11.1.2 If the 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 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 Committee shall remain confidential and shall not be released to any third parties until after the Subject Company has exhausted all appeal procedures and the outcome of any appeal is known.

11.1.3 In the event of the Committee requiring a Company to cease or withdraw a promotional activity, the Company shall at once comply with the Committee's ruling pending any appeal against the decision of the 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 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 Committee's decision.

11.1.5 The 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 Committee of the need for the determination.

11.2 Membership of Committee

The membership of the Committee shall be:

Full Membership

- Chairman — Lawyer with Trade Practices experience

  or

- Deputy Chairman Lawyer with Trade Practices experience
- Representative of the Australian Medical Association
- Representative of the Royal Australian College of General Practitioners
- Representative of the Australian Divisions of General Practice
- Representative of a patient support group, preferably with specialist qualifications.
- Representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
- Representative of a Consumers' Organisation
- 3 x Medicines Australia Association Representatives
- 2 x Medicines Australia Medical/Scientific Directors

Advisers

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

Observers

- Representative of the Therapeutic Goods Administration
- A member of Medicines Australia's Marketing Working Group
- Two employees of Medicines Australia's member companies
- An observer interested in the Code process

11.2 Procedure of appointment

Chairman and Deputy Chairman — appointed by the Medicines Australia Board.

AMA Representative — a general practitioner nominated by the Australian Medical Association.

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.

Patient Support Group Representative — nominated by relevant patient support group.

ASCEPT Representative — nominated by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists.

Consumers' Organisation Representative — nominated by a recognised national consumer organisation.

Medicines Australia Association Representatives — selected from Medicines Australia Association Representatives who have no conflict of interest with product or company against which a complaint has been lodged.

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

TGA Observer — representative with medical/pharmaceutical qualifications nominated by Therapeutic Goods Administration.

Medicines Australia Marketing Working Group Observer — selected from members of the Medicines Australia Marketing Working Group who have no conflict of interest with any of the products or companies against which a complaint has been lodged.

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 with any of the matters being considered at the meeting to which they have been invited to attend.

11.2 *(continued)*

Members and the Therapeutic Goods Administration observer of the Committee will be appointed for a period of three years and will be eligible for re-nomination at the completion of their term.

With the exception of the ASCEPT member, as a general rule alternate members will not be permitted. However Alternate Observers may be permitted providing the prior agreement of the Chairman is obtained. An alternate observer must attend for the duration of the meeting and for that meeting will carry out all the duties of the nominated person.

ASCEPT may nominate a representative and an alternate representative.

Observers and advisers of the Committee have no voting rights.

A meeting of the 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.

11.3 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.

Invited observer — is any 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.

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.

11.4 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 Medicines Australia's Code of Conduct 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 of Conduct 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 of Conduct 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.

11.5 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.

12. Sanctions

12.1 Sanctions against a subject company may be applied 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 five (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.

12.1.3 The issuing of a fine by the Committee to the subject company in accordance with Section 12.1.4 of the Code. The fine to be paid within 30 days of being advised subject to any appeal that may be lodged under Section 13 of the Code.

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

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
Technical Breach*	maximum of $100,000
Minor Breach*	
Moderate Breach*	
Severe Breach*	
Severe Breaches where activities have ceased*	maximum of $200,000
Breach Repetitions*	
Repeat of Previous Breach*	

12.2 If the 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 provision of the Rules of the Association.

12.3 Abuse of the Code

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

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 Guidelines to the Code of Conduct.

13. Appeals

13.1 A subject company who has been found in breach of Section 11 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. Such an appeal, in writing, must be lodged 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 Code of Conduct Appeals Committee.

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

This appeal will be heard by the Medicines Australia Code of Conduct Appeals Committee.

13.2 When a subject company lodges an appeal in accordance with Section 13.1 of the Code, the Subject Company must lodge a bond of $5,000 with the Medicines Australia at the same time as lodging the appeal. The Medicines Australia Code of Conduct Appeals Committee has the discretion to refund all, part or none of the $5,000 bond in the event of the findings and/or the sanction being lifted or changed. If the appeal is rejected the bond of $5,000 will be forfeited and will be used to defray the costs of the appeal.

13.3 A complainant company who has had fines imposed by the Committee under Section 12.3 of the Code may lodge an appeal against such fines. The appeal, in writing, must be lodged by the complainant within five 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.

13.1 The appeal shall not be a strict re-hearing of the original complaint. The Subject Company may appeal the findings where it has been found to be in breach of Section 11 of the Code and/or any sanction that have been imposed on it. The Medicines Australia Code of Conduct Appeals Committee has the power to reverse the findings and/or lift or alter any sanction, which has been imposed. An appeal will be upheld only if the Medicines Australia Code of Conduct Appeals Committee is persuaded that the findings of the Code of Conduct Committee or the sanction imposed by it should be set aside or varied.

Both the Subject Company and the complainant may provide an oral presentation to the Code of Conduct 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.

13.2 There shall be only one bond of $5,000 payable for each complaint, irrespective of the number of findings of breach or sanctions imposed.

13.4 Appeals Committee Membership

The Medicines Australia Code of Conduct Appeals Committee will consist of the following:

Full Membership

- Independent Chairman or Deputy Chairman, a lawyer with Trade Practices experience
- 1 x Representative from the College and/or Society from the therapeutic class of the product
- 1 x Representative from the target audience to which the activity was directed eg: AMA, RACGP, ADGP or a representative consumer organisation
- 1 x Representative from ASCEPT
- 2 x Medicines Australia Association Representatives
- 1 x Medicines Australia Medical/Scientific Director

Advisers

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

Advisers of the 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 Medicines Australia.

13.5 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 Committee of the need for the determination.

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

At each meeting of the Committee, the Chairman will enquire as to whether any Committee member has a conflict of interest regarding either the product against which the complaint has been lodged or the complainant or subject company. The 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 company makes contact with these experts prior to the Appeals meeting.

14. Monitoring

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

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.

The Committee may review all forms of promotional material.

The protocol for the activities of the Monitoring Committee, which are determined by Medicines Australia's Board, are included in this Code at Appendix 3.

14.1 Referral to the Code of Conduct Committee

If in the view of the Monitoring Committee, any promotional material reviewed is considered in breach of the Code of Conduct, the Member will be advised and provided the opportunity to state whether the determination of the Committee is correct and give any answer or explanation deemed necessary. This response will be considered by the Monitoring Committee to determine whether the matter should be referred to the Code of Conduct Committee.

The Monitoring Committee having considered this response may refer the matter to the Code of Conduct Committee for adjudication as a complaint.

14.2 Reporting

The Monitoring Committee will issue an Annual Report that is to be included in 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.

14.3 Review

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

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.

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.

16. Reporting

16.1 Annual Report

Medicines Australia will issue an Annual Report on the activities of the Code of Conduct Committee that will be available to the industry and members of the health care professions. The Code of Conduct Committee Annual Report will contain the following information regarding complaints considered by the Committee during the reporting year:

(a) Names of companies who have had complaints brought against them.

(b) The name of the complainant unless the identify 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 Committee.

(e) The section of the Code, if any, which was breached and the reasons for finding the breach.

(f) Any sanctions imposed for the breach.

(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 of Conduct meetings.

(j) Performance indicators as to the time taken to deal with complaints and activities undertaken to increase healthcare professional's awareness of the Code of Conduct.

(k) All of the information mentioned in paragraphs (a) to (e) above shall remain confidential and shall not be included in the Annual Report of the Code of Conduct Committee until after the exhaustion of all appeals procedures and the outcome of any appeal is known.

16.2 External Reporting

Medicines Australia will also release a summary of all Code breaches, including any sanctions imposed which will be published in appropriate medical journals on at least a six monthly basis.

Medicines Australia, will on occasion, provide information regarding the activities of the Code of Conduct Committee to the general public including media outlets and will on occasion, upon request, provide such information to parties with a genuine interest. Medicines Australia will contact the relevant company before the release of any information.

Information regarding complaints that involve activities directed towards members of the general public will be made available via Medicines Australia website. Information about these complaints will include:

(a) The name of the company against which a complaint has been.

(b) The name of the complainant, where appropriate

(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 Committee.

(e) The section of the Code, if any, which was breached and the reasons for finding the breach.

(f) Any sanctions imposed for the breach.

This information shall remain confidential and shall not be released until after the exhaustion of all appeals procedures and the outcome of any appeal is known.

16.3 Internal Reporting

In addition to the Annual Report, to enhance understanding of the Code of Conduct process and increase compliance, Medicines Australia will publish and provide to Companies on a timely, regular and ongoing basis the following information:

(a) The name of companies against whom complaints have been made

(b) The product, behaviour, conduct and/or promotional material subject to the complaint.

(c) A summary of the complaint, response and deliberations of the Code of Conduct Committee.

(d) The section of the Code, if any, which was breached and the reasons for finding the breach.

(e) Any sanctions imposed for the breach.

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

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

Complainants 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.

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 to assist them with the submission of their complaint or may provide information on the requirements of the Code of Conduct, including possible sections, that will enhance the consideration of an externally generated complaint. This information will not alter or affect the general tenor or character of the complaint.

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 health care professional wishes to remain anonymous the Medicines Australia National Office will work with that health care professional or individual to ensure his or her concerns are addressed by either 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.

Medicines Australia encourages companies to engage in dialogue to discuss any unresolved issues prior to forwarding a complaint to Medicines Australia. 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.

Unless an adequate reason for not complying with these guidelines is given to the satisfaction of Medicines Australia or the Chairman of the Code of Conduct Committee, the Medicines Australia National Office may not accept a complaint for evaluation.

Procedures

Dialogue between both the subject company and the complainant is required and should be meaningful with a willingness from both companies to consider each others position and concerns.

- All inter-company correspondence must have the written endorsement of the Association Representative, Chief Executive or an alternate Association Representative.
- On receipt of a letter from the complainant the subject of the complaint (subject company) shall be invited to respond to any issues raised by the complainant within ten (10) working days.
- Following a response to the issues raised by the complainant, the subject company and complainant should be provided ten (10) working days from the receipt of the response to organise a meeting to discuss any unresolved issues or forward a complaint to the Medicines Australia.
- A teleconference or video conference may be an acceptable form of a meeting. An exchange of letters regarding a 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.

Inter-company complaints should not be used simply as a competitive tool.

Complaints from one pharmaceutical company (whether or not a Medicines Australia Member) against a Medicines Australia member company 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 requirements for intercompany dialogue.

(f) Alleged consequences of the promotional material or activity on health care professionals and/or consumers

(g) Written endorsement of the Association Representative, Alternate Association Representative or chief executive of the complainant company.

If a complaint and supporting data exceeds 10 pages, 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 five (5) working days.

In addition, complainants should note that:

i. 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 complainants case.

ii. 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) Where the response is greater than 10 pages, 20 copies of all documentation is required

(e) 20 original pieces of the promotional material at issue

(f) 20 copies of the product's current Approved Product Information

(g) The signature of the Association Representative or chief executive of the company.

Appendix 2

Rules of Medicines Australia following is an extract of the Rules of the 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.

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;

Rules of Medicines Australia (continued)

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 seven (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.

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 seven (7) days after notice of the resolution is served on the Member, by lodging with the Secretary a notice to that effect.

Rules of Medicines Australia (continued)

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 twentyone 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.

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; and

c) the power to expel or suspend a Member as provided in Rule 13.1;

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.

Appendix 3

Medicines Australia Monitoring Committee Protocol

The following document outlines the guidelines for the activities of the Medicines Australia Monitoring Committee which will examine written and associated product related promotional material and activities for those identified products in light of the Code of Conduct and thereby support the principles of the Quality Use of Medicines.

1. Aim

1. *Review*

   To encourage compliance with the Code of Conduct by the review of all printed, audio visual, computer based and associated product related promotional material and activities for those identified products in light of the provisions of the Code of Conduct.

2. *Statistical Data*

   To obtain and publish statistical data on the rate of compliance with the Code of Conduct.

3. *Assessment*

   To provide an ongoing mechanism for the identification of potential future amendments to the Code of Conduct.

2. Implementation

1. *Monitoring Committee*

   A Monitoring Committee consisting of the following members will be formed to review promotional material, provide relevant advice on current marketing practices to Medicines Australia and, if deemed necessary, forward any complaints as a result of their findings to the Code of Conduct Committee.

2. *Committee Composition*

   Permanent Members

   - Chairman — retired/consulting industry representative with Code of Conduct experience

- one member of the RACGP
- one member from the AMA
- one member of the Medicines Australia National Office Secretariat

Rotating Members

- one expert in a particular therapeutic class, generally representative of the relevant College or Society
- one member of a relevant patient support group
- one Medical Director of a member company without a conflict of interest
- one Marketing Director of a member company without a conflict of interest (Preference will be given to members of the Marketing Working Group)

3. Member Input

Member companies will be required to submit to the Committee nine (9) 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 Medicines Australia's National Office. 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, confirming that the supplied material constitutes all the selected promotional material for the product under review, will be required.

4. Administration

Specific types of promotional material will be requested according to the following Therapeutic Categories on a random basis:

- Cardiovascular system
- Alimentary Tract and Metabolism
- Nervous System
- Blood General anti-infectives for systemic use
- Respiratory and Blood Forming Organs
- Genito-Urinary System and Sex Hormones

- Dermatologicals
- Musculo-skeletal System
- Antineoplastic and Immunomodulating Agents
- Sensory Organs
- Systemic Hormonal Preparations excluding Sex Hormones
- Antiparasitic Products, Insecticides and Repellants
- Various

Following receipt of this material the National Office will undertake a preliminary review of the material and draft a report for consideration of the Monitoring Committee. This report and the accompanying promotional material will be provided to members of the Committee in readiness for their discussion at the Committee meeting.

If, following the review of the submitted material, the 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 Committee is correct and to give any answer or explanation deemed necessary. The Committee will consider the response and provide relevant advice on compliance with the Code or if necessary, refer the matter to the Code of Conduct Committee as a complaint.

It is anticipated that in each year seven therapeutic groups will be reviewed so that every two years all therapeutic groups will be reviewed. Other reviews may also be undertaken throughout the year on request from Medicines Australia, its Marketing Working Group, the Code of Conduct or Monitoring Committees.

5. Reporting

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

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

Glossary

In this Code:

"ADRAC" means the Adverse Drug Reactions Advisory Committee of the Australian Drug Evaluation Committee.

"Association" means the 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 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.

"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 effects 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.

"CMI" means Consumer Medicines 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" 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.

"Continuing Education Program" means the professional training program developed by Medicines Australia and which is compulsory for all medical representatives of Medicines Australia member companies.

"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.

"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 Department of Health and Ageing in accordance with the Australian Guidelines for the Registration of Drugs Vol. 1 or preceding Guidelines.

"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 Guidelines for the Registration of Drugs Vol 1 which form the basis for registration of a product by the Department of Health and Ageing.

"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 Medicines Australia Guidelines to the Code of Conduct.

"Health care 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.

"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.

"Insulin delivery device" is any device used for the administration of insulin but distributed independently from the active ingredient. The device will be listed with the TGA as a device.

"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 man;
(c) testing the susceptibility of man to a disease or ailment; or
(d) destroying or inhibiting micro-organisms that may be harmful to man.

"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.

"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 Department of Health and Ageing after the original registration of the drug.

"Patient Support Program" means a program run by a company with or without involvement from a patient support group, with the aim of increasing patient compliance and positive patient health outcomes.

"PBS" means the Pharmaceutical Benefits Scheme of the Commonwealth Department of Health and Ageing.

"P.B.S. availability" means the availability of a product on the Pharmaceutical Benefits Scheme of the Commonwealth Government.

"P.B.S. 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 Department of Health and Ageing 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 programme" 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 the current Australian Approved Product Information. This Product Information must comply with the format specified in the Department of Health and Ageing' Australian Guidelines for the Registration of Drugs Vol.1 or subsequent revision.

"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.

"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.

"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 Department of Health and Ageing 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.

"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.

"Symposium" means a scientific meeting sponsored by a Company as an independent event or as a satellite to a congress.

"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.

"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 a lower case letter "e".

"Unique" means being the first, different from all others and the only one of its class on the Australian market.