for the purpose of promoting a prescription medicine, to complete the Code of Conduct module of the endorsed MA education program within 12 months of commencing their employment (section 4.14).

It is possible that some provisions of section 14 could involve conduct of the kind in s47(6) or 47(7) of the TPA in that MA will supply services to companies on condition that certain medical representatives and company representatives undertake an endorsed education program.

However, the conduct is not anti-competitive. The objective of the program is to provide participants with the confidence, skills and knowledge needed to effectively and efficiently carry out their responsibilities as medical representatives in the pharmaceutical industry and to maintain appropriate standards of ethics and business conduct.

MA does not currently have the resources to be able to offer such an education program itself. To date, and at present, it has only endorsed one provider at a time to offer the education program. In the light of the detailed requirements of the Code, it is desirable for MA to retain a high degree of control over the content of the program and the parties that can deliver the program.

Overall, the provisions of section 4 heighten awareness of the Code among representatives and other relevant company employees. The education requirements provide public benefit in that they help maintain a high standard of delivery of information to medical practitioners and thereby encourage the quality use of medicines and rational prescribing practices.

#### **4.6 Products starter packs (samples)**

Section 5 regulates the distribution of starter packs and the information to be included with starter packs so as to ensure the safe and appropriate use of the prescription products included in the starter packs. It also regulates the establishment and operation of Product Familiarisation Programs. The section has been extensively revised and expanded as a result of industry and stakeholder consultation and negotiation with the National Coordinating Committee on Therapeutic Goods following the Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (the **Galbally Review**).

Recommendation 12 of the Galbally Review, which was supported by MA, required that the States and Territories repeal provisions relating to the supply of samples of medicines and poisons within their drugs, poisons and controlled substances legislation and that APMA (now Medicines Australia) amend the Code to include standards for clinical samples (known as Starter Packs) with respect to:

- the security of the stock;
- the quantities to be held, carried and supplied;
- quality issues, such as the temperature of storage;
- record keeping; and
- disposal.

A copy of Recommendation 12 of the Galbally Review is enclosed at Annexure 4.

As a consequence of the Galbally Review, the States' and Territories' legislation relating to Starter Packs will be repealed by 1 July 2006. This will bring to an end the current significant differences that exist between States and Territories regarding their requirements for the supply of Starter Packs. The relevant requirements have been incorporated in Section 5 of the Medicines Australia Code of Conduct.

All MA members and other relevant stakeholders were consulted in the development of the proposed revised provisions, and their comments have been incorporated in the draft Code section. A list of all stakeholders consulted is enclosed at Annexure 5.

#### **4.7 Involvement in Educational Symposia, Congresses and Satellite Meetings**

Section 6 was significantly amended in Edition 14. There have been no substantial amendments to this section in Edition 15.

The provisions cover congresses, symposia and satellite meetings. Essentially, they were designed to ensure that activities of companies involved in these events have the primary objective of enhancing medical knowledge and ensuring quality use of medicines in Australia.

Company activities should be such that they are able to withstand both public and professional scrutiny, and conform to professional and community standards of ethics and good taste.

The section includes provisions relating to hospitality. If provided, hospitality must be:

- secondary to the educational purpose of the meeting at which it is provided;
- consistent with standards which would meet professional and community scrutiny; and
- no entertainment may be provided.

As regards sponsoring healthcare professionals to attend such meetings, the Code stipulates that sponsorship must only be offered to healthcare professionals with an interest in the area of medicine being discussed and they must be able to report back to the profession so that quality use of medicines is enhanced.

The Code also includes provisions relating to the selection of venues for educational meetings organised by companies, requiring that they should be suitable for providing education and not be selected on the basis of sporting or leisure activities available at the venue.

As regards travel to these types of events, the Code makes it clear that providing First Class tickets is not appropriate, and family or travelling companions should not have their costs and expenses covered or subsidised.

The Explanatory Notes and the Guidelines indicate the types of activities which may be engaged in by companies in order to comply with these provisions of the Code. The purpose of the provisions is to prevent any chance of promotional and educational events and sponsoring of delegates attending these events being used or being perceived as being used as an incentive to support irrational prescribing practices.

#### **4.8 Sponsorship**

Section 7 relates to sponsorship of healthcare professional organisations and activities involving healthcare professionals, and reflects the objectives of section 6.

Section 7 includes a new provision in relation to companies which offer programs that sponsor a healthcare professional to provide support for medical practice activities. Such programs must be able to successfully withstand public and professional scrutiny, be intended to enhance the quality use of medicines and not be offered or provided conditional upon any obligation to prescribe a particular product.

The purpose of the provisions in section 7 as a whole is to prevent any chance of sponsorship of activities being used or being perceived as being used as an incentive to support irrational prescribing practices.

#### **4.9 Research**

Section 8 includes provisions regulating post-marketing surveillance studies and market research so that such studies are not used as promotional exercises. The Code has been amended to clarify that the only extent of involvement of medical representatives is in recommending or identifying healthcare professionals to participate in a study (section 8.1.3). These provisions encourage rational prescribing practices through the generation of data on safety parameters of products.

#### **4.10 Relationship with the general public**

The provisions in section 9 dealing with general enquiries, product specific media statements, general media articles, promotion to the general public, patient education, use of the internet, patient aids and patient support programs are consistent with the prohibition on direct advertising of prescription products to the general public and help to protect consumers. They also reinforce the industry's obligation to provide consumers with current, accurate and balanced information on medicines available in Australia. The provisions establish a framework which should enable companies to comply with the requirements of the TGAct, by advising companies only to publish material available to consumers which is educational and informative rather than promotional.

Section 9.6 (which is section 3.9 in Edition 14 of the Code) sets out how current, accurate and balanced information regarding prescription medicines available in Australia can be provided to the public via the internet.

New provisions have been added with regard to companies' involvement in patient support programs. Companies are required to develop a rationale for each patient support program which describes the clinical rationale, the anticipated number of patients to be enrolled in the program, the type of educational/informational material to be provided to a patient and contact that may be made with a patient. The Code also clarifies that patient support programs should not interfere in any way with doctor/patient integrity (section 9.8).

A new section 9.9 has been added in relation to the relationship between pharmaceutical companies and Health consumer Organisations, which refers to guidelines developed by MA, the Consumers' Health Forum of Australia and other health consumer organisations.

As above, MA considers that the provisions of the Code, together with the Explanatory Notes and Guidelines, if followed, will better equip companies to comply with the TGAct.

#### **4.11 Relations with healthcare professionals**

Section 10 of the Code of Conduct specifically deals with the industry's relations with healthcare professionals. The industry recognises the importance of the relationship between it and healthcare professionals. The purpose of this section is to set appropriate standards of behaviour with which the industry must comply.

The basic tenets of this section state that all involvement in activities with healthcare professionals must be able to withstand public and professional scrutiny and conform to professional standards of ethics and of good taste.

Section 10.1 expressly prohibits interactions between companies and healthcare professionals from including entertainment. There is an exception in relation to educational meetings of two or more days' duration where "a modest opportunity for unstructured and individual recreational activities at the delegate's own expense" may be incorporated.

Section 10.2 deals with hospitality, including issues such as the level of hospitality allowed and venues at which hospitality may be provided.

Section 10.3 is a new provision dealing with subsidy of a healthcare professional's travel costs, and is equivalent to the provisions of section 6.8.

To an extent, section 10.1 to 10.3 duplicate provisions contained in sections 6 and 7 of the Code. However, they are repeated in section 10 for the sake of clarity and completeness, since section 10 deals with a potentially wider range of events and activities than those covered in sections 6 and 7.

Section 10.6 is also a new provision, setting out the circumstances in which companies may seek the services of suitably qualified and experienced healthcare professionals to provide advice and guidance. It also sets limits on the remuneration and reimbursement that may be provided to such healthcare professionals. This follows on from two complaints that were made to the Code of Conduct Committee that meetings held by two companies were promotional in nature and did not constitute genuine advisory boards.

The purpose of these provisions is that no inappropriate financial or material benefits, including hospitality, are offered to healthcare professionals which may influence them in their prescribing or dispensing of pharmaceutical products.

#### **4.12 Administration of the Code**

Section 11 establishes the Code of Conduct Committee and sets out procedures by which the Code Committee hears complaints about the conduct of both members and non-members. The Code Committee will consider complaints from any organisation or individual that raises concerns regarding any section of the Code. Appendix 1 to the Code sets out the Guidelines for Complaints, relating to making a complaint and how complaints are handled.

Section 11.2 has added to the membership of the Code Committee with the inclusion of a specialist nominated by the Royal Australasian College of Physicians. The TGA member of the Code Committee has been changed from Observer to full member. In addition, the procedure for appointing the Chairman of the Code Committee has been amended to establish a panel of Chairs from which the Chairman for a particular meeting will be appointed. This obviates the need for a Deputy Chairman, and this member has been removed from the membership.

The section also contains amended procedures relating to the appointment of Code Committee members.

There are new provisions in relation to the disclosure of conflicts of interest by Code Committee members prior to and at each meeting (section 11.3).

Section 11.4 provides that MA will carry out a review of the provisions of the Code of Conduct after seeking input from interested parties no later than every 3 years.

New section 11.6 relates to referral of complaints under the Therapeutic Products Advertising Code, which will come into effect with the commencement of the Joint Therapeutics Agency.

#### **4.13 Sanctions**

Section 12 contains a variety of sanctions for promotional activities found to be in breach of the MA Code. These sanctions include the immediate withdrawal or cessation of the promotional activity, the publication of corrective advertising, corrective letters to practitioners and pharmacists, fines and suspension or expulsion from MA membership.

Edition 15 contains a new sanction, by which the Code Committee can impose a fine of up to \$50,000 if corrective action is not taken within 30 calendar days from receipt of the minutes of the Code or Appeals Committee meeting (section 12.1.2).

MA will accept a complaint from any source and actively provides advice and assistance to potential complainants in the development of complaints. This includes individuals and any consumer organisation, which can make a complaint against an activity of a company that it thinks breaches the Code of Conduct.

#### **4.14 Appeals**

Section 13 establishes the MA Code of Conduct Appeals Committee and sets out the procedure for appeals to be made from decisions of the Code Committee.

Aspects of the appeals procedure have been amended:

- an appeal may be lodged by a complainant as well as the Subject Company;
- the appeal bond has increased to \$20,000 for Subject Companies or industry complainants. No bond is payable by non-industry complainants.
- an administration charge of \$6,000 will be retained by MA in all cases.

Changes have also been made to the membership of the Appeals Committee, with the addition of a consumer representative as a permanent member of the Committee and to the procedure for appointment and tenure of Committee members (section 13.2).

A new section has been inserted in relation to conflicts of interest (section 13.3) which is similar to new section 11.3 described above.

#### **4.15 Monitoring**

Section 14 establishes the Monitoring Committee which proactively monitors selected promotional material of member companies on a regular and ongoing basis in order to:

- encourage compliance with the MA Code;
- provide advice on compliance where necessary;
- obtain and publish statistical data on the rate of compliance; and
- provide an ongoing mechanism for the identification of potential future amendments to the Code.

Changes have been made to the membership of the Monitoring Committee, which the addition of a consumer representative as a permanent member of the Committee (section 14.2). A new section

has also been inserted in relation to conflicts of interest (section 14.4) which is similar to new sections 11.3 and 12.3.

The Monitoring Committee Protocol set out in Appendix 3 to Edition 14 of the Code is now included as part of section 14. It specifies the types of promotional material which the Committee will request on a random basis, and its reporting obligations, including its obligations to contribute to the Code of Conduct Annual Report and to report to MA on issues in the Code which require review.

If any behaviour is considered inconsistent with the requirements of the Code, the Monitoring Committee can forward a complaint to the Code of Conduct Committee for consideration. It also has the capacity to provide advice to companies to enhance compliance with the Code of Conduct.

MA submits that its monitoring activities provide assurances that activities undertaken by the industry are regularly reviewed and advice provided to members on compliance with the Code.

In addition to these processes, MA and its members are ever vigilant to the activities occurring in the industry. MA will provide timely advice to companies considering any activities or will accept and deal with, in a timely manner, any complaints involving activities that might fall within these or any other sections of the Code.

#### **4.16 Compliance procedures**

Section 15 encourages compliance with the Code by requiring each MA member to ensure that it has an internal compliance procedure. No amendments have been made to this section in Edition 15 of the Code.

#### **4.17 Reporting**

Section 16 sets out the information to be included in the Annual Report on the activities of the Code Committee and provides for external reporting.

Recently, MA has taken to publishing its Code of Conduct Committee Annual Report on its website together with six monthly Code of Conduct Committee Outcomes and reports on Code of Conduct complaints relating to activities directed at the general public.

Section 16.2 has been amended, so that in addition to the Annual Report, MA will publish a quarterly report on the outcomes of all complaints finalised during the reporting period. In addition, information about complaints about activities directed at members of the general public will be published within one month of finalisation of the complaint. These reports will be available through the MA Website. These amendments go further than the requirement in Condition C2 imposed by the Commission in its determination in relation to Edition 14.

The purpose of these provisions is to enhance companies' understanding of the Code of Conduct process and to increase compliance. The reporting requirements ensure that the activities of the Code of Conduct Committee are transparent to the industry and healthcare professionals and provide further encouragement to members to comply with the Code.

#### **4.18 Guidelines**

The Guidelines to the Code of Conduct supplement the Code and the Explanatory Notes by setting out practical examples of when certain activities or certain conduct of a company would be likely to be deemed appropriate or inappropriate. As experience develops through complaints considered

by the Code Committee, monitoring activity or enquiries from companies or other parties, amendments may be made to the Code's Guidelines, for example, to provide further clarification regarding the application of a particular section of the Code.

Companies are therefore now provided with measurable and clear parameters about what they can and cannot do, expressed in objective terms.

A copy of the Guidelines to be read on conjunction with Edition 15 of the Code are enclosed at Annexure 6.

The Guidelines therefore provide a significant restraint on companies' activities, and clear guidance for the Code of Conduct Committee which has the task of considering complaints brought before it regarding potential breaches of the Code.

MA is happy to continue to provide to the Commission on an annual basis a copy of the Guidelines, showing amendments that have been made during the course of the year and to be subject to a continuing condition in this regard in accordance with Condition C3 imposed by the Commission in its determination in relation to Edition 14. The Guidelines are also available on MA's website.

#### **4.19 Breadth of the Code**

During its consultation process all major healthcare professional organisations were consulted on the content of the Code and possible new areas that should be encompassed.

MA directly invited written submissions to the Review of the Code of Conduct from the following stakeholders:

- Australian Medical Association (AMA)
- Royal Australian College of General Practitioners (RACGP)
- Australian Divisions of General Practice (ADGP)
- Royal Australasian College of Physicians (RACP)
- National Prescribing Service (NPS)
- Consumers' Health Forum of Australia (CHF)
- Therapeutic Goods Administration
- Pharmaceutical Benefits Branch of the Department of Health and Ageing
- Medical Publishers Association
- Advertising Federation of Australia
- Pharmaceutical Health and Rational Use of Medicines Committee
- Australian Pharmaceutical Advisory Council
- The Pharmacy Guild of Australia
- The Pharmaceutical Society of Australia
- Society of Hospital Pharmacists of Australia
- Generic Medicines Industry Association (GMiA)
- Medicines Australia membership



- Non-member companies (Alphapharm, AMRAD (now part of MSD), Arrow, Aspen, Baxter, Biochemie, Dentsply, Ferring, FH Faulding, Galderma, GenPharm, GenRx, Genzyme, Mayne, NovoNordisk (which recently applied for membership), Servier and Sigma. Some of these companies provided written responses and others attended seminars organised by Medicines Australia as described below)

In addition, MA representatives offered face to face meetings with the major stakeholders to expand upon any comments made in written submissions, or simply to elicit comments.

All comments were considered by a Review Panel of 16 member company representatives, which was chaired by Medicines Australia Vice-Chairman, Ms Erica Mann.

MA also conducted seminars in July 2005 to discuss the proposed amendments with member and non-member companies and again in October 2005 to communicate the final proposed changes. The latter seminars also included advertising agencies that provide services to the industry. One reason for the October seminars was to give advance notice to companies of the requirements that will come into effect on 1 January 2006, to encourage companies to ensure that all new promotional materials used in early 2006 comply with Edition 15 of the Code.

## **5. Effect on competition of the proposed arrangement**

### **5.1 Relevant market affected by the proposed arrangement**

MA submits that the relevant market in which to assess the potential effects of the Code is the market in Australia for the supply of prescription products used under medical supervision as permitted under Australian law.

In its determination in relation to Edition 14, the Commission commented (para 5.13) that:

it may be possible to identify regional markets or markets associated with particular classes of prescription medicines. However, the Code would apply across all such markets. Accordingly, the Commission considers that, for the purposes of this authorisation, it is not necessary to consider whether the definition of the relevant markets is narrower than that proposed by Medicines Australia. For convenience, this determination refers to the market for prescription medicines when describing the relevant market.

MA submits that there has been no change in the dynamics of the relevant market such that the Commission should reach a different view in relation to market definition for the purposes of assessing the effect on competition of Edition 15 of the Code.

### **5.2 Legislative framework**

The supply and promotion of pharmaceutical products in Australia is highly regulated. Under the TGAct and Therapeutic Goods Regulations, all prescription products must be approved for registration on the ARTG prior to supply and/or promotion. Direct promotion of prescription products to the general public is prohibited by the TGAct and will continue to be prohibited when the TGA is replaced by the Joint Therapeutics Agency.

Restrictions on the sale and promotion of prescription products have been imposed by the legislature largely in order to protect consumers from the risk of misuse or inappropriate use of these products. Within this framework, the marketing of prescription products is largely self regulated by the industry through the Code which complements the general prohibition on

misleading and deceptive conduct in the TPA and specifies acceptable standards for advertising, thus reinforcing the desire of the legislature to protect consumers from the risk of misuse or inappropriate use of prescription products.

### **5.3 Likely effect on competition and public benefit of the arrangement**

#### **(a) Marketing standards**

MA submits that the Code contributes substantial public benefit, including consumer protection, through the setting out and enforcement of standards of conduct for the marketing of prescription products. In particular, the Code complements and encourages compliance with the prohibition on misleading and deceptive conduct in the TPA and the prohibition on advertising in the TGAct by setting out in detail the types of claims relating to prescription products which will be considered to be in breach of the Code and by setting out details of the level of supporting information which should accompany claims.

In its determination in relation to Edition 14 of the Code, the Commission accepted that these provisions of the Code have minimal effect on competition between pharmaceutical companies and, therefore, minimal (if any) public detriment (paras 5.67 to 5.70).

MA submits that the conclusions reached by the Commission in relation to the minimal public detriment likely to be generated by these provisions of Edition 14 of the code should apply equally to the relevant provisions of Edition 15.

#### **(b) Promotion of the quality use of medicines and rational prescribing practices**

MA submits that the Code contributes substantial public benefit, including that it encourages the quality use of medicines and rational prescribing practices, through the regulation of promotional activity including advertisements, gifts and incentives to medical practitioners and the education of medical company representatives. The Code also encourages good practices of the kinds outlined above in relation to sponsorship, hospitality, etc., which are over and above the legal requirements faced by suppliers of prescription pharmaceutical products. This means that members and non-members that submit to the Code face competitive restraints.

The Code assists in maintaining the reputation of the pharmaceutical industry as a whole and gives members and medical company representatives more guidance than they would otherwise have.

In its determination in relation to Edition 14 of the Code, the Commission accepted that:

- the prescribing habits of at least some healthcare professionals may be inappropriately influenced by benefits provided by pharmaceutical companies (para 5.45 and 5.48); and
- absent the Code, at least some pharmaceutical companies, if not many, would promote prescription medicines to healthcare professionals more aggressively and particularly through the provision of benefits banned by the Code (para 5.49).

The Commission also recognised that in this regard, the Code potentially generates a not insignificant public benefit (para 5.54) arising from:

- a reduction in the likelihood that doctors would prescribe medicines which may not be the most appropriate choice for their patient (paras 5.55 and 5.56); and
- inappropriate prescribing may reduce the incentive to innovate to which pharmaceutical companies are currently subject (para 5.57).

The Commission also concluded that although a restriction on the provision of benefits was likely to constitute some restriction on competition, even if it were significant, it would be unlikely to generate more than a minimal detriment to the public (para 5.72).

MA submits that the amendments to section 16 of the Code in relation to public reporting of Code breaches (also discussed above and below) should diminish the Commission's previous concerns about the practical enforcement of the Code. As a result, the public benefit generated by these provisions is greater than the public benefit generated by the provisions of Edition 14.

MA also submits that the conclusions reached by the Commission in relation to the minimal public detriment likely to be generated by these provisions of Edition 14 of the code should apply equally to the relevant provisions of Edition 15.

#### **(c) Complaints handling**

The Code also contributes substantial benefit because of the fact that it is easier to access than the Court system and less costly. It addresses potential breaches of the misleading and deceptive conduct provisions of the TPA through the handling of complaints made to the Code Committee and the operation of the Monitoring Committee. MA submits that more misleading advertising is prevented than would be the case if the only recourse were to issue Court proceedings. Complaints are dealt with in a less labour intensive manner than Court proceedings and, for the most part, more quickly than Court proceedings or complaints made to the Commission.

The composition of the Code of Conduct Committee, which includes consumers, government, health care professionals and industry representatives, ensures that when considering complaints the public and professional standards required are appropriately considered.

The procedures for dealing with complaints provide public benefits in the form of consumer protection, through the enforcement of conduct for the marketing of prescription products in line with the obligations imposed on companies by the TPA and the TGAct.

Guidelines for making complaints are set out in detail in Appendix 1 to the Code. As regards externally generated complaints, MA may contact the complainant to assist them in making their submission by providing information on the requirements of the Code or provide access to an independent facilitator, at MA's cost, to assist the complainant in either resolving the complaint with the subject company or assisting the complainant to submit the complaint to MA.

In relation to a complaint made by one company against another, the Code contains guidelines which are designed to promote speedy inter-company dialogue and provide an official timeframe in which to undertake such discussions.

Section 11 sets out the procedure which is followed by the Code of Conduct Committee when considering complaints. Once a complaint is received by MA, it must provide an acknowledgment within 5 working days of receipt. The subject company will be given full details of the information lodged with MA and given 10 working days within which to respond. Following the Committee meeting at which the complaint is considered, if a breach is found to have occurred, MA must within 2 working days of the meeting notify the subject company and the complainant that a breach has been found and identify the section(s) that the Committee has determined has been breached. Within 10 working days of the meeting, copies of the extract of the minutes must be provided to the subject company and the complainant including a full explanation of the Committee's decision and the form of any sanction to be applied (as provided for under section 12).

If the Committee considers that no breach has occurred, the parties concerned must be advised of this and supplied with the minutes of the meeting within 10 working days of the decision.

Findings and/or sanctions remain confidential until the subject company has exhausted all appeal procedures (set out in section 13) and the outcome of any appeal is known.

**(d) Public reporting of Code breaches**

As discussed above, section 16 incorporates revised procedures for publicly reporting Code breaches, including publishing quarterly reports on the outcomes of all complaints finalised during the reporting period through the MA website. Section 16, as amended, is designed to further enhance understanding of the Code, to increase compliance and to enable more critical examination of the administration of the Code by the wider community. Public reporting of Code breaches includes:

- in the Annual Report on the activities of the Code of Conduct, Appeals and Monitoring Committees which is available to the industry, members of the health care professions and the general public;
- in addition to the Annual Report, MA will publish a quarterly report on the outcomes of all complaints finalised during the reporting period, which will be available on the MA website (as mentioned above, this is a new provision in Edition 15);
- information regarding complaints that involve activities directed towards members of the general public will be made available via the MA website within one month of finalisation of the complaint;
- companies are provided with information regarding complaints made and the outcomes of those complaints on a timely, regular and ongoing basis through a Code Newsletter and regular updates to the Guidelines.

**(e) Sanctions**

Depending on the type of breach found to have occurred, fines can be up to \$100,000 and, in the case of severe breaches and breach repetitions, up to a maximum of \$200,000 (section 12.1.4).

As discussed above, Edition 15 also contains a new sanction, by which the Code Committee can impose a fine of up to \$50,000 if corrective action is not taken within 30

calendar days from receipt of the minutes of the Code or Appeals Committee meeting (section 12.1.2).

The sanctions provide a public benefit in the form of consumer protection provided through the enforcement of the standards set out in the Code.

**(f) Monitoring Committee**

The overall role of the Monitoring Committee is to encourage compliance with the Code and in order to do this, it will request and review specific types of promotional material. Where it considers that a breach of the Code may have occurred, the Committee will contact the company in question and give them the opportunity to respond. If necessary, the Monitoring Committee will refer the matter to the Code of Conduct Committee as a complaint should it not be satisfied with the company's response.

The Monitoring Committee will also, as a result of its activities throughout the year, report to MA on issues concerning the Code which it considers requires review.

The role of the Monitoring Committee provides significant public benefits because it provides assurance that activities undertaken by the industry are regularly reviewed and advice is provided to members on compliance with the Code through the abovementioned Code Newsletter.

In its determination in relation to Edition 14 of the Code, the Commission imposed a condition on MA under which the Monitoring Committee shall, each year, require each member company to provide full details of all educational meetings and symposia as defined in Sections 6, 7 and 10 of the Code held or sponsored by that company during a defined three month period (Condition C1). If the Monitoring Committee considers that the company's conduct with regard to a meeting may breach the Code, it will refer the matter to the Code of Conduct Committee as a complaint. The Monitoring Committee shall provide a detailed report on its compliance with this condition to MA for publication on the MA website and in the MA Annual Report.

The Commission considered that this condition would be likely to improve the ability of the Code to regulate properly the provision of benefits to healthcare professionals, and assist in the transparency of the Monitoring Committee's operation.

The Monitoring Committee typically meets ten or eleven times each year for a half day meeting. It reviews promotional materials in different therapeutic categories, usually considering one therapeutic class and one type of promotional material at each meeting.

Since Condition C1 was imposed, in addition to the obligations imposed by Condition C1, MA's independent Monitoring Committee has reviewed promotional materials in only six therapeutic categories and reviewed competitions for healthcare professionals, market research activities, company websites and advertisements in electronic prescribing software across all therapeutic classes. The requirements of Condition C1 in 2004 took up five monthly meetings of the Monitoring Committee, and in 2005 three meetings, resulting in the Monitoring Committee being unable to conduct reviews across as broad a range of promotional materials as it would typically have done.

By far the majority of the materials reviewed in accordance with the requirements of Condition C1 complied with the requirements of the Code. In those cases where there was

a potential breach of the Code, member companies were advised to clarify the materials they produced so that healthcare professionals would be able to decide whether or not to attend based on the educational content of the meeting. No complaints needed to be referred to the Code of Conduct Committee.

In view of the limited benefit obtained through the imposition of Condition C1 and the impact of the condition on the regular activities of the Monitoring Committee, MA requests that Condition C1 not be included in any substitute authorisation of the Code.

**(g) Information and education**

MA and its members make extensive efforts to responsibly provide health care professionals with information about medicines, which will improve the health of Australians. In providing this information, the activities of the industry are tailored to meet the needs of healthcare professionals and are cognisant of the pressures, including time, financial and family, placed on them in the current health environment.

The activities provided by the industry meet certain needs of health care professionals including the continuing education responsibilities required by their various professional organisations and the need to be informed of new and developing technologies in the treatment of diseases and conditions in Australia.

MA also undertakes extensive educational campaigns directed at companies (both member and non-member), healthcare professionals, health consumer organisations, publishers and advertising agencies to promote compliance with the Code, provide them with information on the standards set by the industry and on how to make and lodge a complaint, if warranted, to the Code of Conduct Committee. During 2004-2005, MA has provided presentations to 39 different audiences totalling over 890 participants. These included both internal and external stakeholders such as the Royal Australian College of Physicians, the Gastroenterological Society, Kidney Health Australia and the National Sales Managers Group.

## **6. Conclusion**

In its determination in relation to Edition 14 of the Code, the Commission concluded that the Code generated a small public benefit and minimal public detriment. Authorisation was granted subject to three conditions which would seek to increase the public benefit or reduce the anti-competitive detriment sufficiently to remove any concern that authorisation was being inappropriately granted.

For reasons set out above, MA submits that the public benefit generated by the provisions of Edition 15 is greater than that generated by the provisions of Edition 14. Any public detriment arising from Edition 15 of the Code will be minimal. Further, provisions similar to the provisions of Condition C2 to the determination in respect of Edition 14 have been incorporated into Edition 15 of the Code itself. As set out above, MA is also happy to continue to provide to the Commission on an annual basis a copy of the Guidelines, showing amendments that have been made during the course of the year.

In the light of all of the above, MA submits that any lessening of competition which could flow from compliance with the Code of Conduct is clearly outweighed by the public benefits. MA requests that authorisation be granted for 5 years.

If the Commission requires further information regarding any aspect of this application, reference can be made to:

Emma Marsh  
Senior Associate  
Allens Arthur Robinson  
The Chifley Tower  
2 Chifley Square  
Sydney NSW 2000  
Tel (02) 9230 4136  
Fax (02) 9230 5333

## Annexure 1: Final draft of Edition 15 of the Code





# **Code of Conduct**

## **Edition 15**

**Adopted 6 December 2005**  
**Effective 1 January 2006**

Final Draft: November 2005



**Edition 15**  
**Adopted 6 December 2005**

## **Contents**

**Preface.....**

**Preamble .....**

### **1. Nature and Availability of Information and Claims .....**

1.1 Responsibility .....

1.2 Substantiating Data.....

1.2.1 Provision of Substantiating Data.....

1.2.2 Level of Substantiating Data.....

1.3 False or Misleading Claims.....

1.3.1 Unapproved products of indications.....

1.4 Good Taste .....

1.5 Unqualified Superlatives .....

1.6 New Products.....

1.7 Comparative Statements .....

1.8 Imitation.....

1.9 Medical Ethics.....

1.10 Distinction of Promotional Material .....

### **2. Types of Product Information .....**

2.1 Product Information.....

2.2 Abridged Product Information .....

2.3 Minimum Product Information .....

2.4 Changes of Clinical Significance and the addition of a  
Boxed Warning .....

### **3. Promotional Material.....**

3.1 Journal Advertising .....

3.1.1 Primary Advertisement.....

3.1.2 Secondary Advertisement.....

3.1.3 Short Advertisement .....

3.1.4 Company Commissioned Articles .....

|       |  |
|-------|--|
| 3.2   | Reference Manual Advertising.....  |
| 3.2.1 | Primary Advertisement - Reference manuals .....                                    |
| 3.2.2 | Short Advertisement - Reference manuals.....                                       |
| 3.3   | Printed Promotional Material.....  |
| 3.4   | Mailings.....  |
| 3.5   | Document Transfer Media .....  |
| 3.6   | Audiovisual Promotional Material .....   |
| 3.7   | Company Computer Promotional Material.....   |
| 3.8   | The Internet .....   |
| 3.9   | Advertising in Electronic Prescribing Software Packages .....                      |
| 3.9.3 | Primary Advertisement specific to Prescribing Software .....                       |
| 3.9.4 | Short Advertisement specific to Prescribing Software....                           |
| 3.10  | Restricted Access Television Advertising .....                                     |
| 3.11  | Gifts/Offers .....   |
| 3.12  | Brand Name Reminders .....   |
| 3.13  | Competitions .....   |
| 4.    | <b>Company Representatives .....</b>   |
| 5.    | <b>Product Starter Packs.....</b>  |
| 5.2   | Product Familiarisation Programs.....  |
| 6.    | <b>Involvement in Educational Symposia, Congresses and Satellite Meetings.....</b> |
| 6.1   | Trade Displays .....   |
| 6.2   | Hospitality .....  |
| 6.3   | Behaviour .....  |
| 6.4   | Sponsorship or involvement in independently organised congresses .....             |
| 6.5   | Sponsorship of Healthcare Professionals .....                                      |
| 6.6   | Venue Selection .....  |
| 6.7   | Reporting .....  |
| 6.8   | Travel .....   |
| 7.    | <b>Sponsorship .....</b>   |
| 8.    | <b>Research .....</b>  |
| 8.1   | Post Marketing Surveillance (PMS) Studies.....                                     |
| 8.2   | Market Research.....   |

|   |  |
|---|--|
| <b>9. Relationship with the General Public.....</b>                               |  |
| 9.1 General Inquiries.....  |  |
| 9.2 Product Specific Media Statements.....  |  |
| 9.3 General Media Articles.....   |  |
| 9.4 Promotion to the General Public.....  |  |
| 9.5 Patient Education.....  |  |
| 9.6 Use of the Internet .....   |  |
| 9.7 Patient Aids.....   |  |
| 9.8 Patient Support Programs .....  |  |
| 9.9 Relationship with Health Consumer Organisations .....                         |  |
| 9.10 Discredit to and reduction of confidence in the industry.....                |  |
| <b>10. Relationship with Healthcare Professionals .....</b>                       |  |
| 10.1 Entertainment.....   |  |
| 10.2 Hospitality.....   |  |
| 10.3 Travel .....   |  |
| 10.4 Medical Educational Material .....   |  |
| 10.5 Medical Literature/Reprints.....   |  |
| 10.6 Consultants and Advisory Boards.....   |  |
| 10.7 General Remuneration.....  |  |
| 10.8 Discredit to and reduction of confidence in the industry.....                |  |
| <b>11. Administration of the Code .....</b>                                       |  |
| 11.1 Procedures.....  |  |
| 11.2 Membership of Committee.....   |  |
| 11.3 Conflict of Interest .....   |  |
| 11.4 Review of the Code.....  |  |
| 11.5 Complaints against Non-Members .....   |  |
| 11.6 Referral of Complaints to the Therapeutic Products<br>Advertising Code ..... |  |
| 11.7 Discretion for Referral.....   |  |
| <b>12. Sanctions .....</b>  |  |
| <b>13. Appeals .....</b>  |  |
| 13.1 Procedures.....  |  |
| 13.2 Membership of Committee.....   |  |
| 13.3 Conflict of Interest .....   |  |
| 13.4 Referral to Medicines Australia Board .....                                  |  |

|  |       |
|--|-------|
| <b>14. Monitoring</b>  | ..... |
| 14.1 Procedures  | ..... |
| 14.2 Membership of Committee   | ..... |
| 14.3 Conflict of Interest  | ..... |
| 14.4 Referral to Code of Conduct Committee                             | ..... |
| 14.5 Reporting   | ..... |
| 14.6 Review  | ..... |
| <b>15. Compliance Procedures</b>                                       | ..... |
| <b>16. Reporting</b>   | ..... |
| 16.1 Annual Report   | ..... |
| 16.2 Quarterly Reporting   | ..... |
| 16.3 Reporting on complaints where activity directed to general public | ..... |
| 16.4 Report Content  | ..... |
| <b>Appendix 1: Guidelines for Complaints</b>                           | ..... |
| Externally generated complaints  |       |
| Industry generated complaints  |       |
| Procedures   |       |
| Intercompany dialogue  |       |
| Resolution following intercompany dialogue                             |       |
| Repeat Breach  |       |
| Complaints   |       |
| Response by Subject Company  |       |
| <b>Appendix 2: Association Rules</b>                                   | ..... |
| <b>Glossary</b>  | ..... |

## ACCC Authorisation

Application for authorisation of Edition 15 of the Code of Conduct has been made to the Australian Competition and Consumer Commission (ACCC).

Interim authorisation has been granted by the ACCC. While waiting for the final determination on authorisation, companies need to seek their own advice on any activity which might otherwise be in breach of the Trade Practices Act but which is permitted under the Code.\*\*\*\*

\*\*\*\* This anticipates the status of the Code of Conduct on 1 January 2006. Interim authorisation has not been granted at the time of printing.

## Where to find assistance

Explanatory Notes have been provided throughout the Code to assist with its implementation at an operational level. The Explanatory Notes are based on the experiences with review of Code complaints, general inquiries, comments from Medicines Australia Members and determinations made by the Medicines Australia Board.

The "*Code of Conduct Guidelines*" (Guidelines) has also been produced as a separate publication that will enhance a reader's understanding and application of the requirements of the Code. The Guidelines should be read in conjunction with the Code of Conduct.

The *Code of Conduct* and *Code of Conduct Guidelines* are available from Medicines Australia's website at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au) or by contacting Medicines Australia on (02) 6282 6888.

## Preface

The pharmaceutical industry\* promotes the concept of good health, and a positive health oriented approach to daily living, including the Quality Use of Medicines (QUM)\*. The Quality Use of Medicines means:

- selecting management options wisely
- choosing suitable medicines if a medicine is considered necessary
- using medicines safely and effectively

In line with the *National Strategy for Quality Use of Medicines* (this document can be accessed at [www.health.gov.au](http://www.health.gov.au)) it recognises that many people maintain their health without using medicines, while for others, medicines play an important role in maintaining health, preventing illness and curing disease.

The pharmaceutical industry is a partner to Australia's *National Medicines Policy* (NMP), the overall aim of which is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. The NMP has four central objectives based on active and respectful partnerships, taking into account elements of social and economic policy. (The NMP can be accessed at [www.health.gov.au](http://www.health.gov.au))

These objectives are:

- timely access to medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The industry undertakes:

- to provide medicines that conform to the highest standards of safety, efficacy and quality;
- to ensure that medicines are supported by comprehensive technical and information services in accordance with currently accepted medical and scientific knowledge and experience;

- to use professionalism in dealing with our NMP partners including healthcare professionals\*, public health officials and consumers\*; and
- to promote the quality use of medicines and principles within the *National Strategy for Quality Use of Medicines*.

The strategy offers an evidence-based collaborative, systems based approach to optimising health and resource outcomes wherever medicines are used.

The industry is committed to the quality use of medicines and rational prescribing, and strongly recommends that its products be used only in accordance with the directions and advice of healthcare professionals. To ensure that information\* is available upon which to make informed prescribing decisions, it is necessary for companies to disseminate to healthcare professionals the specialised product information gained during the research and development process, and from experience gained in clinical use. In doing so, the company draws attention to the existence and nature of a particular product\* by appropriate educative and promotional measures.

With the full cooperation of the industry, there is adequate legislation designed to safeguard the public by ensuring that all products marketed meet standards of safety, quality and efficacy which are acceptable in the view of present knowledge and experience.

While it is possible to legislate satisfactorily for the testing, manufacture and control of medical products, appropriate standards of marketing conduct cannot be defined by the same means. For this reason, responsible manufacturers have concurred in the promulgation of the Code of Conduct and submitted to its constraints.

A Member\* of Medicines Australia undertakes to comply with the Objects, the Rules\* and the Code of Conduct of the Association\*.

Complaints against any activity of a company\* should be made to the Chief Executive Officer\* or his or her delegate, as provided for in the Code (Section 11 and Appendix 1).

It should be noted that the Therapeutic Goods Administration\* (TGA) requires that promotional material (other than Product Information\*) for registered goods must comply with the requirements of the Code of Conduct and hence complaints can be made against non-Medicines Australia member companies (see Section 11.4).

**If you are considering lodging a Code of Conduct complaint but are unsure of how to go about it, please contact Medicines Australia on (02) 6282 6888 for assistance. A 'Complaints Submission Form' for non-industry complainants is also available on the Medicines Australia website at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)**

**Note:**

A glossary of terms is provided at page 206. The first inclusion in each section of the Code of a word or term defined in the glossary is underlined and denoted by an asterisk (\*).

## Preamble

- (a) This Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation. The Code owes its origin to the determination of Medicines Australia to secure universal acceptance and adoption of high standards in the marketing of prescription medicines for human use.

It is the responsible role of members of the pharmaceutical industry to provide on-going, objective and scientifically valid interpretations of data on prescription medicines to healthcare professionals. The industry also has an obligation to provide appropriate non-promotional information on prescription medicines to members of the general public. The Code provides the standard for the provision of this information.

- (b) It is also the responsibility of members of the pharmaceutical industry to be fully cognisant of the *Advertising Principles* from the Therapeutic Products Advertising Code\* (TPAC)

### Principle 1

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

### Principle 2

Advertisements must be truthful, balanced and not misleading.

Claims must be valid and have been substantiated.

### Principle 3

Advertisements must observe a high standard of social responsibility.

- (c) Acceptance and observance of the Code is a condition of membership of Medicines Australia. In accepting and observing the Code companies must comply with both the letter and the spirit of the Code.

Companies should ensure that all agents acting on their behalf are fully conversant with the provisions of this Code.

Pharmaceutical companies which are not members of Medicines Australia are invited to accept and observe this Code and must comply with its provisions when required by the Therapeutic Goods Administration.

The Code shall be supervised and administered by the Board of Medicines Australia. Medicines Australia may issue determinations from time to time for the purpose of interpretation of certain sections of the Code. Complaints concerning alleged breaches of the Code should be reported to the Chief Executive Officer of Medicines Australia or his or her delegate.

Medicines Australia is also responsible for proposing amendments to the content of the Code of Conduct for adoption by its membership. Medicines Australia consults widely within the pharmaceutical industry and with external stakeholders regarding the Code of Conduct and welcomes comments or suggestions that will improve the Code's content and operation. Comments can be provided to Medicines Australia either by phone on (02) 6282 6888 or email at [secretarycodecommittee@medicinesaustralia.com.au](mailto:secretarycodecommittee@medicinesaustralia.com.au)

- (d) A major guiding principle of the Code is that, whenever a promotional claim\* is made for a product, it shall be accompanied by appropriate information based on the Product Information\* for that product.

- (e) The Code also reflects the industry's commitment that all activities with, or materials provided to healthcare professionals and 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.
- (f) Failure to comply with the Code will result in sanctions being applied under the provisions of Section 12. Adherence to this Code in no way reduces a company's responsibilities to comply with the Trade Practices Act, Commonwealth and State Therapeutic Goods Acts and other requirements, legislation and Codes, including the IFPMA\* Code. It should be recognised that the Medicines Australia Code is based upon the provisions of the IFPMA Code. Promotion\* of prescription-only products to the general public is prohibited by law.

## PROVISIONS OF THE CODE

### 1. Nature and Availability of Information and Claims

#### 1.1 Responsibility

It is the responsibility of companies, their employees and advisers to ensure that the content of all promotional and medical claims is balanced, accurate, correct\*, fully supported by the Product Information\*, literature\* or "data on file"\* or appropriate industry source, where these do not conflict with the Product Information.

Activities of company representatives\* must comply with the Code at all times.

#### 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.

## EXPLANATORY NOTES

- 1.1 This responsibility relates not only to the product being promoted, but to any information given or claims made about other products or disease states or conditions. It also applies to tag lines\* and their ability to be substantiated.

It is fundamental that any claim made must be consistent with the Australian Product Information document, irrespective of the source on which the claim is based.

- 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 registration 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.

## PROVISIONS OF THE CODE

### 1.2.2

#### **Level of Substantiating Data**

Any information used to support a medical claim\* 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

### 1.2.2

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 with the current body of evidence and where (eg peer reviewed journal or pay journal\*) or whether it has been published.

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

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

## PROVISIONS OF THE CODE

### 1.3 False or Misleading Claims

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

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 TGA must not be promoted. However, starter packs\* 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 that 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 TGA.
- (e) Shortening an approved indication (eg in a by-line) so as to remove a qualification or limitation to the indication.

## PROVISIONS OF THE CODE

### 1.4 **Good Taste**

All promotional and educational material (including graphics and other visual representations) must conform to generally accepted standards of good taste and recognise the professional standing of the recipients.

These materials must not contain anything that would be likely to cause serious or widespread offence taking into consideration prevailing community standards.

### 1.5 **Unqualified Superlatives**

Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique\* or has some special merit, quality or property unless this can be substantiated.

The word "safe" must not be used without qualification.

### 1.6 **New Products**

The word "new" must not be used to describe any product, presentation, or therapeutic indication that has been available and promoted for more than 12 months in Australia.

## EXPLANATORY NOTES

### 1.3 (cont...)

- (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 do 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, that, to the casual reader could produce an incorrect perspective. The type size used for qualifying statements must not be less than 2mm as measured by the height of the font's lower case "e". 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. To facilitate easy reading, a clear style of typeface must be used with adequate space between lines. Legibility is impaired by use of "condensed" or "narrow" fonts; by use of upper case letters only; or by use of half-tone rather than solid print.
- (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 in a manner that alters the original author's meaning.
- (j) Use of overseas Product Information to support a claim where that information is inconsistent with the Australian Product Information.

## **PROVISIONS OF THE CODE**

## EXPLANATORY NOTES

- (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 TGA 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.

**1.5** Although in some circumstances "unique" may be used to describe some clearly defined special feature of a medicine, in many instances it may be taken as implying a general superiority. In such instances this is unacceptable unless the claim can be supported in every respect.

Use of the definite article to imply a special merit, quality or property for a medicine is unacceptable under this clause if it cannot be substantiated. For example, a claim that a product is "The analgesic" implies that it is in effect the best, and might not be acceptable under this clause.

## **PROVISIONS OF THE CODE**

### **1.7 Comparative Statements**

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. Comparison of products must be factual, fair and capable of substantiation and referenced to its source; and must not be disparaging. "Hanging" comparatives - those that 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.

### **1.8 Imitation**

Promotional information should not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse.

## 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; and
- the data must not be used to generalise or to indicate superiority or inferiority.

The statement that the difference 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 as measured by the height of the font's lower case "e".

## **PROVISIONS OF THE CODE**

- 1.9        Medical Ethics**  
Healthcare professionals' names or photographs must not be used in any way that is contrary to professional ethics.
- 1.10      Distinction of Promotional Material**  
Promotional material must be clearly distinguishable as such.

## EXPLANATORY NOTES

### Section 1.7 cont'd

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

- 1.9** Wherever a healthcare professional's name is specified in any kind of promotional material, other than by citation of a published reference, the company should ensure that the individual specified is aware of and provides written approval for the use of his/her name in the context of the entire promotional material. For example, if a doctor agrees to introduce an educational video, they should be fully aware of the final content of that video, as such a situation would imply endorsement.

The company should also obtain written approval from the individual if his/her name is used in subsequent promotional material.

- 1.10** Advertisements in a journal\* should not be designed to resemble editorial matter unless clearly identified as an advertisement. See Sections 3.4 and 3.5.

## PROVISIONS OF THE CODE

### 2. **Types of Product Information\***

Certain types of promotional material described in Section 3 must include or be accompanied by Product Information, Abridged Product Information or Minimum Product Information.

Wherever required, Product Information, Abridged Product Information or Minimum Product Information must appear on a plain background sufficiently contrasting for legibility. Major headings should be easily identifiable. To facilitate easy reading, a clear style of typeface must be used with adequate space between lines. Legibility is impaired by use of "condensed" or "narrow" fonts; by use of upper case letters only; or by use of half-tone rather than solid print.

Product Information, Abridged Product Information or Minimum Product Information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance\* (See Section 2.4).

#### 2.1 **Product Information**

2.1.1. The size of the type for this Product Information must not be less than 1 mm as measured by the height of the font's letter "e".

2.1.2 Where a Product Information document has been approved by the TGA, that document must be used in full without alteration unless such alteration is approved by the TGA. When used to accompany promotional material, it should appear under the heading "*Approved Product Information*".

2.1.3 Where a Product Information document has not been approved by the TGA, the document must comply with the format described in the Australian Registration Guidelines for Prescription Medicines. When used to accompany promotional material, it should appear under the heading "*Full Product Information*".

## **EXPLANATORY NOTES**

- 2.** To facilitate easy reading, a clear style of typeface must be used with adequate space between lines. Legibility is impaired by use of "condensed" or "narrow" faces; by use of upper case letters only; or by use of half-tone rather than solid print. Dark print on a light background is preferable.

The date on which Product Information was approved and/or last updated must be included.

- 2.1.3** The Product Information documents for some "grandfather" products have not been evaluated by the TGA. However, such documents can be subjected to review by the TGA if considered necessary, for example on safety grounds. Any complaints received about the content of such documents may be referred to the TGA.

## PROVISIONS OF THE CODE

### 2.2 Abridged Product Information

2.2.1 The size of the type for Abridged Product Information must not be less than 1 mm as measured by the height of the font's lower case letter "e".

2.2.2 Abridged Product Information must accurately reflect the Product Information but may be a paraphrase or précis of the Product Information.

2.2.3 Under the heading "Abridged Product Information", the following shall appear:

- (a) the approved indications for use;
- (b) contraindications;
- (c) clinically significant warnings;
- (d) clinically significant precautions for use;
- (e) clinically significant adverse events and interactions;
- (f) available dosage forms;
- (g) dosage regimens and routes of administration;
- (h) dependence potential of clinical significance;
- (i) reference to special groups of patients (including Australian pregnancy categorisation if issued); and
- (j) boxed warnings\*.

Where the Product Information does not include information relevant to these headings, such information is not required to be included in the document.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 2.3 Minimum Product Information

- 2.3.1 The size of the type for Minimum Product Information must not be less than 1.5 mm as measured by the height of the font's lower case letter "e".
- 2.3.2 The Minimum Product Information must include the following information within the body of the advertisement or item of printed promotional material:
- (a) the approved indication/s together with the dosage and method of use;
  - (b) a succinct statement of the contraindications, precautions and side effects, including any boxed warnings that may appear in the Product Information;
  - (c) a clear and unambiguous statement for prescribers to review the Product Information before prescribing; and
  - (d) a statement to the effect that Product Information is available on request from the company.

### 2.4 Changes of Clinical Significance\* and the addition of a Boxed Warning\*

- 2.4.1 Where a change of clinical significance and in particular the addition of a boxed warning is incorporated into the Product Information, it should be indicated in all representations of the Product Information for a period of 12 months from the date of change by an asterisk(s) to a footnote in type size of not less than 2mm as measured by the height of the font's lower case "e".

Please note change(s) in Product Information

- 2.4.2 The full text of the changed section should be included in any abridged Product Information during this period.
- 2.4.3 Consideration should be given to providing written advice of the change to Product Information to the appropriate healthcare professionals.

## **EXPLANATORY NOTES**

**2.3.2 (b)**      Precautions includes interactions

## PROVISIONS OF THE CODE

### 3. **Promotional Material\***

For products that have a "Boxed Warning\*\*" included in their Approved Product Information\*, all promotional material\* must include the Boxed Warning or include a prominent statement drawing attention to the Boxed Warning.

In addition, all promotional material covered by Sections 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8, 3.9 and 3.10 must include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (PBS)\* listing and restrictions or its non-availability via the PBS.

#### 3.1 **Journal Advertising**

Journal Advertising must conform with the requirements of one of the following categories. The information required for Sections 3.1.1, 3.1.2 and 3.1.3 must appear in each publication in a type size of not less than 1.5 mm as measured by the height of the font's lower case "e" and should appear on a plain background sufficiently contrasting for legibility. The orientation of the text should be the same as that of the main text of the advertisement.

##### 3.1.1 **Primary advertisement\***

3.1.1.1 A Primary advertisement may contain promotional claims that conform to the requirements of Section 1 of this Code.

3.1.1.2 A Primary advertisement is the type of advertisement that is mandatory for advertising of all new chemical entities or the advertising of new indications for 24 months from the date of first advertising in medical publications, or longer at the discretion of the company. Primary advertisements must also be used for at least 12 months following a change of clinical significance made to a product's Product Information.

## EXPLANATORY NOTES

3. Any limitations to the terms of PBS listing should be clearly disclosed and easily identifiable by a reader. No attempt should be made to minimise this disclosure as it should be a prominent feature of any promotional material and a genuine communication vehicle to advise prescribers of this important information. The disclosure of this information must accurately reflect the current PBS listing but may be a paraphrase or précis of that information. Other funding information can be added to the body of the promotional item eg National Immunisation Program

To facilitate easy reading, a clear style of typeface must be used with adequate space between lines. Legibility is impaired by use of "condensed" or "narrow" fonts; by use of upper case letters only; or by use of half-tone rather than solid print.

To satisfy the requirements of this section the requirements for the disclosure of this information can be found in the current edition of the Code of Conduct Guidelines.

- 3.1 Care should be taken to ensure that where an advertisement consists of a double sided or multiple page copy, the information contained on each individual page is not false or misleading when read in isolation.

- 3.1.1.2 (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the brand name.

- 3.1.1.2. (d) See preamble to Section 3 and its Explanatory Note

## PROVISIONS OF THE CODE

**3.1.1.3** A Primary advertisement must contain the following information within the body of the advertisement:

- (a) the brand name\* of the product;
- (b) the Australian Approved Name(s) of the active ingredient(s);
- (c) the name of the supplier and the city, town or locality of the registered office;
- (d) all PBS listings, including any restrictions, as required in the preamble to Section 3;
- (e) either the Product Information or the Abridged Product Information or the Minimum Product Information;
- (f) a clear and unambiguous statement for prescribers to review the Product Information before prescribing; and
- (g) for products listed on the PBS, the current PBS dispensed price\*. If a specific indication is being promoted the price or prices relevant to this indication should be disclosed. If no specific indication is being promoted the price of all presentations should be listed.

**3.1.1.4** If the Minimum Product Information is contained in the body of a Primary advertisement, the Product Information or Abridged Product Information may also be printed in the journal with the Primary advertisement. If the Product Information or Abridged Product Information is printed in the journal, it should be placed adjacent to the advertisement. Where this placement is not practical, the advertisement must include the following statement in a type size not less than 2 mm as measured by the height of the font's lower case "e":

## EXPLANATORY NOTES

- 3.1.1.2 (f) Companies are encouraged to refrain from using the mandatory declaration of PBS prices in a comparative manner as simple comparisons are fraught with difficulty and may ignore complexities such as daily treatment costs or average dose costs that are not encompassed by the PBS price. Simple comparisons, without adequate explanation or clarification, could be considered misleading.

- 3.1.1.3 The wording used to direct the reader to the location of Product Information may be varied but must contain a direction to review the Product Information before prescribing the product.

Loose leaf inserts will not satisfy the requirements of this section.

Section 3.1.1.3 requires that one form of product information must be included within the body of a Primary advertisement. This must be the Product Information, the Abridged Product Information or the Minimum Product Information.

If the Minimum Product Information is included in the body of a Primary advertisement, this does not preclude a company from also printing the Product Information or Abridged Product Information in the journal if it so chooses. The Product Information or Abridged Product Information should be placed adjacent to the Primary advertisement, to assist healthcare professionals to easily refer to this information. If the Product Information or Abridged Product Information cannot be placed adjacent to the Primary advertisement, the advertisement must include a direction to the location of this information as described in Section 3.1.1.4.

## **PROVISIONS OF THE CODE**

### **Section 3.1.1.4 (cont'd)**

"Please review Product Information before prescribing. In this publication, Product Information can be found ...."

At the point ..., insert the page number in the publication where the information can be found or reference to an adequately referenced Product Information section or advertisers index.

Product Information in any form should form a fixed part of the journal.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 3.1.2 Secondary advertisement\*

3.1.2.1 A Secondary advertisement is designed to reinforce information about a product, and may contain promotional claims. The use of a Secondary advertisement in any issue of a publication that does not also contain a Primary advertisement is not permitted.

3.1.2.2 A Secondary advertisement must contain the following information within the body of the advertisement:

- (a) the brand name of the product;
- (b) the Australian Approved Name(s) of the active ingredient(s);
- (c) the name of the supplier and the city, town or locality of the registered office;
- (d) all PBS listings, including any restrictions, as required in the preamble to Section 3 or reference to the Primary advertisement;
- (e) a clear and unambiguous statement for prescribers to review the Product Information before prescribing; and
- (f) a reference to the location of the Primary advertisement or the Product Information index or advertisers index

Product Information should form a fixed part of the journal.

## **EXPLANATORY NOTES**

**3.1.2.2** (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the brand name

**3.1.2.2.** (d) See preamble to Section 3 and its Explanatory Note

## PROVISIONS OF THE CODE

### 3.1.3 Short advertisement\*

3.1.3.1 A Short advertisement is designed to remind a prescriber of a product's existence but must not contain promotional claims. The sole use of a Short advertisement in any one issue of a publication that does not also contain a Primary advertisement is not permitted:

- for 24 months from first advertising of a new chemical entity; or
- for 12 months following a change of clinical significance made to the Product Information.

3.1.3.2 A Short advertisement must contain:

- (a) the brand name of the product;
- (b) the Australian Approved Name(s) of the active ingredient(s);
- (c) the name of the supplier and the city, town or locality of the registered office;
- (d) all PBS listings, including any restrictions, as required in the preamble to Section 3 or reference to the Primary advertisement where it is located in the same publication; and
- (e) a statement to the effect that further information is available on request from the supplier.

3.1.3.3 A Short advertisement may contain:

- (a) up to 5 words describing therapeutic class\*, but without the use of promotional phrases;
- (b) graphics;
- (c) a statement of available dosage forms;

## **EXPLANATORY NOTES**

**3.1.3.1** A promotional tagline may not be used in a Short advertisement

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

**3.1.3.2.** (d) See preamble to Section 3 and its Explanatory Note

## **PROVISIONS OF THE CODE**

### **Section 3.1.3.3 cont'd**

- (d) a statement referring to the location of Product Information in a reference manual; and
- (e) the website address of the company.

No other material is permitted.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### **3.1.4      Company commissioned articles\***

- 3.1.4.1**      Company commissioned articles must be identified as such in a type size of not less than 2 mm as measured by the height of the font's lower case "e".
- 3.1.4.2**      The company which is responsible for the insertion of the company commissioned article must be clearly identified at either the top or the bottom of the company commissioned article in a type size of not less than 1.5mm as measured by the height of the font's lower case "e".
- 3.1.4.3**      Company commissioned articles must conform to all relevant provisions of Section 1 of this Code.
- 3.1.4.4**      Statements by third parties, which are quoted in company commissioned articles, must comply with the requirements of this Section, particularly the requirements of Section 1 of the Code.
- 3.1.4.5**      Where promotional claims are made in company commissioned articles, the article must comply with the requirements for a Primary (Section 3.1.1) or Secondary advertisement (Section 3.1.2).

### **3.2            Reference Manual\* Advertising**

The Australian Prescription Product Guide and MIMS currently satisfy the criteria for reference manuals. For the purposes of this section, MIMS Annual, its Supplements and bi-monthly edition are regarded as one reference manual.

#### **3.2.1            Primary advertisement - reference manuals**

Primary advertisements in reference manuals shall conform to the requirements of Sections 3.1.1.3 (a), (b), (c) and (d) of the Code. These advertisements must also include reference to the product's Therapeutic Class Number or to the page number on which the relevant Product Information is located.

## **EXPLANATORY NOTES**

### **3.1.4**

**Company Commissioned articles (sometimes known as advertorials)**

Independently edited supplements which publish the proceedings of a recognised congress\* are not considered as Commissioned Articles.

### **3.1.4.5**

The requirements for a Secondary advertisement would apply where there is a Primary advertisement elsewhere in the publication.

## **PROVISIONS OF THE CODE**

### **3.2.2**

#### **Short advertisement - reference manuals**

Short advertisements in reference manuals shall correspond to the requirements of Section 3.1.3 of the Code.

## **EXPLANATORY NOTES**

## **PROVISIONS OF THE CODE**

### **3.3 Printed promotional material**

Printed promotional material whether handed directly to a healthcare professional or transmitted by mail or other means must conform with the requirements of one of the following categories. The information required for Sections 3.3.1, 3.3.4 and 3.4 must appear in each publication in a type size of not less than 1.5 mm as measured by the height of the font's lower case "e" and should appear on a background sufficiently contrasting for legibility. The orientation of the text should be the same as that of the main text of the item of printed promotional material.

**3.3.1** All printed promotional material to be provided to a healthcare professional must include the following information within the body of the item:

- (a) the brand name of the product;
- (b) the Australian Approved Name(s) of the active ingredient(s);
- (c) the name of the supplier and the city, town or locality of the registered office;
- (d) all PBS listings, including any restrictions, as required in the preamble to Section 3.
- (e) Minimum Product Information (Section 2.3); and
- (f) a clear and unambiguous statement for prescribers to review the Product Information before prescribing in a font size of not less than 2mm as measured by the height of the font's lower case "e".

**3.3.2** The use of 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.

## **EXPLANATORY NOTES**

**3.3** To cover requirements for PBS disclosure information and Product Information, please refer to section 2 and the Code Guidelines

**3.3.1** This section applies to items such as leave behinds, detail aids, retained sales aids, leaflets and other materials prepared by companies based on the available literature and intended for distribution to healthcare professionals, which contain promotional claims.

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

**3.3.1** (d) See preamble to Section 3 and its Explanatory Note

**3.3.2** Where multiple forms of promotion items are intended to be distributed at one time, the Product Information or Abridged Product Information must be included or offered at least once.

## **PROVISIONS OF THE CODE**

### **Section 3.3.2 cont'd**

During this period a copy of the Product Information must be offered to all healthcare professionals, or in the case of mailed materials provided with the item of printed promotional material. Abridged Product Information may be used subsequent to that period.

**3.3.3** Where an item of printed promotional material is demonstrated, on completion of the presentation, the Product Information or Abridged Product Information must be offered to the individual reviewing the promotional material or, in a group situation, to the audience.

**3.3.4** All printed promotional material intended for display purposes only must include the following information:

- (a) the brand name of the product;
- (b) the Australian Approved Name(s) of the active ingredient(s);
- (c) the name of the supplier and the city, town or locality of the registered office;
- (d) all PBS listings, including any restrictions, as required in the preamble to Section 3;
- (f) a clear and unambiguous statement for prescribers to review the Product Information before prescribing in a font size of not less than 2mm as measured by the height of the font's lower case "e".

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

## EXPLANATORY NOTES

### 3.3.4

This Section applies to items such as trade display banners, panels, posters and other materials prepared by companies based on the available literature and intended for display to healthcare professionals, which contain promotional claims.

- (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the brand name. For large items the Australian Approved Name must appear in a size that can be easily viewed.
- (d) See preamble to Section 3 and its Explanatory Note
- (f) For larger items, this statement to review the Product Information before prescribing should be enlarged to a size that can be easily viewed from a comfortable distance.

## **Provisions of the Code**

### **3.4      Mailings\***

- 3.4.1**      Mailings must comply with all relevant provisions of Section 1 of this Code and Australia's Privacy Legislation\*.
- 3.4.2**      The Product Information or Abridged Product Information as applicable must be included in all mailings where promotional claims are made.
- 3.4.3**      The use of 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 Product Information may be used subsequent to that period.
- 3.4.4**      Mailings should 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 healthcare 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.
- 3.4.5**      Mailing lists should be kept up-to-date.
- 3.4.6**      Exposed mailings including postcards, envelopes or wrappers must not carry matter that might be regarded as promotion to the general public or that could be considered unsuitable for public view.
- 3.4.7**      Any accompanying material sent with a mailing must comply with the requirements of the Code of Conduct as a stand-alone item.
- 3.4.8**      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

- 3.4.4** 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 must comply with Section 1.

- 3.4.6** The display of a product's brand name or Australian Approved Name alone on mailings directed towards healthcare professionals or members of the general public enrolled in a Patient Support Program is not considered as promotion to the general public in these contexts.

- 3.4.7** For example a brand name reminder\* may be included with a mailing but must comply with the requirements of Section 3.12.as a stand-alone item in order to satisfy this Section.

- 3.4.8** See preamble to Section 3 and its Explanatory Notes.

## **Provisions of the Code**

### **3.5**

#### **Document Transfer Media**

Unsolicited electronic transmissions or replicas thereof must not be used for promotional purposes.

## **EXPLANATORY NOTES**

- 3.5** Items suggesting a requirement for urgent attention, whether by general mailing or by replicas of urgent media are not acceptable for promotional purposes.

Electronic transmissions encompass the use of facsimiles and electronic mail.

## **PROVISIONS OF THE CODE**

### **3.6        Audiovisual promotional material**

**3.6.1**        All audiovisual promotional material must include or be accompanied by the following information:

- (a)    the brand name of the product
- (b)    the Australian Approved Name(s) of the active ingredient(s)
- (c)    the name of the supplier and the city, town or locality of the registered office
- (d)    all PBS listing, including any restrictions, as required in the preamble to Section 3
- (e)    Product Information or Abridged Product Information

**3.6.2**        The use of 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 Product Information may be used subsequent to that period.

**3.6.3**        Where an audiovisual item is demonstrated, on completion of the presentation, the Product Information or Abridged Product Information must be offered to the audience.

## **EXPLANATORY NOTES**

**3.6** This section applies to CD ROMs, DVDs, audiotapes and videotapes for private use by healthcare professionals or for demonstration purposes to groups of healthcare professionals.

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

**3.6.1** (d) See preamble to Section 3 and its Explanatory Note

**3.6.1** (e) See Sections 2.1 and 2.2

## **PROVISIONS OF THE CODE**

### **3.7 Company Computer Promotional Material**

- 3.7.1** Computer based promotional material must comply with all relevant provisions of Section 1 of this Code.
- 3.7.2** Where an individual product is being promoted the appropriate Product Information must be offered to an individual reviewing the promotional material, readily accessible via the computer based material or offered to an audience in a group situation on completion of the presentation.
- 3.7.3** Where the Product Information is included in interactive data systems, instructions for accessing it must be clearly displayed.
- 3.7.4** Where promotional or medical claims are included in the computer based promotional material, details of the substantiating references must be readily accessible via the computer based promotional material.
- 3.7.5** All PBS listings, including any restrictions, as required in the preamble to Section 3 must be displayed within the promotional material to allow a prescriber to read and understand this information.
- 3.7.6** The type size and graphics used in all promotional material must be such that allows easy and clear legibility.

## **EXPLANATORY NOTES**

### **3.7 Company Computer Promotional Material**

As a minimum, this section covers the following:

Promotional material designed by companies to promote their products directly to healthcare professionals and includes such promotional tools as software programs used by company representatives during interchanges with healthcare professionals.

## **Provisions of the Code**

### **3.8 The Internet**

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 healthcare professionals. However, the promotion of products covered by the Code of Conduct to the general public via the Internet would breach Sections 9.4 and 9.6 of the Code and the Commonwealth Therapeutic Goods Legislation which stipulates that prescription medicines must not be promoted to the public.

**3.8.1** Promotional material on products covered by this Code must be accessible only to healthcare professionals.

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

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

**3.8.4** 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. Further information relevant to the Australian environment is available from the company or via the Product Information."

## **Explanatory Notes**

- 3.8** See the current Code of Conduct Guidelines for examples of the application of this Section.

- 3.8.4** Where references to other information 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.

### **Provisions of the Code**

- 3.8.5** Where a company's Internet site includes information regarding a product, the address and identity of the company should be provided.
- 3.8.6** The intended audience should be readily apparent on the site.
- 3.8.7** It should be made clear when the reader is leaving the site or being directed to a site that the company has not developed.
- 3.8.8** It is appropriate for companies to link their sites to the text of the Code of Conduct on the Medicines Australia 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 healthcare professionals on the Code of Conduct and the standards it sets.

## **Explanatory Notes**

## **PROVISIONS OF THE CODE**

### **3.9 Advertising in Electronic Prescribing Software Packages**

The following provisions are applicable to advertisements included in electronic prescribing software packages. Advertisements for products covered by this Code can be included in electronic prescribing software.

**3.9.1** A company must ensure that no advertisements are placed with clinical tools or patient education materials which may be used by a prescriber for consultation or discussion with a patient.

**3.9.2** A company shall not negotiate or accept any offer from a software manufacturer to achieve a trigger or mechanism that results in the preferential presentation of its own product or a less favourable presentation of a competitor's product in a way that would directly influence a prescriber's choice.

#### **3.9.3 Primary Advertisements specific to Prescribing Software**

Primary advertisements may contain promotional claims. Primary advertisements must contain:

- (a) the brand name of the product
- (b) the Australian Approved name (s) of the active ingredient(s)
- (c) the name of the supplier
- (d) all PBS listings, including any restrictions as required in the preamble to Section 3
- (e) a clear and unambiguous statement for prescribers to review the Product information before prescribing
- (f) identification and details of substantiating references within the body of the Primary advertisement or accessible via a hyperlink or similar mechanism

## **Explanatory Notes**

**3.9.1** When evaluating whether a clinical tool may be shown to and used in a consultation with a patient, a company should consider the language used (for example whether it is directed to the patient) and the content of the material. No advertisements should be included with Consumer Medicine Information or Patient Education material.

**3.9.2** The instruction to review the Product Information before prescribing may be displayed within the Primary or Short advertisement or immediately adjacent to it in the dialogue box in which the Primary or Short advertisement appears.

**3.9.3** Access to the approved Product Information may be provided through a hyperlink or similar mechanism embedded within the advertisement or through a button linking to a database of Product Information documents within the software.

Medicines Australia also encourages the electronic availability of Consumer Medicine Information via prescribing software packages.

## PROVISIONS OF THE CODE

- (g) a statement to the effect that further information is available on request from the supplier

### 3.9.4 Short advertisements specific to Prescribing Software

Short advertisements must not contain promotional claims. Short advertisements must contain:

- (a) the brand name of the product
- (b) the Australian Approved name (s) of the active ingredient(s)
- (c) a clear and unambiguous statement for prescribers to review the Product information before prescribing
- (d) all PBS listings, including any restrictions, as required in the preamble to Section 3

3.9.5 Primary and Short advertisements must provide easy access to the Australian Product information for the product being advertised.

3.9.6 Graphics contained within Primary and Short advertisements must not be such as to cause any offence, alarm or concern.

3.9.7 The type size and graphics used in Primary and Short advertisements must be such that allows easy and clear legibility having regard to sizes and resolution standards of screens likely to be used and contrast between text and background.

3.9.8 Consistent with current printed reference manual advertising, it is acceptable for software prescribing packages to display, at random, Primary or Short advertisements for products in the therapeutic class being reviewed.

3.9.9 Lists of products may be provided in the prescribing window, in alphabetical order, by brand name, by generic name or both.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 3.10 Restricted Access Television Advertising

**3.10.1** Television Advertising is permitted for transmissions restricted to an audience of healthcare professionals. Television advertising must comply with all relevant provisions of Section 1 of this Code. Following the promotion, the following items must appear on one screen and are mandatory for all television advertisements irrespective of the other content of that advertisement or the length of time that the product has been advertised.

- (a) the brand name of the product;
- (b) the Australian Approved Name(s) of the active ingredient(s);
- (c) the name of the supplier and the city, town or locality of the registered office;
- (d) all PBS listings, including any restrictions, as required in the preamble to Section 3.
- (e) a statement to the effect;

"Please review Product Information before prescribing. Product Information and substantiating references can be obtained from (the company) or by phoning (Telecaster's phone number)."

## **EXPLANATORY NOTES**

**3.10** The provisions of the Code as they apply to Primary advertisements (Section 3.1.1) should be applied to medical television advertising.

However, as it is not practical to display the Product Information or Abridged Product Information in conjunction with a television advertisement the use of a screen containing mandatory information is required.

**3.10.1** (d) See preamble to Section 3 and its Explanatory Note

## **PROVISIONS OF THE CODE**

- 3.10.3** The type face must be clearly legible and appear on a contrasting background. The background may contain a pack or product photograph but no other graphics.
- 3.10.4** The mandatory items must appear on screen for not less than 10 seconds unless the words are concurrently spoken at a clearly audible rate in a shorter time.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 3.11 Gifts/Offers

No items or services shall be offered or given to family members or employees of healthcare professionals. No items or services shall be offered or given to healthcare professionals unless they are sanctioned by one of the following sections of this Code:

- (a) Section 3.12 Brand Name Reminders
- (b) Section 3.13 Competitions
- (c) Section 6 Involvement in Educational Symposia, Congresses and Satellite Meetings
- (d) Section 7 Sponsorship
- (e) Section 10.2 Hospitality
- (f) Section 10.3 Medical Educational Material

### 3.12 Brand name reminders\*

#### 3.12.1 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); and
- (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

## EXPLANATORY NOTES

- 3.12** An individual brand name reminder should 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.

Only items that are relevant to the working environment of a healthcare professional (that is in a doctor's surgery, practice, consulting rooms or institutional environment) are suitable as brand name reminders. Items that are more likely to be regarded as being for use in the home or for recreational activities are unacceptable.

For further explanation regarding the application of this Section please refer to the current edition of the *Code of Conduct Guidelines* available on the Medicines Australia website [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au).

- 3.12.1** (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the brand name.

## **PROVISIONS OF THE CODE**

- 3.12.2** Brand name reminders must not contain any promotional claims including promotional tag lines and/or statements.
- 3.12.3** Brand name reminders will be acceptable only if it is possible to clearly and legibly display the product's brand name and Australian Approved Name(s) of the active ingredient(s).
- 3.12.4** 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 3.12.1 that brand name reminder must not be used for that product.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 3.13 Competitions\*

#### 3.13.1 Competitions must fulfil all of the following criteria:

- (a) the competition is based entirely on medical knowledge or the acquisition of medical knowledge;
- (b) the prize is directly relevant to the practice of medicine or pharmacy; and
- (c) individual prizes offered are of low monetary value or an item of educational material.

#### 3.13.2 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.

#### 3.13.3 The conduct of competitions shall comply in all respects with relevant Commonwealth and State regulations.

## EXPLANATORY NOTES

- 3.13** Competition questions must be designed to increase medical knowledge in a therapeutic area, be appropriately referenced, and have answers must be clear and unambiguous. The number and difficulty of questions used in a competition must also reflect the value of the competition prize. The value of prizes permitted to be used in competitions needs to be assessed on an individual basis.

Competitions for the same product with high value prizes within a calendar year would constitute a breach of the Code.

There must be an appropriate process for determining the winner, initially on the basis of correct answers and subsequently by a process of chance. Competitions must be clearly separate from market research surveys and starter pack requests.

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

For further information regarding the application of this Section please refer to the current *Code of Conduct Guidelines*.

## PROVISIONS OF THE CODE

### 4. Company Representatives\*

- 4.1 All material for use by company representatives must conform with the provisions of Section 3 of this Code. Verbal statements made regarding a product must also comply with the provisions of Section 1 of this Code.
- 4.2 Companies have a responsibility to maintain high standards of ongoing training for company representatives.
- 4.3 Company representatives should possess sufficient medical and technical knowledge to present information on the company's products in a current, accurate and balanced manner and should be cognisant of all provisions of this Code.
- 4.4 Company representatives should at all times maintain a high standard of ethical conduct and professionalism in the discharge of their duties.
- 4.5 It is the responsibility of company representatives visiting a hospital or other institution to make themselves aware of all hospital policies, including operating theatre procedures and conduct their business accordingly.
- 4.6 Companies should ensure that company representatives have a thorough knowledge of Australia's Privacy Legislation\* and its implications for their role.
- 4.7 Company representatives must not employ any deception to gain an appointment.
- 4.8 Company representatives should ensure that the frequency, timing and duration of appointment, together with the manner in which they are made, are such as not to cause inconvenience to the healthcare professional\*. The wishes of an individual healthcare professional, or the arrangements in force at any particular establishment, must be observed by company representatives.

## EXPLANATORY NOTES

4. Companies should ensure that company representatives are familiar with the provisions of the Code and Australia's Privacy Legislation. Particular attention is drawn to Section 3 on Promotional Material\*, Section 5 on Product Starter Packs\* and Section 6 on Involvement in Educational Symposia\*, Congresses\* and Satellite Meetings\* and Section 10 Relations with Healthcare Professionals.

- 4.3 The endorsed Medicines Australia education program provides sufficient background to satisfy the general requirements of this Section.

- 4.8 Detailing of healthcare professionals should not occur in an environment where promotional information could be easily overhead by members of the general public.

## PROVISIONS OF THE CODE

- 4.9 Company representatives including company agents must not use the telephone to promote products to healthcare professionals except with the consent of the healthcare professional.

Where information about a prescription product is provided to the healthcare professions via the telephone it must be undertaken in an appropriate and responsible manner so as not to cause any inconvenience or concern to the healthcare professional.

- 4.10 Wherever a promotional claim\* is made, the company representative must offer the current Product Information\* and must advise of all PBS listings and restrictions or make reference to them in any printed promotional material provided. Where multiple forms of promotion items are intended to be distributed at one time, the Product Information or Abridged Product Information should be offered at least once.

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

- 4.12 All medical representatives\* who have been employed in the Australian prescription pharmaceutical industry\* since April, 1983 are required to have completed or be currently undertaking an endorsed Medicines Australia education program for medical representatives.

## EXPLANATORY NOTES

- 4.10** Where promotional material is used during the appointment, the Product Information which is required by the Code to accompany that material is sufficient to satisfy this Section.

The disclosure of any PBS listing information should be clear and distinct. No attempt should be made to minimise any limitations to the terms of listing. The communication of PBS listing should be undertaken in a responsible manner to advise prescribers of this important information. The disclosure of this information may be via printed material that complies with the requirements of Section 3.

- 4.11** The provision of personal domestic type services and products to healthcare professionals, their families or practice staff would be a breach of this section. The provision of a meal, which complies with the requirements of Section 10, would not be a breach of this Section.

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

## **PROVISIONS OF THE CODE**

- 4.13** All medical representatives entering the Australian prescription pharmaceutical industry for the first time must enrol in the Code of Conduct component of the endorsed Medicines Australia education program within the first six months of employment and must complete the full program requirements for medical representatives within two years. .
- 4.14** Any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public (this includes Product Managers, medical, marketing or sales staff); or has direct interaction with healthcare professionals for the purpose of promoting a prescription medicine, whether part time or full time, must complete the Code of Conduct component of the endorsed Medicines Australia education program within the first twelve months of commencement of employment.

## EXPLANATORY NOTES

**4.13** No exemptions will be granted for the currently endorsed Medicines Australia education program as it has been designed to meet the needs of the Australian environment particularly those of healthcare professionals.

**4.14** The requirement to complete the Code of Conduct component of the endorsed Medicines Australia education program does not include Managing Directors, Clinical Research Associates, Medical Information or Corporate Affairs personnel unless these personnel are also responsible for the development, review and approval of promotional material and patient education material.

For further information on the application of this Section please refer to the current *Code of Conduct Guidelines*.

## PROVISIONS OF THE CODE

### 5. **Product Starter Packs\***

5.1 The distribution of Starter Packs must be carried out in a reasonable manner including compliance with product Conditions of Registration, which control the supply and storage conditions of products, and with QUM principles.

5.1.1 *[Who can supply]* Starter packs of products may only be supplied by representatives employed by the holder of a manufacturer's licence or wholesale dealer's licence.

5.1.2 *[Who can be supplied]* Starter Packs may only be supplied at their request to authorised healthcare professionals\*, including medical practitioners, dentists, veterinarians, hospital pharmacists and nurse practitioners. They may only be supplied when required for any of the following reasons:

- (a) for immediate use in the surgery for relief of symptoms;
- (b) for the use of alternative treatments, prior to a prescription being written;
- (c) for after hours use; or
- (d) for gaining familiarisation with products.

Distribution of Starter Packs in hospitals must comply with individual hospital requirements.

5.1.3 Authorised healthcare professionals may be supplied with Starter Packs of Schedule 4 medicines. The supply of Starter Packs of Schedule 8 medicines is prohibited under State and Territory legislation.

## **EXPLANATORY NOTES**

5. Companies should ensure that they are kept informed of any changes in Commonwealth and State laws concerning the supply of Starter Packs.

## PROVISIONS OF THE CODE

- 5.1.4 *[Size]* Starter Packs should not exceed 1/3 of the PBS primary quantity for each strength of a product. For non-PBS products, Starter Packs should be no larger than 1/3 of the smallest trade pack. Where it is not practical to produce a 1/3 pack, the smallest trade pack may be used.
- 5.1.5 *[Quantity supplied]* The maximum quantity of Starter Packs to be supplied to an authorised healthcare professional must be at the healthcare professional's discretion, and should reflect their needs until the next visit by their representative.
- 5.1.6 *[Quantity carried]* The maximum quantity carried by a representative (as described in Section 5.1) at any one time must be an amount that can be reasonably justified for supply to requesting healthcare professionals (as described in 5.2). A reasonable maximum quantity would be that required during the course of one business trip, lasting up to one working week. The quantity must be such that QUM principles and a meaningful level of accountability can be followed by the company represented.
- 5.1.7 *[Records that must be kept]* The representative must obtain a signed request from an authorised person, including the name & address of person supplied, name, strength and quantity of the substance supplied. The healthcare professional must write the quantity requested and sign the request/receipt form.

Starter Packs left with receptionists for the attention of the healthcare professional without a signed request will be in breach of the Code of Conduct.

Immediately upon supplying the Starter Pack(s), the representative must sign and date the request form to certify that the sample has been delivered.

Representatives must make a record of every sample received or supplied together with request forms, consignment notes, invoices and advice notes. Records should be made of the return and disposal of unwanted substances.

## EXPLANATORY NOTES

- 5.1.4** Examples of products where 1/3 may not be practical would include ear and eye drops, small aerosols, ampoules, products taken in a specific order where pack presentation dictates the order of taking of the product and packs of 15g or less of ointments and creams. Reasons such as cost or availability will not be accepted as being impractical.

Primary quantity means most commonly prescribed PBS quantity.

- 5.1.5** While the medical practitioner, dentist or hospital pharmacist are required to state the maximum number required, it is not mandatory for the company to supply that quantity. However, the company must not supply in excess of that stated by the medical practitioner, dentist or hospital pharmacist.

For further information on the application of this Section please refer to the current *Code of Conduct Guidelines*.

## PROVISIONS OF THE CODE

### 5.1.7 [Cont'd]

Companies must keep all records of the request, supply, return and disposal of Starter Packs for at least 3 years, in a way that they are available for inspection by appropriate authorities. Reconciliation of records should be carried out at least every three months.

Companies should develop an appropriate recording system so that if a product recall is necessary, relevant Starter Packs will be included in the recall.

### 5.1.8

*[Labelling]* Primary labelling of all Starter Packs distributed must comply with the current Therapeutic Goods Order on labelling. Where possible, the primary label should allow sufficient space for a dispensing label. In addition, the representative should supply adhesive labels, pre-printed with the fields 'Name and telephone number of Medical Practitioner', 'Name of Patient', 'Dosage Instructions' and 'Date', leaving sufficient space for these details to be entered by the medical practitioner. Alternatively, these fields may be pre-printed on the label.

*[PI, CMI]* Product Information\* and Consumer Medicine Information\*, when available, should be offered at the time of distribution or, in the case of CMI, included in the starter pack.

### 5.1.9

*[Transport and Storage]* Starter Packs must be transported and stored in a manner which maintains the storage conditions on the label.

### 5.1.10

*[Security]* Representatives must take adequate precautions to ensure the security of Starter Packs in their possession. When the Starter Packs are stored other than at a wholesaler, they must be stored in a lockable storage facility in accordance with Section 5.9.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 5.1.10 *[Cont'd]*

It may be necessary to send starter packs by mail to requesting parties, especially in the case of regional centres. When sent by mail or courier, Starter Packs must be packed so as to be reasonably secure against the package being opened by young children. When mail is used to forward Starter Packs, Registered Mail (or its equivalent) must be used. There must be nothing on the packaging which indicates the nature of the contents.

Loss or theft of Starter Packs must be reported immediately to the employer and the police.

Starter Packs must only be kept in a vehicle when it is being used in the course of business. Where substances are carried in a motor vehicle by an agent or representative the vehicle shall be kept locked except when the agent or representative is present. Starter Packs carried in a vehicle must be kept out of sight of the general public, and must not be transported or stored in the passenger compartment.

5.1.11 *[Returns & Disposal]* On request companies must promptly accept the return of Starter Packs of their products. Returned stock must be disposed of in an environmentally sound manner according to the requirements in each State or Territory.

### 5.2 Product Familiarisation Programs \*(PFP)

5.2.1 Companies must ensure that all Product Familiarisation Programs have the aim of allowing the medical profession to evaluate and become familiar with a product. Companies should develop a rationale for each PFP which describes the clinical rationale for the program, the total number of patients to be enrolled in the program and the duration that the medicine will be provided to each patient enrolled in the program based on a clinical assessment.

## **EXPLANATORY NOTES**

### **5.2.1**

A clinical rationale should take into account the nature of the treatment, but primarily the time for a healthcare professional to gain familiarity with the product.

A company will make available the rationale for a PFP without delay but in any event in no longer than 10 working days.

## PROVISIONS OF THE CODE

- 5.2.2** Companies should not offer any monetary or any other type of reward to healthcare professionals, their families and/or employees for taking part in PFPs.
- 5.2.3** PFPs should involve patients being treated for approved indications of the product.
- 5.2.4** The company will provide a patient information document to be given to the patient by the healthcare professional which explains that the medicine will be provided under a PFP for a fixed period, after which it may only be available on a private prescription if it is not reimbursed under the PBS.
- 5.2.5** PFPs should be initiated only in the first 12 months following first supply of the product approved for registration, the approval of new indications\* or where the management of the patient might be different to current therapy and is justified by the clinical rationale. The enrolment period for patients into the PFP must not exceed 6 months. The length of time each patient may receive treatment under a PFP would be determined by the clinical rationale.
- 5.2.6** Starter packs that comply with the requirements of Section 5, may be supplied free of charge for these programs. A PFP will allow an individual healthcare professional to enrol a maximum of 10 patients in the program.
- 5.2.7** No formal protocol is required for PFPs. No individual patient data may be collected in a PFP.
- 5.2.8** Suspected adverse drug reactions spontaneously reported during the PFP must be reported to ADRAAC in accordance with the current TGA "Australian Guidelines for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch."

## **EXPLANATORY NOTES**

- 5.2.6** When justified by clinical need, two or more Starter Packs may be combined in a package with patient education documents which explain that the medicine is provided under a PFP for a fixed period, after which it may only be available on a private prescription if not reimbursed under the PBS. The Consumer Medicine Information should also be provided with any Starter Packs.
- 5.2.7** Aggregated data on a healthcare professional's experience with the product may be collected, but no individual patient data can be collected within a PFP.

## PROVISIONS OF THE CODE

### 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 healthcare 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 healthcare 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.

## EXPLANATORY NOTES

6. For further information on the application of this Section please refer to the current *Code of Conduct Guidelines*.

6.1 All promotional material used at trade displays must be consistent with the requirements of Section 3.

### International Congresses

In the case of international congresses held in Australia, it may be acceptable to display or supply information for a product not approved for registration in Australia or a non approved indication of a product registered in Australia, provided that any 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.

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.

### Australasian Congresses

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.

## PROVISIONS OF THE CODE

- 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 3.13 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 A company may offer brand name reminders \*(Section 3.12), involvement in complying competitions\* (Section 3.13), an item of Medical Educational Material\* (Section 10.3) or hospitality\* in accord with Section 6.2 at trade displays.
- 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.

## EXPLANATORY NOTES

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 New Zealand. Such Product Information must be available and distributed in accordance with this Code of Conduct.

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 3.13

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

## **PROVISIONS OF THE CODE**

### **6.2 Hospitality**

**6.2.1** Any hospitality provided by companies either directly or by sponsorship or assistance to the 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 consistent with the professional standing of the delegates. Meals provided at an educational meeting should not be extravagant or exceed standards which would meet professional and community scrutiny. 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 representatives must be beyond reproach and must not bring discredit upon the industry.

### **6.4. Sponsorship or Involvement in independently organised congresses**

Companies may assist and make financial contributions to educational meetings organised by third parties and may sponsor the attendance of healthcare 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; and
- 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.

## EXPLANATORY NOTES

**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; and
- 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.

## **PROVISIONS OF THE CODE**

### **6.5 Sponsorship of Healthcare Professionals**

The selection criteria for sponsorship to allow healthcare professionals to attend educational meetings must be based solely on their interest in the area of medicine being discussed and their ability to communicate any relevant information to Australian healthcare professionals to enhance the quality use of medicines. (See also Section 7 Sponsorship)

### **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 Sections 10.4 and 10.5 of this Code.

## EXPLANATORY NOTES

- 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 healthcare 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 further information on the application of this Section please refer to the current *Code of Conduct Guidelines*.

## **PROVISIONS OF THE CODE**

### **6.8 Travel**

The following applies to companies sponsoring healthcare professionals travelling to, from and within Australia to symposia and/or congresses:

- travel may be subsidised provided the meeting is directly related to the healthcare 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; and
- travel costs and expenses for family or travelling companion(s) must not be paid for or subsidised by the sponsoring company.

## **EXPLANATORY NOTES**

**6.8** This provision covers the sponsorship of healthcare professionals at symposia and congresses.

For further information on the application of this Section please refer to the current *Code of Conduct Guidelines*.

## PROVISIONS OF THE CODE

### 7. Sponsorship

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

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

**7.1.1** Where companies undertake the sponsorship of a healthcare professional such 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.

**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 healthcare professional's prescribing or dispensing practices.

**7.1.3** Clear guidelines which can be publicly disclosed if required, must be developed in relation to the awarding of sponsorship to healthcare professionals. These guidelines must reflect the requirements of Section 7.1.1.

**7.1.4** Sponsorship of educational meetings and sponsorship of healthcare 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.

## **PROVISIONS OF THE CODE**

### **7.1.5**

Where a company sponsors a healthcare professional to provide support for medical practice activities, such programs must:

- be able to successfully withstand public and professional scrutiny;
- be intended to enhance the quality use of medicines through the implementation of an appropriately defined program supported by a clinical rationale
- not be offered or provided conditional upon any obligation to prescribe a particular product

## **EXPLANATORY NOTES**

- 7.1.5** Programs involving sponsorship of practice support staff which involves encouraging the prescribing of a particular medicine or switching to a particular medicine would be in breach of the Code.

## PROVISIONS OF THE CODE

### 8. Research

The following provisions apply to research whether it is carried out directly by the company or by an organisation acting under its direction. Companies must ensure that the requirements of Australia's Privacy Legislation\* are complied with during any research activity and that any research activities are undertaken by suitably qualified and experienced individuals or organisations.

#### 8.1 Post Marketing Surveillance (PMS) Studies\*

8.1.1. Post-Marketing Surveillance Studies should have scientific or medical merit and objectivity and not be designed for, or conducted as, a promotional exercise.

8.1.2 Post Marketing Surveillance studies must be research which is intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the Product Information.

8.1.3 Post Marketing Surveillance studies are part of clinical research and the only extent of involvement of Medical representatives\* is in recommending or identifying healthcare professionals to participate in the study. The study must be managed through the company's medical department.

8.1.4 Post-Marketing Surveillance Studies must have a formal protocol, a requirement for data collection and generation of a report.

8.1.5 When a company is intending to carry out a Post-Marketing Surveillance Study it must advise ADRAC\* of its intention.

8.1.6 Only patients being treated for approved indications of the product are to be included in the Post-Marketing Surveillance Study.

## EXPLANATORY NOTES

8. This section does not apply to evaluations being carried out under the approval of the Human Research Ethics Committees in hospitals.

Clinical trials of products approved for registration are not covered by the above categories and are considered to be subject to the *"Note for Guidelines on Good Clinical Practice (CPMP/ICH/135/95)"* as adopted by the TGA in Australia.

- 8.1 Companies' attention is also directed to the *"Joint ADRAC-Medicines Australia Guidelines for the Design and Conduct of Company Sponsored Post-Marketing Surveillance (PMS) Studies"*.

## PROVISIONS OF THE CODE

- 8.1.7 Decisions by the medical profession to prescribe the product should be based solely on their clinical judgement.
- 8.1.8 No Starter Packs\* or free Trade Packs\* should be distributed as part of the Post-Marketing Surveillance Study.
- 8.1.8 Any payment to the medical profession must be commensurate with the work involved and not based upon the number of prescriptions written.
- 8.1.9 Suspected adverse drug reactions noted during Post-Marketing Surveillance Studies must be reported to ADRAC in accordance with the current TGA "Australian Guidelines for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch."
- 8.1.10 A prompt report on the outcome of the study should be provided to participating doctors and ADRAC.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **8.2        Market Research\***

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

- 8.2.1.**        Market Research studies must be clearly identified as such when the initial approach is made.
- 8.2.2.**        Any payment (whether cash or voucher in lieu of cash) must be kept to a minimum and should not exceed a level commensurate with the work involved.
- 8.2.3.**        Promotion should not be represented as Market Research or research of any type.
- 8.2.4**        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

When selecting individuals or organisations to undertake any research activities companies may wish to refer to the Australian Market and Social Research Society - Code of Professional Behaviour at [www.amsrs.com.au](http://www.amsrs.com.au)

### 8.2.2

If a voucher is provided in lieu of cash payment, the voucher must be valid only to obtain an item that is directly relevant to the practice of medicine or pharmacy.

A voucher to purchase entertainment, such as movie tickets or lottery tickets is not acceptable.

A donation to a registered charity in lieu of cash payment to the healthcare professional is acceptable if the amount remains commensurate with the work undertaken.

## **PROVISIONS OF THE CODE**

### **9. Relationship with the General Public**

This Section of the Code of Conduct establishes the ways in which the industry appropriately interacts with members of the general public to enhance the quality use of medicines by being a credible source of current, accurate and balanced information about prescription medicines approved for use in Australia.

Any activities with, or materials provided to, members of the general public must not bring discredit upon, or reduce confidence in the pharmaceutical industry.

#### **9.1 General Inquiries**

Inquiries regarding the use of products must be handled by appropriately qualified personnel. Requests from individual members of the public for information or advice on the diagnosis of disease or choice of therapy must always be refused and the inquirer recommended to consult their doctor.

#### **9.2 Product Specific Media Statements**

**9.2.1** The purpose of a media release 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.

## **EXPLANATORY NOTES**

**9.1** Where a specific request is made by a patient or a member of a patient's family about a product which has been prescribed, the company may clarify matters using a Consumer Medicine Information leaflet or a patient aid as described in Section 9.7, but should otherwise recommend inquirers to consult their doctor.

**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 are 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.

## PROVISIONS OF THE CODE

The media release may include the product's brand 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 for 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 comparative 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 in an educative and non promotional manner.

**9.2.3** Media releases should not be accompanied by any material which encourages or is designed to encourage the use of any prescription medicine. 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.

### **9.3 General Media Articles**

General media articles concerning specific prescription products must not be initiated by companies. However, information on medical conditions is allowed.

Companies should not attempt to encourage the publication of general media articles or their content with the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.

## **EXPLANATORY NOTES**

- 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.
- 9.3** Upon specific request, companies may provide educational material to medical journalists in the same manner as provided to healthcare professionals. Such information must be current, accurate and balanced, and comply with the provisions of Section 1 of the Code.

## PROVISIONS OF THE CODE

### 9.4 Promotion to the General Public

Prescription products may be promoted only to healthcare professionals\*. Any information provided to members of the general public must be educational. Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is prohibited.

### 9.5 Patient Education

It is acknowledged that members of the general public should have access to information on medical conditions and the treatments which may be prescribed by their doctors. The purpose of such information should be educational and should encourage patients to seek further information or explanation from the appropriate healthcare professional.

In addition, the following criteria should be satisfied.

- 9.5.1 The educational material\* must be current, accurate and balanced.
- 9.5.2 The educational material should not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.
- 9.5.3 Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general.
- 9.5.4 The educational material must include the name and the city, town or locality of the registered office of the supplier of the material, but their location should not be given prominence.

## EXPLANATORY NOTES

- 9.4** Promotion of a medicine delivery device\* to the general public is permitted in restricted circumstances. A medicine delivery device which is used for the administration of a prescription medicine, including Schedule 3 medicines that are predominantly prescribed by a medical practitioner, that is distributed independently from the active ingredient and can be used to administer products from more than one company, is permitted as long as the medical device is not branded with the name of a particular medicine. The device must be listed with the TGA as a device.
- 9.5** Examples of patient educational material which could be used include:
- (a) Patient information about a medical condition which may discuss all medically important treatment methods but only in very broad terms (no emphasis on any one product). This type of material could be distributed directly to the general public as a "community service".
  - (b) Patient information about a medical condition or specific treatment (not brand name) which is prepared in conjunction with the relevant professional society and is endorsed by that society. This type of material may be distributed to the general public, as a "community service". However, the endorsement of a professional society does not preclude a finding of a breach of this Section if the other provisions of this Section are not fulfilled.
  - (c) General information on medical advances in healthcare. This could include information on the discovery of new drugs, and research plan of the individual company, but that material must satisfy general interest and not promotional purposes.

## **PROVISIONS OF THE CODE**

**9.5.5** The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her doctor. Such statements must never be designed or made for the purpose of encouraging members of the public to ask their doctor to prescribe a product.

**9.5.6** The tone of the message must not be presented in a way that unnecessarily causes alarm or misunderstanding in the community.

**9.5.7** On all occasions the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes of successful treatment or stimulating the demand for prescription of a particular product

### **9.6 Use of the Internet**

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 members of the general public. The promotion of products covered by the Code of Conduct to the general public via the Internet would breach Sections 9.4 and 9.6 of the Code and the Commonwealth Therapeutic Goods legislation which stipulates 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.

## **EXPLANATORY NOTES**

### **Section 9.5 cont'd**

Examples of patient educational material which might be considered to breach the Code include:

- (a) use of brand names in a manner that promotes a product rather than as an informative and educational tool.
- (b) material which is not educational or contains medically incorrect educational material.
- (c) inclusion of response rates for a specific product or comparative claims.

### **9.6**

Where references to other information sources or Internet sites are made, companies must take all reasonable steps to ensure that these information sources and Internet sites contain valuable educational material that can be readily understood by members of the general public and would enhance their knowledge of disease states.

## PROVISIONS OF THE CODE

- 9.6.1** 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.

- 9.6.2** 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 to understand how this product works, its uses and compliance advice.

In relation to company disease state websites there should not be a focus on the company product. In discussing prescription medicine treatment options for the disease state, a company may list all the available medicines, but must not compare any available products. A company sponsored disease state website must not have links to websites with information on a company's product/s. The website should always contain a statement to the effect *"For further information talk to your doctor."*

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

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

- 9.6.3** A copy of the product's Consumer Medicine Information (CMI). CMIs must appear in their entirety. They must not be amended, abridged or displayed in a promotional manner.
- 9.6.4** Reference or linkages to other reputable information sources that provide valuable educational information 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; and
  - any information provided by this source should be discussed with the reader's healthcare professional and does not replace their advice.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 9.7 Patient Aids

Patient aids that are solely intended to provide information for the patient once a decision to prescribe that product has been made, may be product specific. The content of such material must be designed to assist with patient compliance by providing information which clarifies method of administration, precautions, special instructions and like information. It must not make comparisons or include promotional claims.\*

### 9.8 Patient Support Programs\*

Companies may arrange or become involved in programs that support patients already prescribed a prescription-only medicine to improve positive health outcomes. To ensure that such activities could not be considered as promotional, companies must ensure that any statements made or material provided to members of the general public are not promotional and could not be considered as having the intention of promoting a prescription medicine to members of the general public.

Companies should develop a rationale for each patient support program which describes the clinical rationale for the program, the anticipated number of patients to be enrolled in the program, the type of educational/informational material to be provided to a patient, number of calls (if any) that may be made to a patient and the duration of the program.

## **EXPLANATORY NOTES**

- 9.8** Any communication with a patient enrolled in a Patient Support Program should clearly identify the company, what materials or calls the patient may receive. It should advise the patient that they may opt out of the program at any time by advising the company or nominated agent. Patients should also be advised who will be holding any details disclosed in the enrolment form and that these will not be used for purposes other than this program.

Companies can report on whether the program delivers any improvement in compliance and on the rationale for the program.

## PROVISIONS OF THE CODE

### 9.8 Patient Support Programs (cont'd)

Companies should ensure compliance with the following requirements if they are considering becoming involved in any patient support program:

- any payment for the work undertaken by a healthcare professional in such programs is commensurate with the work undertaken. Such payment should not be capable of influencing or intended to influence the prescribing of a specific prescription medicine;
- no incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs;
- the program complies with all Australian Privacy Legislation\*;
- all information provided to patients must comply with Sections 9.5 and 9.7 of this Code;
- the data collected from these programs will not be used for any purpose other than to increase positive health outcomes and never for promotional activities;
- the duration of these programs is appropriate to the disease state treated by the product involved; and
- the program should not interfere in any way with doctor/patient integrity.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 9.9 Relationship with Health Consumer Organisations\* (HCOs)

Medicines Australia recognises and supports positive and beneficial relationships between industry and health consumer organisations. Companies may enter into relationships with health consumer organisations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

Through collaboration between Medicines Australia, the Consumers' Health Forum of Australia and other health consumer organisations, a set of guidelines "Working Together – A Guide to relationships between health consumer organisations and pharmaceutical companies" has been developed. Companies should consider these principles when entering into relationships with health consumer organisations. The guidelines and manual are available on the Medicines Australia website [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

### 9.10 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.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 10. **Relations with Healthcare Professionals\***

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 healthcare 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 healthcare professional must not include entertainment.

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

## **EXPLANATORY NOTES**

- 10** This section also relates to educational meetings provided by companies relating to practice and professional development, such as practice management, communication skills and conflict resolution.

- 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 delegate's 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 healthcare professionals is to increase medical knowledge and enhance the Quality Use of Medicines in Australia.

## PROVISIONS OF THE CODE

### 10.2 Hospitality\*

Any hospitality offered by companies to healthcare professionals must be secondary to the educational content, provided in an environment that enhances education and learning and reflect the professional standing of the audience. The venue and location at which a company provides hospitality to healthcare professionals must be conducive to education and learning and must not be chosen for its leisure or recreational facilities. Meals provided by companies at an educational meeting should not be extravagant or exceed standards which would meet professional and community scrutiny.

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

## EXPLANATORY NOTES

### 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 other hospitality provided by companies at an educational meeting should not differ from that expected at any professional business meeting.

Examples of activities that would be seen as acceptable include:

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

In relation to companions and family members it is not acceptable for a company to pay for, subsidise or reimburse a healthcare 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.

## PROVISIONS OF THE CODE

### 10.3 Travel

The following applies to all healthcare professionals:

- travel may be subsidised provided the meeting is directly related to the healthcare 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; and
- travel costs and expenses for family or travelling companion(s) must not be paid for or subsidised.

### 10.4 Medical Educational Material\*

**10.4.1** Materials supplied for medical education must include the name of the supplier and city, town or locality of the registered office.

**10.4.2** Material supplied with medical education may include promotional claims\* and/or statements, but must comply with Sections 1 and 3 of the Code of Conduct. This accompanying material should be clearly identified as promotional material\*.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 10.5 Medical literature/reprints

10.5.1 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:

- the sponsor's products; and
- any competitor's products with which a comparison is being made.

10.5.2 Quotations from medical literature or from personal communications must accurately reflect the meaning of the author and significance of the study.

10.5.3 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

### 10.5

Healthcare professionals may request literature on subjects not covered by the Product Information\* such as unapproved 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 Product Information. Information must be balanced and not promotional and should be distributed by the Medical Department. Medical representatives must not promote the use of unapproved indications or products to healthcare professionals.

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 incorporate promotional claims.

It is recommended that if a company sponsors an independently edited supplement this should be stated clearly in the supplement. If a company does sponsor the reporting of a congress or symposium this activity must comply with the requirements of the Code, particularly those contained in Section 1.

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.

In addition to those reports prepared by a company, this Section applies to reports prepared by individuals on behalf of companies

## PROVISIONS OF THE CODE

### 10.6 Consultants\* and Advisory Boards

Companies may legitimately seek the services of suitably qualified and experienced healthcare professionals to provide advice and guidance on a range of matters. It is appropriate that healthcare professionals who provide these services be offered remuneration and reimbursement for reasonable travel, accommodation and meal expenses incurred as part of providing those services.

Consultancy arrangements, including membership of Advisory Boards, must meet all the following criteria.

- 10.6.1 A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants.
- 10.6.2 The purpose and objectives of the interaction must be to obtain advice and must be clearly articulated in the original advice to healthcare professionals
- 10.6.3 There must be a written contractual agreement outlining the nature and duration of the services to be provided.
- 10.6.4 The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose.
- 10.6.5 The formation of multiple Advisory Boards for a single product must be justifiable, for example as a result of registered indications in different medical specialties. Where there are recognised differences in medical practice between States it may be acceptable to have more than one Advisory Board.

## EXPLANATORY NOTES

**10.6.1** Companies should be cognisant that a document summarising the purpose, objectives, justification of the size/number of the Advisory Board/s must be publicly available for scrutiny by the Code of Conduct Committee and complainant should a complaint be lodged

**10.6.5** Given the purpose of the Advisory Board the size of the group must be such that would withstand public and professional scrutiny and adhere to the principles for the quality use of medicines.

More detailed information on multiple boards and the number of members can be found in the current *Code of Conduct Guidelines* which is available on the Medicines Australia website at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

## **PROVISIONS OF THE CODE**

- 10.6.6** Records concerning the use of the services provided by consultants must be maintained including meeting minutes approved by the Chair of the Advisory Board.
- 10.6.7** Meetings must be held in Australia, at venues consistent with the requirements of Section 6 of the Code. Two exceptions are allowed, firstly when meetings are held in conjunction with international scientific meetings, and secondly when Australian healthcare professionals are part of an international advisory board organised by a parent company.
- 10.6.8** A company must not subsidise or pay for the costs of family or companions of consultant or Advisory Board members.
- 10.6.9** Interactions between companies and consultants and Advisory Boards must not include entertainment.
- 10.6.10** Membership of Advisory Boards or consultancy arrangements should be disclosed to relevant bodies by the individual healthcare professional, or company, as appropriate.
- 10.6.11** All relationships between companies and consultants and Advisory Board members should be able to successfully withstand public and professional scrutiny and not bring the industry into disrepute.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **10.7 General Remuneration**

Any remuneration for services rendered should not exceed that which is commensurate with the services supplied.

### **10.8 Discredit to and reduction of confidence in the Industry**

Activities engaged in by companies with healthcare professionals or materials provided to healthcare 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

10.8

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 healthcare professionals; and
- 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 current *Code of Conduct Guidelines*.

## PROVISIONS OF THE CODE

### 11. Administration of the Code

The administration of the Code shall be supervised by the Code of Conduct Committee, (the Code Committee) which will be responsible to the Medicines Australia Board. Expert advice may be sought externally by the Committee in reaching a decision as to whether or not a breach has occurred.

#### 11.1 Procedures

The following procedures shall apply in the event of Medicines Australia receiving information alleging contravention by a company of the Code of Conduct.

##### 11.1.1 On the receipt of such information, the Chief Executive Officer\* of the Association or his or her delegate shall acknowledge the complaint in writing within five (5) working days of receipt. All such complaints shall be dealt with as expeditiously as possible.

All Code of Conduct documents are required to be kept confidential until the complaint is deemed finalised.

The company that is the subject of the complaint (Subject Company) shall be given full details of the information lodged with the Association. The Subject Company will be invited to state within ten (10) working days whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

The Subject Company may obtain external advice in order to respond to a Code of Conduct complaint. If external advice is sought, all Code of Conduct documents must be kept confidential and can only be provided for the purpose of seeking such advice.

The Subject Company and complainant will provide the Association with whatever references or information is

## **EXPLANATORY NOTES**

- 11.1.1** If external advice is sought by a company responding to a complaint, that company must ensure that the individual to whom a request for advice is sought is provided with sufficient information to form a full and proper view of the complaint under consideration.

## PROVISIONS OF THE CODE

deemed by the Chief Executive Officer or his or her delegate to be necessary to fully investigate the complaint. The information and response shall be provided to the Code Committee.

### 11.1.2

If the Code Committee, after making such further inquiry as is necessary or desirable, meets and reaches a decision that a breach of the Code has occurred, the Chief Executive Officer or his or her delegate will:

- (a) within two (2) working days of the Committee meeting notify the Subject Company and the complainant in writing that a breach has been found and identifying the section of the Code that the Committee has determined has been breached.
- (b) within ten (10) working days of the Committee meeting provide copies of the extract of the minutes of the Committee meeting to the subject company and the complainant which will include a full explanation for the decision made and the form of any sanction to be applied to the subject company, as provided for under Section 12 of the Code.

The Code Committee may also request the Code of Conduct Secretary\* to notify Medicines Australia's Board, and any other bodies or individuals with a direct interest, of the Committee's decision.

All findings and/or sanctions of the Code Committee shall remain confidential and shall not be released to any third parties until after the Subject Company and complainant have exhausted all appeal procedures and the outcome of any appeal is known.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

- 11.1.3** In the event of the Code Committee requiring a company to cease or withdraw a promotional activity, the company shall at once comply with the Code Committee's ruling pending any appeal against the decision of the Code Committee pursuant to the Rules of the Association. A promotional activity thus suspended shall not be reactivated before the appeal process has been concluded, nor shall any other promotional activity thus suspended be recommenced during the period in question.
- 11.1.4** If the Code Committee considers that no breach has occurred, it will so advise the Chief Executive Officer or his or her delegate who will so advise the parties concerned and also supply them with the minutes of the proceedings within ten (10) working days of the Code Committee's decision.
- 11.1.5** The Code Committee may refer questions on the interpretation of the Code to the Medicines Australia Board for determination. The Board shall consider such questions and make a determination as soon as possible after it receives notice from the Code Committee of the need for the determination.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **11.2 Membership of the Code Committee**

The membership of the Code Committee shall be:

#### **Full Membership:**

- Chairman - Lawyer with Trade Practices experience
- One representative of the Australian Medical Association (AMA)
- One representative of the Royal Australian College of General Practitioners (RACGP)
- One representative of the Australian Divisions of General Practice (ADGP)
- One specialist nominated by the Royal Australasian College of Physicians (RACP)
- One representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- One consumer representative nominated by the Consumers' Health Forum of Australia (CHF)
- One representative of the Therapeutic Goods Administration (TGA)
- Three Medicines Australia member company Association Representatives
- Two Medicines Australia member company Medical/Scientific Directors

#### **Observers**

- Maximum of two employees of Medicines Australia member companies
- One observer nominated by Medicines Australia

#### **Secretariat**

- Code of Conduct Secretary
- Medicines Australia Chief Executive Officer or delegate
- Medicines Australia officer responsible for Scientific and Technical Affairs

## EXPLANATORY NOTES

### 11.2 Procedure of appointment

**Chairman** – a panel of five (5) suitably qualified and experienced lawyers will be appointed by the Medicines Australia Board. Members of the panel will be appointed for a period of five (5) years. The Chairman for a particular Committee meeting will be appointed from the panel taking into consideration that the person has no conflict of interest with therapeutic area/s or company/ies against which a complaint has been lodged or with the complainant.

**AMA Representative** – a general practitioner nominated by the Australian Medical Association Ltd.

**RACGP Representative** – a general practitioner nominated by the Royal Australian College of General Practitioners.

**ADGP Representative** – a general practitioner nominated by the Australian Divisions of General Practice.

**RACP Representative** – selected from a panel of three (3) specialist physicians nominated by the Royal Australasian College of Physicians. The RACP representative for a particular Committee meeting will be appointed from the panel taking into consideration that the person has no conflict of interest with product/s or company/ies against which a complaint has been lodged

**ASCEPT Representative** – selected from a panel of four (4) nominated by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. The ASCEPT representative for a particular Committee meeting will be appointed from the panel taking into consideration that the person has no conflict of interest with product/s or company/ies against which a complaint has been lodged

## **PROVISIONS OF THE CODE**

### **11.2 (cont)**

Members of the Code Committee other than the Chairman will be appointed for a period of three years and will be eligible for re-nomination at the completion of their term.

Observers and members of the Secretariat on the Code Committee have no voting rights.

A meeting of the Code Committee will require a quorum of six full members, two of which must be representatives from Medicines Australia and one of which must be a representative of ASCEPT.

## EXPLANATORY NOTES

**Consumer Representative** – nominated by the Consumers' Health Forum of Australia

**Medicines Australia Association Representatives and Medical/Scientific Directors** - selected from Medicines Australia Association Representatives who have no conflict of interest with the product or company against which a complaint has been lodged.

**TGA Representative** - representative with medical/pharmaceutical qualifications nominated by Therapeutic Goods Administration.

**Medicines Australia member company observer** - any employee of a Medicines Australia member company nominated by its Association Representative who would gain an educational benefit from attendance at a Code of Conduct meeting and who has no conflict of interest.

**Invited observer** – is a person nominated by Medicines Australia who would gain an educational benefit from attendance at a Code of Conduct meeting and who has no conflict of interest with any of the matters being considered at the meeting to which they have been invited to attend, either financial or perceived bias with any of the matters being considered at the meeting to which they have been invited to attend

The Explanatory Notes to Section 11.2, regarding the qualifications of the members and observers of the Committee, are only intended as a guide. The Committee may, if it thinks fit, appoint a member or observer without the specific qualifications referred to in the Explanatory Notes to this Section 11.2.

At each meeting of the Committee, the Chairman will inquire as to whether any Committee member has a conflict of interest against the product against which a complaint has been lodged, the complainant or subject company. The Committee will determine any appropriate action following this disclosure.

## **PROVISIONS OF THE CODE**

### **11.3 Conflict of Interest**

Prior to each Code Committee meeting advice will be sought from the permanent members of the Committee as to whether there is any conflict of interest with the products subject to complaint, the Subject Company or complainant.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered in a meeting of the Code Committee, members should also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Code Committee may be influenced in reaching a decision by factors other than the merits of the case as presented by the Subject Company and complainant.

At the Code Committee meeting the Chairman will again enquire as to whether any Committee Member has a conflict of interest regarding either the product against which a the complaint has been lodged, the complainant or Subject Company. The Committee will determine any appropriate action following this disclosure.

### **11.4 Review of the Code**

Medicines Australia will carry out a review of the provisions of the Code of Conduct after seeking input from interested parties no later than every three years.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **11.5 Complaints against non-members**

Complaints concerning promotional activities of non-members will be forwarded to the non-member with an invitation to have the complaint adjudicated by the Code Committee in accordance with Section 11.1 and to abide by the Committee's decision and any sanctions imposed.

If the non-member accepts the invitation to have the complaint adjudicated by the Code Committee, the complaint will proceed in accordance with the provisions of the Code of Conduct.

If the non-member declines the invitation to have the complaint adjudicated by the Code Committee, Medicines Australia shall have the right, but not the obligation, to forward this complaint to the Therapeutic Goods Administration or the Australian Competition and Consumer Commission.

### **11.6 Referral of Complaints under the Therapeutic Products Advertising Code\***

Complaints about advertisements published or broadcast in Australia thought to be in breach of the Therapeutic Products Act or Rules, including the Advertising Principles, Advertising Requirements and the Code, can be lodged with the Central Complaints Panel (the Panel), through the Central Support Unit. The functions and powers of the Central Complaints Panel are established in Australia as set out in the Rules.

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

The Central Complaints Panel handles all complaints about advertisements directed to members of the general public, and complaints involving matters of serious risk to public health and safety.

## **EXPLANATORY NOTES**

**11.6**

Section 11.6 will come into effect with the commencement of the Joint Therapeutics Agency

## **PROVISIONS OF THE CODE**

### **Section 11.6 cont'd**

Complaints about advertisements for prescription medicines directed to members of the general public that are submitted to the Medicines Australia Code of Conduct Committee will be referred to the Central Complaints Panel through the Central Support Unit.

Complaints that are submitted to the Central Complaints Panel by members of the general public, healthcare practitioners or competitors about advertisements for prescription medicines directed to healthcare practitioners, which do not involve matters of serious public health and safety, will be referred to the Medicines Australia Code of Conduct Committee for consideration.

Complaints by members of the general public, healthcare practitioners or competitors that are submitted to the Medicines Australia Code of Conduct Committee about advertisements for prescription medicines directed to healthcare practitioners, which involve matters of serious public health and safety, will be referred to the Central Complaints Panel through the Central Support Unit.

### **11.7**

#### **Discretion for Referral**

Medicines Australia retains the discretion to refer complaints against a Medicines Australia member which is also a member of the Australian Self-Medication Industry (ASMI), to that Association for consideration under its own Code, having regard to the category or product and the target audience for the promotion subject to the complaint.

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

### 12. Sanctions

**12.1** Sanctions against a subject company may be applied only where breaches of the Code of Conduct have been established. Sanctions may consist of one or more of the following under the procedures laid down in Section 11 of the Code:

**12.1.1** The requirement that the Subject Company take immediate action to discontinue or modify any practice which is determined to constitute a breach of the Code. Written notification of this action must be provided to Medicines Australia within 5 working days of the receipt of the decision of the Committee.

**12.1.2** Retraction statements, including corrective letters and advertising, to be issued by the Subject Company. The number, format, size, wording, mode of publication, prominence, timing and method of distribution of such statements shall be subject to the approval of the Committee or its delegate prior to release and will in general conform with the original statement. The Committee or its delegate, pursuant to the Rules, will ensure that such statement is made.

It is the company's responsibility to ensure that the requirements of the Committee or its delegate are met and to immediately inform and provide evidence to Medicines Australia of their fulfilment.

As a general rule, there is a requirement for corrective action to be taken where Moderate\* or Severe\* breaches have been found.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

Any corrective action required by the Code Committee should be completed within 30 calendar days of the company being advised of the decisions (subject to any appeal that may be lodged under Section 13 of the Code). Companies are required to provide a statement to the effect that the action has been undertaken together with a copy of the published advertisement or a copy of the final version of a corrective letter signed by the company Managing Director or Medical Director.

Where corrective action has not been actioned within the required 30 calendar days from receipt of the minutes of the Code or Appeals Committee meeting, the Code Committee may impose a fine of up to \$50,000 for that breach of not actioning the corrective action.

### **12.1.3**

The imposition of a fine by the Code Committee on the Subject Company in accordance with Section 12.1.4 of the Code. The fine must be paid within 30 calendar days from receipt of the minutes of the Code Committee meeting subject to any appeal that may be lodged under Section 13 of the Code.

## **EXPLANATORY NOTES**

- 12.1.2** Any corrective statement or letter required by the Committee should be mailed in an envelope that indicates the importance of its contents.

It will be usual for the Code Committee to require that a statement advising of the availability of the Code of Conduct should be made in corrective letters and advertising.

## PROVISIONS OF THE CODE

- 12.1.4** The schedule of fines that may be imposed by the Committee for breaches under Section 11 of the Code of Conduct is as follows. A range of fines is available to the Committee.

| Breach   | Fines                     |
|--|---------------------------|
| <u>Technical Breach *</u>                                | } maximum of<br>\$100,000 |
| <u>Minor Breach*</u>                                     |                           |
| <u>Moderate Breach*</u>                                  |                           |
| <u>Severe Breach*</u>                                    |                           |
| <u>Severe Breaches where<br/>activities have ceased*</u> | } maximum of<br>\$200,000 |
| <u>Breach Repetitions*</u>                               |                           |
| <u>Repeat of Previous Breach*</u>                        |                           |

- 12.2** If the Code Committee believes that the breach of the Code warrants the suspension or the expulsion of the Member, it will make such a recommendation to the Medicines Australia Board. The Board, under the Rules of the Association, may impose the following Sanctions:

- 12.2.1** Suspension of the Member from the Association for a period to be determined by the Board, under the provisions of the Rules of the Association.

- 12.2.2** The expulsion of the Member from the Association, under the provisions of the Rules of the Association.

**12.3 Abuse of the Code**

If, in the Code Committee's view, a complaint by a company is considered frivolous or vexatious the Code 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

**12.2** The decision to suspend or expel can only be made by the Medicines Australia Board.

**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 current *Code of Conduct Guidelines*.

## **PROVISIONS OF THE CODE**

### **13. Appeals**

#### **13.1 Procedures**

The following procedures shall apply in the event of Medicines Australia receiving an appeal from a complainant or Subject Company. The appeal will be heard by the Code of Conduct Appeals Committee (Appeals Committee).

All Code of Conduct Appeal documents are required to be kept confidential until the complaint is finalised. (See Appendix 1)

##### **13.1.1**

A Subject Company who has been found in breach of the Code and had a sanction imposed under Section 12 of the Code may lodge an appeal against the findings and/or sanction that has been imposed. Notification of an appeal must be lodged in writing by the Subject Company within five (5) working days of receiving advice of the findings and/or sanctions, addressed to the Secretary of the Code of Conduct Committee. On receipt of this appeal, the complainant will be notified and provided with a copy of the Subject Company's response to the complaint.

The Subject Company will be given five (5) working days to prepare a written response in support of its appeal. This written appeal will be provided to the complainant who shall be given five (5) working days to prepare any response. The written appeal and any response shall be provided to the Appeals Committee.

The complainant's response will be provided to the Subject Company for review.

All documents relating to a complaint and appeal shall remain confidential and shall not be released to any third parties until after the Subject Company and complainant have exhausted all appeal procedures and the outcome of any appeal is known.

## **EXPLANATORY NOTES**

**13.1.1** The Subject Company may appeal the findings where it has been found to be in breach of the Code and/or any sanction that has been imposed on it under Section 11 of the Code. The Appeals Committee has the power to affirm, set aside or vary the findings and/or any sanction which has been imposed by the Code Committee.

The Appeals Committee shall not uphold an appeal unless it is persuaded that the findings of the Code Committee or the sanction imposed by it involved an error on the basis of which they should be set aside or varied. The appeal shall not be a strict re-hearing of the original complaint. The Appeals Committee shall have a discretion to receive new evidence (being evidence which was available but not presented to the Code Committee), but shall otherwise determine the appeal on the basis of the evidence before the Code Committee, the submissions made to that Committee, and the submissions made to the Appeals Committee.

The appeal is to be dealt with during a meeting of the Appeals Committee. Both the Subject Company and the complainant may provide an oral presentation to the Appeals Committee, although the meeting of the Committee is not a hearing as such.

Where a company enlists the assistance of an external expert, the expert shall not act as an advocate for the company's promotional activities.

## **PROVISIONS OF THE CODE**

- 13.1.2** A complainant may also lodge an appeal in relation to the findings of the Code Committee. Notification of an appeal must be lodged in writing by the complainant within five (5) working days of receiving advice of the findings and/or sanctions, addressed to the Secretary of the Code of Conduct Committee. On receipt of this appeal, the Subject Company will be notified.

The complainant will be given five (5) working days to prepare a written submission in support of its appeal. This written appeal will be provided to the Subject Company who shall be given five (5) working days to prepare any response.

The written appeal and any response shall be provided to the Appeals Committee.

The Subject Company's response will be provided to the complainant for review.

- 13.1.3** When a Subject Company or industry complainant lodges an appeal in accordance with Section 13.1 of the Code, the company must lodge a bond of \$20, 000 with Medicines Australia at the same time as lodging the appeal. A non industry complainant will not be required to lodge an appeal bond in the event of lodging an appeal against the Subject Company. In all appeals an administration charge of \$6,000 will automatically be retained by Medicines Australia. The Appeals Committee has the discretion to refund all, part or none of the \$14, 000 component of the bond in the event of the findings and/or the sanction being lifted or changed. The bond will be used to defray the costs of the Code and Appeals Committee meetings and contribute to Code education programs.

## **EXPLANATORY NOTES**

- 13.1.3** There shall be only one bond of \$20,000 payable by an industry complainant for each complaint, irrespective of the number of findings of breach or sanctions imposed.

## **PROVISIONS OF THE CODE**

- 13.1.4** In the event of an appeal being lodged by the Subject Company and the complainant in relation to the same complaint, both appeals will be heard concurrently by the Appeals Committee.
- 13.1.5** 10 copies of the appeal submission from the Subject Company or complainant should be provided to Medicines Australia.
- 13.1.6** 10 copies of the response to and appeal from the Subject Company or complainant should be provided to Medicines Australia.
- 13.1.7** A complainant company who has had fines imposed by the Code Committee under Section 12.3 (Abuse of the Code) may lodge an appeal against such fines. The appeal, in writing, must be lodged by the complainant within five (5) working days of receiving advice of the fines, addressed to the Secretary of the Code of Conduct Committee. This appeal will be heard by the Medicines Australia Board.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **13.2 Appeals Committee Membership**

The membership of the Appeals Committee shall be:

#### **Full Membership**

- Chairman - Lawyer with Trade Practices experience
- One representative from the College and/or Society from the therapeutic class of the product subject to appeal
- One representative from the target audience to which the activity was directed eg: AMA, RACGP, ADGP
- One consumer representative nominated by the Consumers' Health Forum of Australia
- One representative from ASCEPT
- Two Medicines Australia member company Association Representatives
- One Medicines Australia member company Medical/Scientific Director

#### **Secretariat**

- Code of Conduct Secretary
- Medicines Australia Chief Executive Officer or delegate

Members of the Appeals Committee other than the Chairmen will be appointed for a period of three years and will be eligible for re-nomination at the completion of their term.

Secretariat members of the Appeals Committee have no voting rights.

A meeting of the Appeals Committee will require a quorum of three full members, one of which must be a representative from the Medicines Australia.

## EXPLANATORY NOTES

### 13.2 Procedure of appointment

**Chairman** – A panel of suitably qualified and experienced lawyers will be appointed by the Medicines Australia Board. Members of the panel will be appointed for a period of five (5) years. The Chairman for a particular Appeals Committee meeting will be appointed from the panel taking into consideration that the person has no conflict of interest with product/s or company/ies against which a complaint has been lodged and did not chair the Code Committee meeting at which the original complaint was heard.

**ASCEPT Representative** – selected from a panel of four (4) nominated by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. The ASCEPT representative for a particular Appeals Committee meeting will be appointed from the panel taking into consideration that the person has no conflict of interest with product/s or company/ies against which a complaint has been lodged and did not chair the Code Committee meeting at which the original complaint was heard.

**Consumer Representative** – nominated by the Consumers' Health Forum of Australia

**Medicines Australia Association Representatives and Medical/Scientific Directors** - selected from Medicines Australia Member Companies who have no conflict of interest with the product or company against which a complaint has been lodged.

## **PROVISIONS OF THE CODE**

### **13.3 Conflict of Interest**

Prior to each Appeal Committee meeting advice will be sought from the full members of the Committee as to whether there is any conflict of interest with the products subject to complaint, the Subject Company or complainant.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered in a meeting of the Appeals Committee, members should also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Appeals Committee may be influenced in reaching a decision, by factors other than the merits of the case as presented by the Subject Company and complainant.

At the Appeals Committee meeting the Chairman will again enquire as to whether any Appeals Committee member has a conflict of interest regarding either the product against which the complaint has been lodged, the complainant or Subject Company. The Appeals Committee will determine any appropriate action following this disclosure.

It is acceptable for Medicines Australia to release to the complainant or the Subject Company, the names of the external experts nominated by the College and/or Society, on the proviso that neither party makes contact with these experts prior to the Appeals meeting.

### **13.4 Referral Medicines Australia Board**

The Appeals Committee may refer questions on the interpretation of the Code to the Medicines Australia Board for determination. The Board shall consider such questions and make a determination as soon as possible after it receives notice from the Appeals Committee of the need for the determination.

## **EXPLANATORY NOTES**

### **13.2 (continued)**

Members of the Appeals Committee, both from the industry and the College and/or Society etc must not have sat on the Code Committee which heard the original complaint.

Members of the Code Committee other than the Chairman will be appointed for a period of three years and will be eligible for re-nomination at the completion of their term.

## **PROVISIONS OF THE CODE**

### **14. Monitoring**

To support compliance with the Medicines Australia Code of Conduct, the Medicines Australia Monitoring Committee (Monitoring Committee) will proactively monitor selected promotional material and activities of Member Companies on a regular and ongoing basis.

The Monitoring Committee may review all forms of promotional material and activities for those identified products in light of the Code of Conduct and thereby support the Quality Use of Medicines.

The aims of this monitoring process are to encourage compliance with the Code of Conduct, provide advice on compliance where necessary, obtain and publish statistical data on the rate of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code of Conduct.

#### **14.1 Procedures**

Member companies will be required to submit to the Committee ten copies of the selected type of promotional material used over the past three months for the product under review. It is acknowledged that although the Committee has the right to request all types of promotion material during a review, companies will only be required to submit promotional material of the type specified by the Medicines Australia Secretariat. For example, the Committee review may look only at printed advertisements during the first review but may choose to look at audio-visual material in the next review.

A written statement, signed by the Association Representative, or Alternate Association Representative confirming that the supplied material constitutes all the selected promotional material for the product under review, will be required.

## EXPLANATORY NOTES

**14.1** The review of promotional material will be according to the following Therapeutic Classes\*:

- Alimentary System
- Cardiovascular System
- Central Nervous System
- Analgesia
- Musculoskeletal System
- Endocrine and Metabolic Disorders
- Genito-urinary System
- Infections and Infestations
- Neoplastic Disorders
- Immunology
- Respiratory System
- Ear, Nose and Oropharynx
- Eye
- Skin
- Contraceptive Agents

The Monitoring Committee may also review materials or activities across all therapeutic classes in any on review.

## PROVISIONS OF THE CODE

### 14.2 Membership of the Committee

The membership of the Committee shall be:

#### Permanent Members

- Chairman - Consultant with industry experience in marketing and knowledge of the Code of Conduct
- One representative of the RACGP
- One representative of the AMA
- One consumer representative nominated by the Consumers' Health Forum of Australia

#### Rotating Members

- One representative from the College and/or Society from the therapeutic class being reviewed
- One Medicines Australia member company Medical Director without a conflict of interest in the therapeutic class
- One Medicines Australia member company Marketing Director without a conflict of interest in the therapeutic class

#### Advisors

- Code of Conduct Secretary
- Medicines Australia officer responsible for Scientific and Technical Affairs

### 14.3 Conflict of Interest

Prior to each Monitoring Committee meeting advice will be sought from the permanent members of the Committee as to whether there is any conflict of interest with the products subject to complaint, the Subject Company or complainant.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered in a meeting of the Monitoring Committee, members should also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Monitoring Committee may be influenced in reaching a

## EXPLANATORY NOTES

### 14.2 Procedure of appointment

**Chairman** – a panel of three (3) suitably qualified and experienced experts will be appointed by the Medicines Australia Board. Members of the panel will be appointed for a period of five (5) years. The Chairman for a particular Committee meeting will be appointed from the panel taking into consideration that the person has no conflict of interest with product/s or company/ies against which a complaint has been lodged

**AMA Representative** – a general practitioner nominated by the Australian Medical Association Ltd.

**RACGP Representative** – a general practitioner nominated by the Royal Australian College of General Practitioners.

**Consumer Representative** – nominated by the Consumers' Health Forum of Australia

## PROVISIONS OF THE CODE

decision, by factors other than the merits of the case as presented by the Subject Company and complainant.

At the Monitoring Committee meeting the Chairman will again enquire as to whether any Committee member has a conflict of interest regarding either the product, against which the complaint has been lodged, the complainant or subject company. The Committee will determine any appropriate action following this disclosure.

### 14.4

#### Referral to the Code of Conduct Committee

If, following the review of the submitted material or activities, the Monitoring Committee consider that a breach of the Code of Conduct may have occurred, the company in question will be contacted and asked to state whether the determination of the Monitoring Committee is correct and to give any answer or explanation deemed necessary. The Monitoring Committee will consider the response and provide relevant advice on compliance with the Code or if necessary, refer the matter to the Code Committee as a complaint.

The Monitoring Committee will review different therapeutic classes and types of promotional material each year with the aim of covering a minimum of three therapeutic classes and three different promotional activities each year.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **14.5 Reporting**

The Monitoring Committee will contribute to the Medicines Australia Code of Conduct Annual Report. This report will include the therapeutic categories and type of promotional materials reviewed, the number of items reviewed, the number and type of breaches detected and the number of Code of Conduct complaints generated.

In addition, the Monitoring Committee will provide a report to Medicines Australia of issues concerning the Code of Conduct requiring possible review.

### **14.6 Review**

The operations of the Monitoring Committee will be reviewed on a regular basis.

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **15. Compliance Procedures**

It is the responsibility of all companies to ensure that an internal compliance procedure exists that strives for compliance with all provisions of the Code and the spirit it embodies. This procedure should be documented and provided to relevant employees to further enhance Code of Conduct compliance.

## **EXPLANATORY NOTES**

- 15.** In order to comply with this provision companies should consider the creation of a Compliance Panel whose purpose is to review promotional material and planned activities for compliance with the Code of Conduct. This panel should consist of relevant individuals from departments such as medical, marketing and sales to ensure that all aspects of promotional material and activities comply with the Code of Conduct. These individuals should possess suitable qualifications and experience to undertake such tasks.

This panel should review promotional material or activities from conception to release in final form or being undertaken.

## **PROVISIONS OF THE CODE**

### **16. Reporting**

#### **16.1 Annual Report**

Medicines Australia will issue an Annual Report on the activities of the Code of Conduct, Appeals and Monitoring Committees that will be available to the industry, members of the healthcare professions and general public. The Code of Conduct Annual Report will contain the following information regarding complaints considered by the Code and Appeals Committees during the reporting year:

- (a) names of companies that have had complaints brought against them;
- (b) the name of the complainant unless the identity has been suppressed at the request of the complainant and agreement of the Code of Conduct Committee Chairman;
- (c) the product, behaviour, conduct and/or promotional material subject to the complaint;
- (d) a summary of the complaint, response and deliberations of the Code of Conduct and Appeals Committees;
- (e) the Section/s of the Code, if any, which was breached and the reasons for finding the breach;
- (f) any sanctions imposed for the breach/es;
- (g) the total number of complaints received and the totals from the various sections of the industry;
- (h) the total number of breaches found;
- (i) a record of attendance of the independent organisations at Code Committee meetings;

## EXPLANATORY NOTES

## **PROVISIONS OF THE CODE**

### **16.1 Annual Report (cont'd)**

- (j) performance indicators as to the time taken to deal with complaints and activities undertaken to increase healthcare professional's awareness, agencies working for the industry and members of the general public of the Code of Conduct;
- (k) all of the information mentioned in paragraphs (a) to (f) above shall remain confidential and shall not be included in the Code of Conduct Annual Report until after the exhaustion of all appeals procedures and the outcome of any appeal is known.

### **16.2 Quarterly Reporting**

In addition to the Annual Report, Medicines Australia will publish a quarterly report on the outcomes of all complaints finalised during the reporting period. This report will be available on the Medicines Australia website.

### **16.3 Complaints where the activity was directed towards the general public**

Information regarding complaints that involve activities directed towards members of the general public will be made available on the Medicines Australia website within one month of finalisation of the complaint.

### **16.4 Reports pertaining to Sections 16.2 and 16.3 will include the following information:**

- (a) the name of the company against which a complaint has been made;
- (b) the name of the complainant, unless the identity has been suppressed at the request of the complainant

## EXPLANATORY NOTES

## PROVISIONS OF THE CODE

and agreement of the Code of Conduct Committee Chairman;

- (c) the product, behaviour, conduct and/or promotional material subject to the complaint;
- (d) a summary of the complaint, response and deliberations of the Code and Appeals Committee;
- (e) the section/s of the Code, if any, which was breached and the reasons for finding the breach/es; and
- (f) any sanctions imposed for the breach

### 16.2.3

The disclosure of this information will not occur until after the exhaustion of all appeals procedures and the outcome of any appeal is known.

## EXPLANATORY NOTES

## **Appendix 1**

### **Guidelines for Complaints**

These guidelines are intended to assist both complainants and subject companies to ensure that a fair and full review is conducted. If these general criteria are not met, the complaint may be returned for more information, or the review may be conducted in the absence of a complete response.

### **Externally generated complaints**

Where a complaint is generated from sources external to the industry, the complainant can simply report what is perceived as a problem provided the complainant states the nature of the practice being complained about, and a simple explanation of the reason(s) for the objection. Detailed literature reviews are not necessary, but where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review. It is expected that where medical literature is cited, a copy of that literature will be made available to Medicines Australia by the complainant for the purpose of review.

Medicines Australia may contact an external complainant and provide a range of options to assist them with the submission of their complaint. Medicines Australia may either provide information on the requirements of the Code of Conduct, including identifying possible sections, which will enhance the consideration of an externally generated complaint or provide access to an independent facilitator to assist the complainant with this process. This information will not alter or affect the general tenor or character of the complaint.

Complainants either as an individual/organisation or through the independent facilitator are encouraged to contact the Subject Company prior to lodging a complaint with Medicines Australia, as a satisfactory explanation or solution may be immediately available.

Failing resolution, the complainant may forward the complaint to Medicines Australia, using the 'Code of Conduct Submission Form'. This form can be found on the Medicines Australia website at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au) or by phoning the Medicines Australia office on 02 6282 6888.

To ensure a complaint receives the best consideration and that the responding company has full information, anonymous complaints will not be considered by the Code of Conduct Committee. If an individual or healthcare professional wishes to remain anonymous the Medicines Australia Secretariat will work with that healthcare professional or individual to ensure his or her concerns are addressed by the company concerned, the Code of Conduct Committee or Monitoring Committee.

### **Industry generated complaint**

#### **Intercompany Dialogue Guidelines**

The purpose of the guidelines is to promote successful intercompany dialogue between companies and provide an official timeframe for companies to undertake dialogue. These guidelines apply to both members of Medicines Australia and non-Medicines Australia member companies. Dialogue between the Subject Company and the complainant should be meaningful with a willingness from both companies to consider each others position and concerns.

The following Guidelines should apply to matters where it is clearly apparent that the lodgement of a Code of Conduct complaint is imminent. These Guidelines are not designed to restrict dialogue between companies in order to clarify promotional issues.

Medicines Australia will not accept a complaint from a company unless it has been clearly demonstrated that inter company dialogue has taken place and that, despite every effort on the part of both the complainant and the Subject Company, resolution of the matter has not been achievable. There must also be evidence of the active involvement of the most senior executive responsible for the company's prescription medicines business in attempting to resolve the complaint. Medicines Australia will not accept a complaint from a company where there is no endorsement by the Association Representative, alternate Association Representative (or for non-member companies the most senior executive responsible for the company's prescription medicines business.). If both the Association Representative and Alternate Association Representative are likely to be uncontactable when a complaint is lodged, a letter authorising the Medical Director to act as a signatory to the letter of complaint during a specified period will be acceptable.

#### **Procedures**

The complainant and Subject Company are both encouraged to initiate dialogue at any point in the process. In any event however, it is expected that dialogue will take place once the complainant company has received a written response from the Subject Company on the issues raised.

On receipt of a letter from the complainant the Subject Company is expected to respond to any issues raised by the complainant within 10 working days.

Following a response to the issues raised by the complainant, the Subject Company and complainant should within 10 working days from the receipt of the response organise a meeting to discuss any unresolved issues. Such a meeting must occur before a complaint can be submitted to Medicines Australia. In the event that no response to this request is received within the 10 working days, the Association Representatives of the respective companies must be informed. A request for direct contact between the Association Representatives should help to further this intercompany dialogue. Following this communication if no meeting can be convened within 2 working days the complaint may be forwarded directly to Medicines Australia (in the case of the complainant) or the matter is deemed finalised (in the case of the Subject Company). Any further interactions must occur on the basis of a new complaint with all the required timeframes.

- all inter-company correspondence must have the written endorsement of the Association Representative or alternate Association Representative.
- a teleconference or video conference may be an acceptable form of dialogue. An exchange of letters regarding the complaint will not usually be sufficient.
- at this meeting senior representatives from all relevant departments of both companies should be present
- if the Association Representatives are not present at this meeting, a record of the meeting should be provided to them for their signature. This signed record of the meeting must be submitted with the complaint.
- Medicines Australia is willing to act as a mediator should the companies desire.

#### **Resolution following dialogue**

Following the process of inter company dialogue, companies should have documented clearly the position of each party, ie including offers on the part of the Subject Company for resolution and whether or not the complainant is willing to accept such offers. There should also be clear evidence of any corrective action undertaken by the Subject Company as a result of the inter company dialogue. Should the complainant still wish to progress the matter to Medicines Australia, the complaint should be accompanied by the consensus minutes and any subsequent correspondence relating to offers for resolution and actions taken.

Under the current provisions of the Code, the response from the Subject Company must be provided to Medicines Australia within 10 working days of receipt of the complaint notification. If companies are directed to, or wish to continue intercompany dialogue after the acceptance of a complaint and this action results in a decision by the complainant to withdraw the complaint, notification must be provided to Medicines Australia by midday on the Tuesday prior to the next scheduled Code Committee meeting.

Should the complaint proceed for review by Medicines Australia, and there is evidence that corrective action has already been taken by the Subject Company, the Code of Conduct Committee may choose to take one or more of the following actions:

- (a) reduce the sanctions if the corrective action taken by the Subject Company is at least what the Code Committee would require
- (b) require the complainant to justify their decision to progress the complaint to Medicines Australia in view of an apparent resolution at inter-company level.
- (c) require the complainant to justify why their action in submitting the complaint did not constitute a breach of Section 12.3 (Abuse of the Code).

#### **Repeat Breach\***

In the case of an alleged repeat breach of the Code, the complainant may direct the complaint to Medicines Australia without a renewal of inter-company dialogue. However, Medicines Australia always encourages Companies to continue to discuss any complaint prior to, and following and complaint being submitted to Medicines Australia.

Medicines Australia will not accept a complaint from a company in relation to an alleged repeat breach if the activity does not fall within the definition of 'repeat breach' or where new activities are introduced into the complaint. The complaint will be returned to the complainant for the mandatory intercompany dialogue.

Inter-company complaints should not be used simply as a competitive tool.

#### **Complaints**

Inter-company complaints (whether or not a Medicines Australia Member) must include the following information to ensure a complete review:

- (a) if the complaint relates to promotional material, a copy or original of the material alleged to breach the Code of Conduct. If the complaint

relates to conduct, a copy or any original of any material documenting the alleged breach of the Code of Conduct;

- (b) clear identification of the Sections of the Code alleged to have been breached;
- (c) an explanation of the alleged breach;
- (d) sufficient supporting data and evidence to support the complaint;
- (e) details of any attempts to resolve the matter with the subject company in accord with the requirement for intercompany dialogue;
- (f) alleged consequences of the promotional material or activity on healthcare professionals or members of the general public; and
- (g) written endorsement of the Association Representative or alternate Association Representative of the complainant company.

20 copies of all documentation must be provided. One copy may be sent to Medicines Australia in the first instance provided the remaining 19 copies are forwarded within 5 working days. The complaint should follow the recommended format as set out in the 'Complaints Protocol' document. This document can be accessed by emailing [secretarycodecommittee@medicinesaustralia.com.au](mailto:secretarycodecommittee@medicinesaustralia.com.au)

In addition, complainants should note that:

- (a) when challenging a claim on medical/scientific grounds, it is not sufficient to simply state that the claim is not supported. Evidence must be provided to support the complainant's case.
- (b) if these criteria are not met, Medicines Australia may return the complaint to the complainant for further information.

### **Response by Subject Company**

When a complaint has been accepted for evaluation, the Subject Company is asked to state whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

When providing this information, the Subject Company should include:

- (a) a response to each alleged breach of the Code of Conduct;
- (b) substantiation of the specific alleged breaches with full supporting data;
- (c) details of attempts to resolve the matter with the complainant as required by the Code's intercompany dialogue guidelines;
- (d) 20 copies of all documentation are required;
- (e) 20 original pieces of the promotional material at issue;
- (f) 20 copies of the product's current Approved Product Information; and
- (g) The signature of the Association Representative or alternate Association Representative of the Subject Company

The complaint should follow the recommended format as set out in the 'Complaints Protocol' document. This document can be found obtained by emailing [secretarycodecommittee@medicinesaustralia.com.au](mailto:secretarycodecommittee@medicinesaustralia.com.au)

## Appendix 2

### Rules of Medicines Australia

The following is an extract of the Rules of Medicines Australia which refer to the disciplining of Members and rights of appeal.

#### **13. DISCIPLINING OF MEMBERS**

##### **13.1. *Where the Board is of the opinion that a Member:***

- a. has infringed or neglected to comply with any provision or provisions of the Objects, the Rules or Sections 12.2 or 12.3 of the Code of Conduct; or*
- b. is guilty of any act, proceeding or practice which the Board considers to be inconsistent with his position as a Member, or has acted in a manner prejudicial to the interests of the Association,*

*the Board may, by resolution:*

- i. expel the Member from the Association; or*
- ii. suspend the Member from membership of the Association for a specified period or until the breach for which he was suspended is remedied;*

*and/or*

- iii. ratify the imposition of a fine under Section 12.3 of the Code of Conduct*

##### **13.2 *A resolution of the Board under Rule 13.1 is of no effect unless the Board, at a meeting held not earlier than 14 days and not later than 28 days after service on the Member of a notice under Rule 13.3 confirms the resolution in accordance with this rule.***

**Rules of Medicines Australia (continued)**

**13.3** *Where the Board passes a resolution under Rule 13.1, the Secretary shall as soon as practicable, cause a notice in writing to be served on the Member:*

- a. setting out the resolution of the Board and the grounds on which it is based;*
- b. stating that the Member may address the Board at a meeting to be held not earlier than 14 days and not later than 28 days after service of the notice;*
- c. stating the date, place and time of that meeting; and*
- d. informing the Member that the Member may do either or both of the following:*
  - i. attend and speak at that meeting;*
  - ii. submit to the Board at or prior to the date of that meeting written representations relating to the resolution.*

**13.4** *At a meeting of the Board held as referred to in Rule 13.3, the Board shall:*

- a. give to the Member an opportunity to make oral representations;*
- b. give due consideration to any written representations submitted to the Board by the Member at or prior to the meeting; and*
- c. by resolution determine whether to confirm or to revoke the resolution.*

**13.5** *Where the Board confirms a resolution under Rule 13.5 the Secretary shall within 7 days after that confirmation, by notice in writing, inform the Member of the fact and of the Member's right of appeal under Rule 14.*

#### **Rules of Medicines Australia (continued)**

**13.6** *A resolution confirmed by the Board under Rule 13.4 does not take effect:*

- a. until the expiration of the period within which the Member is entitled to appeal against the resolution pursuant to Rule 14 where the Member does not exercise the right of appeal within that period; or*
- b. where within that period the Member exercises the right of appeal, unless and until the Association confirms the resolution pursuant to Rule 14.4.*

#### **14. RIGHT OF APPEAL OF DISCIPLINED MEMBER**

**14.1** *A Member may appeal to the Association in general meeting against a resolution of the Board which is confirmed under Rule 13.4, within 7 days after notice of the resolution is served on the Member, by lodging with the Secretary a notice to that effect.*

**14.2** *Upon receipt of notice from a Member under Rule 14.1, the Secretary shall notify the Board which shall convene a general meeting of the Association to be held within 21 days after the date on which the Secretary received the notice.*

**14.3** *At a general meeting of the Association convened under Rule 14.2:*

- a. no business other than the question of the appeal shall be transacted;*
- b. the Board and the Member shall be given the opportunity to state their respective cases orally or in writing, or both; and*
- c. the Members present shall vote by secret ballot on the question of whether the resolution should be confirmed or revoked.*

**Rules of Medicines Australia(continued)**

- 14.4** *If, at the general meeting, the Association passes a resolution in favour of the confirmation of the resolution, the resolution is confirmed. If the resolution fails, then the resolution of the Board is revoked.*

**23. DELEGATION BY BOARD TO COMMITTEE**

- 23.1** *The Board may, by instrument in writing, delegate to one or more Committees the exercise of such of the functions of the Board as are specified in the instrument, other than;*
- a. this power of delegation;*
  - b. a function which is a duty imposed on the Board by the Act or by any other law;*
  - c. the power to expel or suspend a Member as provided in Rule 13.1;and*
  - d. the power to impose a charge for abuse of the Code as recommended by the Code of Conduct Committee.*
- 23.2** *A Committee may consist of the representatives of such Member or Members of the Association as the Board thinks fit and, in the case of the Code of Conduct Committee and the Code of Conduct Appeals Committee, may also include such other persons, not being representatives of Members, as the Board considers to be suitably qualified.*

## Glossary

In this Code:

**"Advertisement"** means any communication which promotes or discourages the use, sale or supply of products (whether or not in conjunction with the supply of services, and whether or not the communication identifies particular products or services). This definition is the same as that included in the Therapeutic Products Advertising Code.

**"ADRAC"** means the Adverse Drug Reactions Advisory Committee of the Australian Drug Evaluation Committee.

**"Association"** means Medicines Australia Inc.

**"Australasian Congress"** means a congress held in Australia that is organised and controlled by an Australasian (or Australian and New Zealand) College or Society, or where a College or Society in New Zealand is actively organising and has joint control over the congress with an Australian Society or College.

**"Australian Privacy Legislation"** means the Privacy Act 1988 (Cth) and related legislation.

**"Boxed Warning"** is a mechanism adopted by the TGA for highlighting special warning statements in Product Information.

**"Brand name"** for the purpose of the Code of Conduct has the same meaning as "proprietary name" which is the registered trade mark of the therapeutic product or the unique name assigned to the product.

**"Brand name reminders"** means such items of low monetary value which are intended to remind healthcare professionals of the existence of a product.

**"Breach repetitions"** means when a company repeats the same breach in the promotion of any of the Company's products.

**"Breaches where activities have ceased"** means Severe Breaches of this Code where the promotional activity has been completed before the breach has been found and there is no opportunity for corrective action.

**"Change of clinical significance"** is any change in the Product Information that could alter a decision to prescribe or not to prescribe the product and may include the following:

- (a) approved indications for use
- (b) precautions for use
- (c) contra-indications
- (d) warnings
- (e) adverse events and interactions
- (f) available dosage forms
- (g) dosage regimens and routes of administration
- (h) dependence potential
- (i) reference to special groups of patients (where necessary)
- (j) boxed warnings

**"Chief Executive Officer"** means that person appointed to manage the affairs of the Association in accordance with the Rules of the Association.

**"Clinical tool"** means a dialogue box that opens within the prescribing software with diagnostic or medical information used to evaluate a patient

**"CMI"** means Consumer Medicine Information

**"Code of Conduct Secretary"** means that person appointed by the Medicines Australia Board to act as Secretary to the Code of Conduct Committee.

**"Company"** means all companies supplying prescription medicines in Australia.

**"Company Commissioned article"** (also known as an advertorial) means an article or series of articles which is paid for by a Company which represents the independent opinion of a third party and/or has the appearance of editorial material.

**"Company representatives"** are those persons, including medical representatives, authorised by a Company to disseminate information about a product to healthcare professionals.

**"Competition"** means any activity that includes an element of chance or random selection.

**"Congress"** means an event sponsored and organised by a Society, College, university or other non-company entity.

**"Consumers"** are persons other than healthcare professionals.

**"Consultant"** means a person engaged by a company to provide services or advice for a fee (not an employee of a company).

**"Continuing Education Program"** means the professional training program developed by Medicines Australia and which is compulsory for all medical representatives employed by companies or their agents.

**"Correct"** means representative of all the evaluable data.

**"Data on File"** is that body of unpublished clinical or scientific information held by a company. It does not include evaluated data submitted to the TGA in accordance with the Australian Registration Guidelines for Prescription Medicines.

**"Educational material"** means any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims.

**"Entertainment"** means the provisions of any diversion or amusement.

**"Evaluated data"** means data which have been submitted as part of an application for marketing in accordance with the Australian Registration Guidelines for Prescription Medicines which form the basis for registration of a product by the TGA.

**"General Public"** are persons other than healthcare professionals.

**"Graphics"** means the use of any pictorial or graphical representation in promotional material, including photographs, drawings, x-rays, graphs and bar charts, but excludes any related promotional text.

**"Guidelines"** means the current edition of the Code of Conduct Guidelines.

**"Healthcare professions and healthcare professionals"** includes members of the medical, dental, pharmacy or nursing professions and any other persons who in the course of their professional activities may prescribe, supply or administer a medicine.

**"Health consumer organisations"** are not for profit organisations that represent the interests and views of consumers of health care.

**"Hospitality"** means the provision of food and/or beverages.

**"IFPMA"** means International Federation of Pharmaceutical Manufacturers Associations.

**"Information"** means educational facts regarding the attributes of a product.

**"Industry"** means companies supplying prescription medicines in Australia

**"International congress"** means a congress held in Australia where a Society or College in an overseas country is actively organising and has joint control over the conference with an Australian Society or College.

**"Journal"** means a serial publication whose distribution is restricted to the members of the healthcare professions.

**"Literature"** means that body of published trials, findings and reviews which have appeared in medical and scientific publications.

**"Mailings"** means promotional material designed for distribution through the postal system or by private means.

**"Manufacturer"** includes the manufacturer, importer or Australian distributor of a pharmaceutical product.

**"Market research"** is the gathering of data on the scope or dimensions of a market and its components, including the needs of the customers in that market.

**"Medical claims"** includes any statement that conveys information about a disease state or the attributes of a product in respect of its therapeutic use, that is, a use for the purpose of or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, defect or injury in man;
- (b) influencing, inhibiting or modifying a physiological process in humans;
- (c) testing the susceptibility of man to a disease or ailment; or
- (d) destroying or inhibiting micro-organisms that may be harmful to humans.

**"Medical content"** means that portion of promotional material which makes a medical claim.

**"Medical representative"** means a person expressly employed by a company whose main purpose is the promoting of the company's products to healthcare professionals.

**"Medicine delivery device"** is any device used for the administration of a prescribed medicine, including Schedule 3 medicines that are predominantly prescribed by a medical practitioner that is distributed independently from the active ingredient and can be used to administer products from more than one product. The device will be listed with the TGA as a device.

**"Member"** means any person, firm or company holding Ordinary or Associate membership of the Medicines Australia Inc., as defined in the Rules of the Association.

**"Minor breach"** is a breach of this Code that has no safety implications to the patient's wellbeing and will have no major effect on how the medical profession will prescribe the product.

**"Moderate breach"** is a breach of this Code that has no safety implications to the patient's wellbeing but may have an effect on how the medical professional will prescribe the product.

**"New chemical entity"** means a product containing an active pharmaceutical ingredient which has not been previously included in a product approved for registration in Australia for human use, including new combinations, salts or esters of previously marketed substances.

**"New indication(s)"** means an additional indication for the drug which was approved by the TGA after the original registration of the drug.

**"Patient Support Program"** means a program run by a company with or without involvement from a health consumer organisation, with the aim of increasing patient compliance and positive patient health outcomes.

**"Pay journal"** means a journal that accepts a fee for publication.

**"PBS"** means the Pharmaceutical Benefits Scheme of the Commonwealth Department of Health and Ageing.

**"PBS availability"** means the availability of a product on the Pharmaceutical Benefits Scheme of the Commonwealth Government.

**"PBS Dispensed Price"** is the current dispensed Price for Maximum Quantity for a product found in the Schedule of Pharmaceutical Benefits.

**"Post-marketing surveillance studies"** means research intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the approved Product Information.

**"Primary advertisement"** is the type of advertisement that is mandatory for advertising of all new chemical entities or the advertising of new indications for 24 months from the date of first advertising in medical publications, or longer at the discretion of the company. Primary advertisements must also be used for at least 12 months following a change of clinical significance made to a product's Product Information. These advertisements are described in Section 3.1.1 of this Code.

**"Product"** means any pharmaceutical dose form and/or delivery method that is approved for registration by the TGA for human therapeutic use, provided that such compound has been scheduled for sale or distribution by prescription only in at least one of the States of Australia or that such compound is primarily promoted to medical practitioners for the purpose of encouraging them to prescribe or recommend usage of that compound.

**"Product familiarisation program"** means a programme run by the company with the aim of allowing the medical profession to evaluate and become familiar with the product.

**"Product Information"** means either the current Australian Approved Product Information or in the case of a product whose registration pre-dates the current regulatory review ("Grandfathered Product") the document registered is known as the Full Product Information. This Product Information must comply with the format specified in the TGA "Australian Registration Guidelines for Prescription Medicines". Product Information may also be presented as an Abridged Product Information or Minimum Product Information.

**"Product Manager"** means any person who is directly involved in the generation and development of promotional material. The identification of these individuals is the responsibility of the Association Representative.

**"Promote"** means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.

**"Promotion", "Promotional" or "Promotional claim"** means any statement made by a company or company's representative, whether verbal or written, which conveys the positive attributes of a product which

extend beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse reactions or other cautionary aspects of the product and comparative information.

**"Promotional material"** means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product.

**"Proprietary name"** means the registered trade mark of the therapeutic product or the unique name assigned to the product. For the purpose of the Code of Conduct, brand name has the same meaning as proprietary name.

**"Quality Use of Medicines" (QUM)** means

- selecting management options wisely
- choosing suitable medicines if a medicine is considered necessary
- using medicines safely and effectively

**"Reference manual"** is a serial or monographic publication designed by its publisher to provide information in classified sequence for the purposes of ready reference to pharmacological or medical data.

**"Registration"** is the issue by the TGA of an AUST.R number for a product approved for marketing in Australia in accordance with the Therapeutic Goods Act and Regulations.

**"Repatriation Pharmaceutical Benefit availability"** means the availability of a product on the Repatriation Pharmaceutical Benefit Scheme of the Commonwealth Government.

**"Repeat of previous breach"** means where the same or similar breach is repeated in the promotion of a particular product of a company which had been found in breach.

**"Rules"** means the Rules of the Association for the time being in force. See Appendix 2.

**"Satellite Meetings"** are meetings held in conjunction with international or Australasian congresses and are under the auspices of the Society, College or other non-company entity in question.

**"Secondary advertisement"** is the type of advertisement that is designed to reinforce information about a product, and may contain promotional claims. The sole use of a secondary advertisement within any one issue of a publication is not permitted before 24 months from first advertising of a new chemical entity or before 12 months following a change of clinical significance made to the Product Information. These advertisements are described in Section 3.1.2 of this Code.

**"Serious risk to public health and safety"**

Public health and safety generally is considered in terms of quality, safety and efficacy. In an advertising context, serious risk to public health and safety includes advertisements failing to protect the public by leading to an increase in the misuse, overuse and under-use of therapeutic products, or by inappropriate use, causing increased problems such as adverse events. In particular, those advertisements that:

- make claims beyond the approved indications or the intended purpose of use;
- (for medicines) promote self-diagnosis and treatment, prevention, cure or management of serious forms of diseases, conditions, ailments or defects, unless prior approval has been given (the agreed definition of 'serious' is given below);
- (for devices) promote the use of a device that is intended to be used/ and or administered solely by healthcare practitioners, unless prior approval has been given;
- contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects;
- promote inappropriate use or excessive use, which is contrary to warning statements or acceptable practice for that class of therapeutic product; and
- fail to disclose adverse reactions, which have a high frequency in terms of severity and clinical importance, in advertisements.

"Serious" in the context of advertisements for therapeutic products means those diseases, conditions, ailments and defects (or symptoms of the aforementioned) which are generally accepted as not being suitable

**"Severe breach"** is a breach of this Code that will have safety implications to the patient's wellbeing, and/or will have a major effect on how the medical profession will prescribe the product and/or will have a significant commercial impact on the relevant market. A Severe breach of the Code will also be found for activities that bring discredit upon or reduce confidence in the pharmaceutical industry.

**"Short advertisement"** is the type of advertisement that is designed to remind a prescriber of a product's existence but must not contain promotional claims. The sole use of a short advertisement within any one issue of a publication is not permitted before 24 months from first advertising of a new chemical entity or before 12 months following a change of clinical significance made to the Product Information. These advertisements are described in Section 3.1.3 of this Code.

**"Starter pack"** means a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists. Starter packs are also referred to as "samples" by healthcare professionals.

**"Substantiation"** means to give reasonable grounds in support of a promotional claim. Substantiating information should conform with the requirements of Section 1.3, and must not rely solely on data on file.

**"Sponsor"** as defined in the current Therapeutic Goods Act

**"Supplier"** means the same as "company" - companies supplying prescription medicines in Australia.

**"Symposium"** means a scientific meeting sponsored by a Company as an independent event or as a satellite to a congress.

**"Tagline"** means a phrase or statement consistently associated with a brand name.

**"Technical breach"** means a breach of this Code that refers to the type size that is specified in this Code or inaccurate or incorrect referencing.

**"Therapeutic class"** means the classification system used for defining and grouping products in an approved reference manual.

**"Therapeutic class number"** means the system of notation used in an approved reference manual.

**"Therapeutic Goods Administration"** is the Division of the Commonwealth Department of Health and Ageing that is responsible for the regulation of therapeutic goods in Australia. In mid 2006 this responsibility will be transferred to the Joint Therapeutics Agency of Australia and New Zealand. Throughout the Code reference to the Therapeutic Goods Administration should be regarded as synonymous with reference to the Joint Therapeutics Agency once this agency commences operation.

**"Therapeutic Products Advertising Code"** will take effect with the establishment of the Joint Therapeutics Agency of Australia and New Zealand in mid 2006.

**"Trade Display"** means a display or exhibit of promotional or educational material about a product or products.

**"Trade pack"** means a package of a product which is sold by the Company.

**"Type size"** means the height of the font's lower case letter "e".

**"Unique"** means being the first, different from all others and the only one of its class on the Australian market.

## Annexure 2: Copy of TGA Marketing Approval Letter

1. THE GOODS MUST CONFORM WITH THE FOLLOWING DESCRIPTION, MANUFACTURING INFORMATION, PRODUCT DETAILS, INDICATIONS, PRODUCT INFORMATION AND CONSUMER PRODUCT INFORMATION.

**DESCRIPTION OF GOODS FOR ACCEPTABILITY TO SUPPLY**

**NAME:** [Proprietary name] [Drug] [Dose Form]

**MANUFACTURER INFORMATION:**

**MANUFACTURER:**  
**STEP(S):**

**MANUFACTURER:**  
**STEP(S):**

**PRODUCT DETAILS**

**PRODUCT PROPRIETARY NAME:**

**PRODUCT GENERIC NAME:**

**PACK SIZE:**

**POISON SCHEDULE:**

**DOSAGE FORM:**

**ADMINISTRATION ROUTES:**

**CONTAINER TYPE:**

**VISUAL IDENTIFICATION:**

**STERILE:** Yes/No

**STERILISATION TYPE:**

**ANIMAL ORIGIN:** Yes/No

**Type of animal/insect/microbe:**

**FORMULATION:**

**Active ingredients:**

---

---

**Excipients:****Proprietary ingredients:**

**SHELF LIFE:** (The potency of this product lies between ... - ...% of the labelled content of ... during its approved shelf life.)

**Time:**

**Temperature:**

**Other Conditions:**

**INDICATIONS:****PRODUCT INFORMATION:**

The text of the Product Information submitted with your letter of [Date PI Cleared] is considered satisfactory. The approved document is attached to this letter as Attachment 1.

**PATIENT INFORMATION:**

You are reminded that in accordance with Regulation 9(A) of the Therapeutic Goods Regulations a Patient Information document is required to be available for supply to the patient or agent. The format of this document is set out in Schedule 12 of the Regulations. The Patient Information document submitted with your letter of ... {insert date} is considered to meet the format as presented in Schedule 12 and not to contain any statement contrary to the approved Product Information.

You are reminded that there is a continuing obligation to ensure that at all times the patient information document (Consumer Medicine Information - CMI) complies with the statutory requirements. Following amendment of the Product Information, any changes needed to the patient information to ensure consistency with the Product Information must be made within 3 months of the approval or notification of the change to the Product Information. In the case of changes relating to the safety or safe use of the product, more rapid change of the patient information may be warranted.

**2. THE STANDARD CONDITIONS APPLICABLE TO ALL REGISTERED GOODS ARE TO BE FOUND AT ATTACHMENT 2**

**3. SPECIAL CONDITIONS APPLYING TO THIS PRODUCT**

- (1) The Therapeutic Goods Administration Laboratories Branch (TGAL) is to be notified immediately the first production batches of this/these products are available for official sampling, under the terms of Regulation 24 of the Therapeutic Goods Regulations. This information should be sent to the Director, Therapeutic Goods Administration Laboratories Branch, PO Box 100 WODEN ACT 2606.

- (2) Appropriate quantities of the reference material for the active ingredient, as well as of precursors, degradation products and other impurities for which limits are set in the

finished product specifications are to be provided free of charge to the TGA, if required by TGAL.

- (3) Proposed changes to the approved chemical, pharmaceutical and biological details and specifications should be forwarded for evaluation by the Drug Safety and Evaluation Branch (DSEB) and must be approved prior to implementation, apart from a self-assessable change or a change which can be notified to the DSEB or the Australian Register of Therapeutic Goods (ARTG) as detailed in Appendices 7 and 8 to the document entitled:

Australian Guidelines for Registration of Drugs, Vol 1 - Prescription and Other Specified Drug Products, 2nd Edition (AGRD1). [Appendices 7 and 8 are entitled, respectively, Changes to Drug Products - Is Notification or Prior Approval Required? and Changes which may be made to Pharmaceutical Aspects of Drug Products without Prior Approval ('Self-Assessable Changes')]. Changes to test methods and specifications may also be required following laboratory analysis of the product by TGAL.

**Please note:** approved chemical, pharmaceutical and biological details and specifications include all those details on which approval is based in relation to sponsor, finished product details, formulation, active raw materials, excipients, manufacturing process, quality control, and packaging. (Refer to the AGRD Appendices 7 and 8 specified above.)

- (4) The Product Information (reference 4.20 AGRD1, 2nd edition) must meet with the TGA's approval at all times. With the exception of safety related changes that further restrict the use of the product, which must be notified to the TGA within five working days, any proposed changes to the approved text must be submitted and be approved by the Administration prior to distribution.

The safety related changes referred to above are defined as those that delete an indication or reduce the patient population, or add a warning, precaution, adverse reaction or contraindication.

The Product Information should conclude with a statement that it has been approved by the Therapeutic Goods Administration (TGA), citing the date of the approval letter. **Two copies of the final printed version of the Product Information are to be forwarded to the Drug Safety and Evaluation Branch.** For all injectable products the Product Information must be included with the product as a package insert.

Abridged Product Information must accurately reflect the approved Product Information, including safety related statements, but may be a paraphrase or precis of the approved Product Information.

- (5) Promotional material (other than Product Information) relating to the registered good must comply with the requirements of the Code of Conduct of the Australian Pharmaceutical Manufacturers' Association.
-

- (6) The actual date of commencement of supply is to be notified to the Director, Drug Safety and Evaluation Branch, in addition to notifying the ARTG. Should it be decided not to proceed to supply, notification to this effect should be provided.
- (7) Post marketing reports are to be provided annually until the period covered by such reports is not less than three years from the date of this approval letter. No fewer than three annual reports are required. The reports are to meet the requirements for Periodic Safety Update Reports as described in ICH document Topic E2 (CPMP/ICH/228/95). Unless agreed separately between the supplier who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 15 calendar months after the date of this approval letter. The subsequent reports must be submitted no less frequently than annually from the date of the first submitted report. The annual submission may be made up of two Periodic Safety Update Reports each covering six months. If the sponsor wishes, the six monthly reports may be submitted separately as they become available. Submission of the report must be submitted within the sixty days of the data lock point for the report (or, where applicable, the second of the two six monthly reports), as required by CPMP/ICH/228/95.

In the absence of the availability of Periodic Safety Update Reports, a report is to be provided annually for three years from the date of approval which shall include details of:

- (a) all investigational studies relating to the chemical and physical properties, including stability of the drug under storage;
- (b) all pharmacological and toxicological studies conducted or reported, including studies recorded in scientific literature;
- (c) all clinical studies conducted or reported in Australia or abroad, including studies recorded in scientific literature, and a bibliography of these reports;
- (d)
  - (i) all suspected adverse reactions or similar experiences occurring in Australia received, including full clinical details (For adverse reactions occurring outside Australia, see Appendix 20 of AGRD1, 2<sup>nd</sup> Edition. Note: for the three year period specified, reporting is mandatory); and,
  - (ii) significant foreign adverse events which may have implications for the product information documents for this chemical entity.

Each report is to be accompanied by a statement of the amount of each presentation of the product issued in Australia in the same period (or a period up to the same data lock point).

The above information should be forwarded to the TGA at the appropriate time.

- (8) Details of the distribution of the drug including quantities and forms of products distributed and related batch numbers should be supplied on request while the drug remains on the ARTG.

You should be aware that:

Pursuant to the Customs (Prohibited Imports) Regulations a current permit to import is required for antibiotics and may be obtained from:

The Antibiotics Import Officer  
Chemistry Section  
Therapeutic Goods Administration Laboratories.  
Telephone: (02) 6232 8452; Facsimile: (02) 6232 8450

or

This drug is of biological origin and a permission to import should be requested from:

Australian Quarantine and Inspection Service  
Department of Primary Industries and Energy  
GPO Box 858  
CANBERRA ACT 2601  
Telephone: (02) 6272 4578 Facsimile: (02) 6273 2097

or

The active ingredient of this product is listed in the 8th Schedule of the Customs (Prohibited Imports) Regulations and a current permission to import is attached. (See also Condition No 20 of the attached Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989).

or

You should contact the Treaties Monitoring Section, Chemicals and Non Prescription Drugs Branch, TGA, Department of Health and Family Services, GPO Box 9848 CANBERRA ACT 2601, for approval to import or export this product. (See also Condition No 20 of the attached Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989).

or

This product contains radioactive materials and approval to import must be obtained before importation from the Director, Australian Radiation Laboratory, Lower Plenty Road YALLAMBIE VIC 3085. Telephone: (03) 943 32211; Facsimile: (03) 943 21835.

Please note that the Chief Pharmaceutical Adviser, Department of Veterans' Affairs, would like to be provided with a copy of the approved product information for this product. The Therapeutic Goods Act does not permit the TGA to supply this now. Please consider providing a copy to:

The Chief Pharmaceutical Adviser  
Department of Veterans' Affairs  
PO Box 21  
WODEN ACT 2606

This decision is an initial decision within the meaning of Section 60 of the Therapeutic Goods Act 1989 (the Act). This means that if your interests are affected by the decision, you may seek review of the decision by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister  
for Health and Aged Care  
Parliament House  
CANBERRA ACT 2600

**The letter should be headed APPEAL UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989".**

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours faithfully

DELEGATE OF THE SECRETARY

**Attachments:**

1. Approved Product Information
2. Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989
3. Registration Form

## Annexure 3: Background to the Joint Therapeutics Agency

On 10 December 2003, the Australian and New Zealand Governments signed an agreement to establish a joint regulatory scheme for therapeutic products. The joint scheme will regulate medicines (including complementary medicines) and medical devices.

The founding Treaty that establishes the Joint Therapeutics Agency is broad-brush in scope; the detail will be included in the new Therapeutic Products Act, which will include the operating framework for the Joint Therapeutics Agency, associated Rules that will provide the details currently set out in the TGAct and Regulations, Orders that will cover matters such as labelling requirements, standards and regulatory Guidelines.

In order to achieve a harmonised system of advertising between Australia and New Zealand, the Report of a Review of Advertising Therapeutic Products in Australia and New Zealand (the Toogoolawa Report) recommended that 'a set of high level Principles be agreed upon in Australia and New Zealand as the basis for inclusion in parallel legislation; and that this be done in consultation with relevant interest groups in both countries'.

Further to this recommendation, a set of key Advertising Principles (as outlined below) has been developed and agreed upon in Australia and New Zealand following broad consultation with stakeholders. These embody the spirit and intent of the requirements for responsible advertising of therapeutic products and underpin the proposed system of regulatory controls.

### PRINCIPLE 1

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

### PRINCIPLE 2

**Advertisements must be truthful, balanced and not misleading.**

**Claims must be valid and have been substantiated.**

### PRINCIPLE 3

**Advertisements must observe a high standard of social responsibility.**

Under the terms of the Treaty, the Ministerial Council has the power to determine Rules which regulate the promotion of therapeutic products. It is proposed that Advertising Requirements, which expand on the above principles, be included in the Rules and given equal legislative force in Australia and New Zealand.

It is expected that the Therapeutic Products Advertising Code will be adopted by and incorporated into the individual industry and professional bodies' codes of practice to provide the minimum standard for advertising of therapeutic products both to consumers and to healthcare professionals. The industry codes of practice may expand upon the Code for further guidance or to allow for other provisions, in particular those relating to the conduct of their members.

## Annexure 4: Galbally Report - Recommendation 12

### Supply of sample packs of medicine and poisons

That all Commonwealth, State and Territory jurisdictions agree that:

- (a) States and Territories repeal provisions relating to the prospective supply of products including samples of medicines and poisons within their drugs, poisons and controlled substances legislation. (With the exception of those relating to the prospective supply of *Schedule 7* products and *Schedule 8* substances, where the prohibition should be maintained).
- (b) The Australian Pharmaceutical Manufacturers Association, in consultation with government, consumers and health professional organisations, amend their Code of Conduct for the Supply of Clinical Samples. The Code should include standards for:
  - the security of the stock;
  - the quantities to be held, carried and supplied;
  - quality issues, such as the temperature of storage;
  - record keeping; and
  - disposal.
- (c) State and Territory drugs and poisons legislation be amended to provide that:

**National Competition Review of Drugs, Poisons and Controlled Substances  
Legislation: Part A**

  - it be a condition of licence that manufacturers and wholesalers comply with the Australian Pharmaceutical Manufacturers Association Code of Conduct for the Supply of Clinical Samples; and
  - authorised representatives of manufacturers and wholesalers be exempted from requirements in medicines and poisons legislation that would make it an offence for them to supply scheduled medicines provided they do so in compliance with the Australian Pharmaceutical Manufacturers Association Code of Conduct for the Supply of Clinical Samples.
- (d) A requirement be included in medicine and poisons legislation to ensure that those supplying medicines, including clinical samples, provide the consumer with adequate instructions, including labelling the samples with the directions for use, to enable the consumer to use the clinical sample safely and effectively.
- (e) The Australian Chemical Specialties Manufacturing Association, together with other chemical industry associations and in consultation with government, consumers and health professionals, develop a Code of Practice for the Supply of Consumer Samples of Poisons. The Code should include standards for:
  - the substances which may be supplied as consumer samples;
  - the way in which the consumer samples may be distributed;

- to whom they may be distributed;
  - the size of the sample packs and the quantities which may be distributed to a consumer;
  - the labelling and packaging requirements for the samples; and
  - disposal.
- (f) State and Territory drugs and poisons legislation be amended to provide that, for consumer samples of *Schedule 5* and *6* poisons, distribution should be permitted provided such supply takes place in accordance with a Code of Conduct for the Supply of Consumer Samples of Poisons.



## Annexure 5: Stakeholder Consultation in relation to Galbally Review recommendations

- Medicines Australia membership
- Royal Australasian College of Physicians
- PGA
- Society of Hospital Pharmacists
- Australian Medical Association
- PSA
- ADGP
- Rural Doctors Association
- Doctors Reform Society
- Therapeutic Goods Administration
- Consumers Health Forum
- ASCEPT
- RACGP
- PHARM
- Ms Melissa Raven, Flinders University
- Dr Ken Harvey, Latrobe University

## Annexure 6: Guidelines to be read in conjunction with Edition 15 of the Code



## **Code of Conduct Guidelines**

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

**1 January 2006**

## INDEX

| <u>Provision</u>  | <u>Page</u> |
|---|-------------|
| Introduction .....  | 4           |
| Format .....  | 4           |
| Section 1 Nature and Availability of Information and Claims                           |             |
| 1.2 Substantiating Data .....   | 5           |
| 1.3 False and Misleading Claims .....   | 8           |
| 1.7 Comparative Statements .....  | 9           |
| PBS Information Disclosure Requirements   |             |
| 3.1 Journal Advertising .....   | 10          |
| 3.1.4 Company Commissioned Articles .....   | 13          |
| 3.2 Reference Manual Advertising .....  | 13          |
| 3.3 Printed Promotional Material .....  | 13          |
| 3.6 Audiovisual Promotional Material .....  | 14          |
| 3.7 Company Computer Based Promotional Material .....                                 | 14          |
| 3.8 Advertising in Electronic Prescribing Software .....                              | 14          |
| 3.10 Restricted Access Television Advertising .....                                   | 14          |
| 4.10 Company Representatives .....  | 14          |
| 6.1 Trade Displays .....  | 14          |
| 10.4 Medical Education .....  | 14          |
| Section 3 Promotional Material  |             |
| 3.1 Journal Advertising .....   | 15          |
| 3.3 Printed Promotional Material .....  | 15          |
| 3.4 Mailings .....  | 16          |
| 3.9 Advertising in Electronic Prescribing Software .....                              | 17          |
| 3.11 Gifts/Offers .....   | 18          |
| 3.12 Brand Name Reminders .....   | 19          |
| 3.13 Competitions .....   | 20          |
| The use of the internet for pharmaceutical information                                |             |
| 3.8 Healthcare Professionals .....  | 22          |
| 9.6 General Public .....  | 22          |
| Section 4 Company Representatives .....   | 25          |
| Section 5 Product Starter Packs .....   |             |
| 5.1 Product Starter Packs .....   | 27          |
| Section 6 Involvement in Educational Symposia, Congresses and Satellite Meetings      |             |
| 6.1 Trade Displays .....  | 29          |
| Invitations .....   | 30          |
| 6.4 Sponsorship or Involvement in Australasian Congresses and Satellite Meetings..... | 31          |
| 6.5 Sponsorship of Healthcare Professionals .....                                     | 31          |
| Section 7 Sponsorship .....   | 32          |
| Section 8 Research  |             |
| 8.2 Market Research .....   | 34          |

|   |    |
|---|----|
| Section 9 Relationship with the General Public                    |    |
| 9.2 Product Specific Media Statements .....                       | 35 |
| Discredit to and reduction of confidence in the industry          |    |
| 9.8 General Public .....  | 36 |
| 10.8 Healthcare Professionals .....                               | 36 |
| Relationship with Health Care Professionals                       |    |
| 6.2/10.2 Hospitality .....  | 37 |
| 6.6 Venues .....  | 37 |
| 6.8 Travel .....  | 38 |
| 10.1/10.6.9 Entertainment .....                                   | 38 |
| 6.8/10.2/10.3 Costs incurred by partners or family .....          | 39 |
| 10.4/10.5 Medical Education and Medical Literature/reprints ..... | 40 |
| 10.6 Consultants and Advisory Boards .....                        | 41 |
| Section 12 Sanctions  |    |
| 12.3 Abuse of the Code .....                                      | 42 |
| Appendix 1 Complaints Handling Process .....                      | 43 |
| Appendix 2 Appeals Procedures .....                               | 44 |
| Appendix 3 Code of Conduct Summary .....                          | 45 |
| Appendix 4 Journal and Reference Manual Advertising .....         | 47 |
| Appendix 5 Advertising in Electronic Prescribing Software .....   | 50 |
| Appendix 6 Non - Paper Based Advertising .....                    | 51 |
| Appendix 7 Invitation Checklist .....                             | 52 |

## Introduction

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

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

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

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

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

## Format

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

|   |
|---|
| <b>Section 1    Nature and Availability of Information and Claims</b> |
|---|

**Section 1.2    Substantiating Data**

The purpose of this section is twofold. First, it affirms that in response to a reasonable request, supporting evidence must be made available to both 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 latter documents do not conflict with the Product Information.

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

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

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

These publications can be accessed from the NHMRC website at [www.health.gov.au/nhmrc/publications/pdf/cp69.pdf](http://www.health.gov.au/nhmrc/publications/pdf/cp69.pdf)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Code of Conduct Committee, when considering a complaint, requires that any substantiating data is provided to it and will rigorously review this data to ensure that it is of sufficient quality and weight to support the claims being made. The addition of a member of Australian Society for Clinical, Experimental Pharmacologists and Toxicologists (ASCEPT) and the other 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

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

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

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

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

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

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

## Section 1.7 Comparative Statements

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

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

The intent of any comparison should be that it provides valuable and accurate information comparing products for the benefit of 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.

### Journal Advertising (Section 3.1)

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

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

### 1. General Requirements

These requirements apply to advertisements and printed promotional material:

- 1.1 The PBS disclosure information should be contained within a text box that has a white background and is outlined in black.
- 1.2 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.)
- 1.3 The text should appear in solid black with no half tones.
- 1.4 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.
- 1.5 The text size should reasonably fill the text box with the minimum size to be not less than 2mm.
- 1.6 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

- 2.1. 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**

- 2.2 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.**

- 2.3 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**

- 2.4 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**

- 2.5 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.**

- 2.6 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.

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

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

#### 3.1 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 cm<sup>2</sup> 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".

#### 3.2 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 cm<sup>2</sup> 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".

#### 3.3 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 cm<sup>2</sup> and must allow text of no smaller than 2mm. For example, a text box could measure 10cm x 1cm, 5cm x 2cm, 7.5cm x 1.33 cm or 8cm x 1.25cm.

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

#### Short Advertisements (Section 3.1.3)

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

Company Commissioned Articles (Section 3.1.4)

Company commissioned articles that contain a reference to any specific product must comply with the PBS disclosure requirements of the Code and its Guidelines and inclusion of Product Information as required by Section 3.1.1. or Section 3.1.2.

Congress Reports (Sections 3.1.4 and Section 10.5)

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

Reference Manual Advertising (Section 3.2)

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

e.g

|  |
|--|
| <b>For PBS Information refer to Section 2(f)</b> |
|--|

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)

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

For small promotional documents the following requirements apply:

Medi-message telephone message pads

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

Doctors' Desk sets

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

Diaries/Calendars

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

Audiovisual Promotional Material (Section 3.6)

Company Computer Based Promotional Material (Section 3.7)

Advertising in Electronic Prescribing Software Packages (Section 3.9)

Restricted Access Television Advertising (Section 3.10)

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

Company Representatives (Section 4.10)

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

Trade Displays (Section 6.1)

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

Medical Education Material (Section 10.4)

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

|   |
|---|
| <b>Section 3     Promotional Material</b> |
|---|

**Section 3.1     Journal Advertising****Section 3.1.1 Primary Advertisement**

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

**Section 3.1.3 Secondary Advertisement**

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

**Section 3.1.3 Short Advertisement**

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

**Section 3.3     Printed Promotional Material**

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

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

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

*"Please review Product Information before prescribing. Product Information is available from the trade display."*

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

For small promotional documents the following requirements apply:

**Medi-message telephone message books**

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

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

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

#### Doctors' Desk sets

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

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

#### Diaries

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

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

#### Calendars

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

### **Section 3.4 Mailings**

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

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

### Section 3.9 Advertising in Electronic Prescribing Software

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

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

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

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

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

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

### Section 3.11 Gifts/Offers

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

- |    |              |  |
|----|--------------|--|
| a) | Section 3.12 | Brand Name Reminder  |
| b) | Section 3.13 | 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 10.4 | Medical Educational Material   |

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

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

### Section 3.12 Brand Name Reminders

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.

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

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

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

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

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

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

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

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

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

### Section 3.13 Competitions

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

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

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

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

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

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

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

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

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

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

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

## Use of the Internet for Pharmaceutical Information

### Section 3.8 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 9.6 Information to the General Public

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## Section 4 Company Representatives

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

### Section 4.5 Hospital policies and operating theatre procedures

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

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

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

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

### Section 4.8

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

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

### Section 4.11

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

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

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

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

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

As of 1 January 2006, any person newly employed in a role (whether a new employee or a transfer from another position) where their primary employment is the development, review and approval of promotional materials for prescription medicines or the review of promotional materials must have completed the Code of Conduct component of the endorsed Medicines Australia education program within 12 months. If staff transferring to a new company were previously in this role (development, review and approval of materials) there is no requirement to complete the Code of Conduct component of the currently endorsed Medicines Australia education program. However if the company representative was not employed in this role previously they must complete the Code of Conduct component of the endorsed Medicines Australia education program within 12 months of commencing employment in this role. If a company takes the decision to require additional training to that referred to in the Code eg require all staff to complete the Code of Conduct component of the endorsed Medicines Australia education program that is at the company's discretion.

## Section 5 Product Starter Packs

### Section 5.1 Supply of Starter Packs

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

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

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

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

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

#### Labeling

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

#### Number of Starter Packs

The Code does not stipulate a maximum number of starter packs that can be provided to various 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 Product Information, the Code Committee has expressed the view that if it was in the best interest of patients this could be justification for providing sufficient tablets in the starter kit to achieve a quality use of medicine outcome.

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

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

Requirement for signature when requesting or receiving starter packs

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

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

**Section 6      Involvement in Educational Symposia, Congresses and Satellite Meetings**

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

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

The purpose of this section is to detail how the industry should contribute to educational meetings and its behaviour at such meetings. The Code recognises that the industry plays a vital role in the provision of accurate and reliable information to 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.

**Trade Displays**

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

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

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

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

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

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

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

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

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

#### Invitations to company-sponsored educational meetings

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

##### *Length of meetings*

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

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

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

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

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

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

### *Partner Payments*

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

### *Venues*

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

It is also acceptable to provide appropriate hospitality to attendees at a third party educational meeting, such as dinner for visiting 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 incidental entertainment such as a string quartet in the background. The intention is that any entertainment included in a dinner that is sponsored by a company should not be a focal point during the dinner, such as a concert presentation, dance band etc. The test will be whether the entertainment detracts from the educational intent of the meeting in total and would be able to successfully withstand public and professional scrutiny. A useful test for companies may be whether they could support their choices if questioned by the media. This test applies to both domestic and international events.

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

### **Sponsorship of Health Care Professionals**

This section applies when companies sponsor healthcare 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.

## Section 7 Sponsorship

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

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

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

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

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

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

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

Sponsorship should not be used as a vehicle to avoid other requirements of the Code. For example, a College or Society should not be influenced to hold a sporting event for 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 Code recognises the importance of the pharmaceutical industry's support of these worthwhile activities and encourages industry participation. However the Code does require companies to consider several issues when they are considering providing sponsorship for charitable or philanthropic organisations or events.

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

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

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

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

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

**Section 8     Research****Section 8.2     Market Research**

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

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

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

**Section 8.2.2**

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

Any remuneration must be commensurate for the time spent.

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

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

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

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

See also Section 3.13 dealing with competitions.

## Section 9 Relationship with the General Public

### Section 9.2 Product Specific Media Statements

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

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

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

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

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

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

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

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

|   |
|---|
| <b>Discredit to and reduction of confidence in the industry</b> |
|---|

**Section 9.8 General Public**

**Section 10.5 Healthcare Professionals**

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

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

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

## Section 10 Relationship with Healthcare Professionals

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

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

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

### Sections 6.2/10.2 Hospitality

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

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

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

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

### Section 6.6 Venue Selection

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

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

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

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

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

## Sections 6.8 Travel

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

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

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

## Sections 10.1/10.6.9 Entertainment

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

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

An allowance has been made in relation to educational meetings of two days' duration or longer, where it is possible for a period of no longer than half a day to be allocated for 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 organise 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.

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

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

#### Section 10.4 Medical Education and Section 10.5 Medical Literature/Reprints

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

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

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

## Section 10.6 Consultants and Advisory Boards

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

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

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

## Section 12 Sanctions

### Section 12.3 Abuse of the Code

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

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

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

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

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

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

## Appendix 1 - Medicines Australia Complaints Handling Process

