7. Appropriate centres for symposia or press conferences would be conference centres or meeting facilities in city or suburban hotels or the equivalent. The choice of luxury resort hotels in isolated locations emphasising leisure and sporting facilities is not recommended.

A venue for a satellite meeting would be considered acceptable if held at the same or similar venue as the congress. If challenged on the venue, it would be required that the Member substantiate the choice of venue.

The use of international First Class travel must be able to be substantiated by the company.

See also Section 10.

8. Research

The following provisions apply to Market Research whether the research is carried out directly by the Member or by an organisation acting under its direction.

8.1 Post Marketing Surveillance (PMS) Studies

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

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

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

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

8.1.5. Decisions by the medical profession to prescribe the product should be based on their clinical judgement.

8.1.6. No starter packs or free trade packs* should be distributed as part of the Post-Marketing Surveillance Study.

8.1.7. Any payment to the medical profession must be commensurate with the work involved and not based upon the number of prescriptions written.

8.1.8. Suspected adverse drug reactions noted during Post-Marketing Surveillance Studies must be reported to ADRAC in accordance with the current TGA "Guidelines for Reporting of Adverse Drug Reactions by Pharmaceutical Companies".

8.1.9. A prompt report on the outcome of the study should be provided to participating doctors and ADRAC.

EXPLANATORY NOTES

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

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

8.2 Product Familiarisation Programmes (PFP)

8.2.1. Members should not offer any monetary or any other type of reward to healthcare professionals, their families and/or employees for taking part in PFPs.

8.2.2. PFP should involve patients being treated for approved indications of the product.

8.2.3. Product Familiarisation Programmes should only be initiated in the first 12 months following first supply of the product approved for registration, the approval of new indications* or substantive changes to the product. PFP should not be carried out for a period exceeding 12 months.

8.2.4. Starter packs may be supplied free of charge for these programmes but must still comply with Section 5 of the Code of Conduct.

8.2.5. No formal protocol is required for PFPs and collection of data is optional, as is the intention of publishing a report.

8.2.6. Suspected adverse drug reactions noted during the PFP must be reported to ADRAC in accordance with the current TGA "Guidelines for Reporting of Adverse Drug Reactions by Pharmaceutical Companies."

8.3 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.

8.3.1. Market Research studies must be clearly identified as such when the initial approach is made.

8.3.2. Any payment must be kept to a minimum and should not exceed a level commensurate with the work involved.

8.3.3. Promotion should not be represented as Market Research or research of any type.

EXPLANATORY NOTES

General

Clinical trials of products approved for registration are not covered by the above categories and are considered to be subject to the TGA "Guidelines for Good Clinical Research Practice (GCRP) in Australia".

9. Communications with the General Public

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 Media Statements

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

The written media release must be confined to the use of the Australian Approved Name of the product, approved indications and Therapeutic Class. No reference to the launch date must be made and no promotional claims or comparisons to other products made.

9.2.2 No other promotional media releases are permitted except under Section 9.2.1. but it is acceptable to respond to an inquiry.

9.3 General Media Articles

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

Members 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

9.1 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 Member may clarify matters using a Consumer Medicine Information leaflet or a patient aid as described in Section 9.6, but should otherwise recommend inquirers to consult their doctor.

9.2 Members are encouraged to seek the advice of the APMA Chief Executive Officer or delegate prior to arranging press statements or media conferences.

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

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

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

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 general provisions of Section 1 of the Code.

9.4 Promotion to the General Public

It is the intention of the Code that prescription products be promoted only to healthcare professionals. Non-promotional material used in patient education must not contain material which could be regarded as advertising to the general public.

Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only product is unacceptable.

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 professionals.

In addition, the following criteria should be satisfied.

9.5.1 The educational material should 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 the location of such information should not be given prominence.

EXPLANATORY NOTES

9.4 Promotion of prescription products in Patient Association publications is regarded as promotion to the general public.

The inclusion of pack photos of prescription products and listing of company products in these publications is regarded as promotion.

Promotion of an insulin delivery device* to the general public is permitted.

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.

(cont...)

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 which 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 Patient Aids

Patient aids which 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.

(Section 9.5 continued)

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

a) Use of trade names except as described in Section 9.5.2.

b) Material which is not educational or contains medically incorrect educational material.

c) Inclusion of response rates for a specific product or comparative claims.

d) Prominent use of Member's name in a manner which suggests to the public that the unnamed product of the cited Member should be sought.

PROVISIONS OF THE CODE

10. Relations with Healthcare Professionals

Members 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 standards of ethics and of good taste.

10.1 Entertainment

Entertainment or other hospitality offered to healthcare professionals should be appropriate, secondary to the educational content and in proportion to the occasion; its cost should not exceed that level which the recipients might reasonably be expected to incur for themselves under similar circumstances.

Inappropriate financial or material benefits, including inappropriate hospitality, should not be offered to healthcare professionals to influence them in their prescribing or dispensing of pharmaceutical products.

10.2 Medical Educational Material

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

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

10.3 General Remuneration

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

EXPLANATORY NOTES

PROVISIONS OF THE CODE

11. Administration of the Code

The administration of the Code shall be supervised by the Code of Conduct Committee, (hereinafter referred to as The Committee) which will be responsible to the APMA 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 the APMA receiving information alleging contravention by a Member 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 5 working days of receipt. All such complaints shall be dealt with as expeditiously as possible.

The Member 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 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 to the Association whatever references or information is 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 of Conduct Committee.

11.1.2 If the Committee, after making such further inquiry as is necessary or desirable, forms the opinion that a breach of the Code has occurred, it shall specify the Section found to be breached and a full explanation for that decision.

11.1.1 If external advice is sought, Members should ensure that the recipient receives sufficient information to form a full and proper view of the complaint under consideration.

11.1.2. (continued)
It shall also specify the form of sanction to be applied to the subject company, as provided for under Section 12 of the Code.

The Chief Executive Officer or his or her delegate will notify the subject company and the complainant of the decisions of the Committee together with the minutes of the proceedings in all cases dealt with according to the provisions of the Code where a breach as defined in Section 11.1.2 has occurred.

The Committee shall request the Code of Conduct Secretary* to notify the APMA 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 Member to cease or withdraw a promotional activity, the Member 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.

11.1.5 The Committee may refer questions on the interpretation of the Code to the APMA Board for determination. The APMA 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.

EXPLANATORY NOTES

11.2 Membership of Committee

The membership of the Committee shall be:

Full Membership:

- Chairman - Lawyer with Trade Practice experience
  or
- Deputy Chairman Lawyer with Trade Practice experience
- Representative of the Australian Medical Association
- Representative of the Royal Australian College of General Practitioners
- 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 APMA Association Representatives
- 2 x APMA Medical/Scientific Directors

Advisers

- Code of Conduct Secretary
- APMA Chief Executive Officer or delegate
- APMA Manager of Scientific and Technical Affairs

Observers

- Representative of the Therapeutic Goods Administration
- A member of APMA's Marketing Committee
- Two employees of APMA member companies

EXPLANATORY NOTES

11.2 Procedure of appointment

Chairman and Deputy Chairman - appointed by the APMA Board.

AMA Representative - nominated by the Australian Medical Association Ltd.

RACGP Representative - nominated by the Royal Australian College of General Practitioners.

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.

APMA Association Representatives - selected from APMA Association Representatives who have no conflict of interest with product against which complaint has been lodged.

APMA Medical/Scientific Directors - selected from APMA Member company Medical/Scientific Directors who have no conflict of interest with product against which complaint has been lodged.

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

APMA Marketing Committee Observer - selected from members of the APMA Marketing Committee who have no conflict of interest with any of the products against which a complaint has been lodged.

11.2 (cont)

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, 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 the APMA and one of which must be a representative of ASCEPT.

11.3 Review of the Code

The APMA 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

APMA member company observer - any employee of an APMA member company nominated by the 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 products against which a complaint has been lodged.

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 either the product against which a complaint has been lodged or the complainant. 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 the APMA Code of Conduct Committee in accordance with Section 11.1.

If the non-member accepts the invitation to have the complaint adjudicated by the APMA 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 APMA Code of Conduct Committee, APMA 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

APMA retains the discretion to refer complaints against an APMA 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

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 the APMA 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 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.

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.

The dispatch of corrective letters and/or publishing of corrective advertising will be undertaken as soon as possible following the exhaustion of all appeal mechanisms.

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 *	$Nil - $50,000
Minor Breach*	
Moderate Breach*	
Severe Breach*	
Severe Breaches where activities have ceased*	$50,000 - $75,000
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 APMA Board. The APMA 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 APMA 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

In the event of the complaint not being found in breach of the Code of Conduct and the complainant being a Member within the industry, the Committee may request the complainant to show cause it should not impose a charge of a maximum of $10,000 for repeated abuse of the Code of Conduct. Such a decision must be ratified by the APMA Board.

12.2 The decision to suspend or expel can only be made by the APMA Board.

12.3 A Member may be found in breach of this Section if a single complaint is considered to be frivolous or following a series of complaints against a single or number of competitors within a therapeutic class.

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 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 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 5 working days to prepare any response. The written appeal and any response shall be provided to the Code of Conduct Appeals Committee.

The complainants response will be provided to the subject company for review. This appeal will be heard by the APMA 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 APMA at the same time as lodging the appeal. The APMA 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 charges imposed by the Committee under Section 12.3 of the Code may lodge an appeal against such charges. The appeal, in writing, must be lodged by the complainant company within five working days of receiving advice of the charge, addressed to the Secretary of the Code of Conduct Committee. This appeal will be heard by the APMA 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 APMA 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 APMA 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 APMA 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 promotional activity was directed eg: AMA or RACGP
- 1 x Representative from ASCEPT
- 2 x APMA Association Representatives
- 1 x APMA Medical/Scientific Director

Advisers

- Code of Conduct Secretary
- APMA 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 the APMA.

13.5 The Appeals Committee may refer questions on the interpretation of the Code to the APMA Board for determination. The APMA 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.

EXPLANATORY NOTES

13.4 Members of the Appeals Committee, both from the industry and the College and/or Society 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 APMA 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.

PROVISIONS OF THE CODE

14. Monitoring

To support compliance with the APMA Code of Conduct, the APMA 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.

All forms of promotional material may be reviewed by the Committee.

14.1 Protocol for the activities of the Monitoring Committee

At the discretion of the APMA Board, a protocol for the monitoring of Member companies' promotional material will be developed. This protocol will include the identification of the type of material to be collected for review, membership of the Monitoring Committee and procedure for review of this material.

14.2 Membership of the Monitoring Committee

The APMA Board will determine the composition of the Monitoring Committee which will include adequate representation from the medical profession, patient support groups or consumer groups, and industry.

The Chairman of the Monitoring Committee will be independent from APMA and its Member companies.

14.3 Referral to the APMA Code of Conduct Committee

If in the view of the Monitoring Committee, any promotional material reviewed is considered in breach of the APMA 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 APMA 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.

14.4 Reporting

The Monitoring Committee will issue an Annual Report that is to be included in the APMA 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 the APMA's Marketing Committee of issues concerning the Code of Conduct requiring possible review.

14.5 Review

The operations of the Monitoring Committee will be reviewed on an annual basis.

EXPLANATORY NOTES

PROVISIONS OF THE CODE

15. Compliance Procedures

It is the responsibility of APMA Members 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

In order to comply with this provision Members 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

The APMA will issue an Annual Report on the activities of the Code of Conduct Committee. 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 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.

f) The total number of complaints received and the totals from the various sections of the industry.

g) The total number of breaches found.

h) A record of attendance of the independent organisations at Code of Conduct meetings.

i) 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.

j) 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.

EXPLANATORY NOTES

16.2 External Reporting

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

The APMA, 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. APMA will contact the relevant company before the release of any information.

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.

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

Complainants are encouraged to contact the subject company prior to lodging a complaint with APMA, 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 APMA by the complainant for the purpose of review.

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 the APMA and non-APMA member companies.

The APMA encourages companies to engage in dialogue to discuss any unresolved issues prior to forwarding a complaint to the APMA. 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.