7. CONSUMER PRODUCT INFORMATION

7.1 Background

From 1 July 1995 all new Schedule 3 products will be required to develop Consumer Product Information (CPI).

Existing Schedule 3 products will be required to have CPI available by 1 January 2004. Companies will be encouraged to progressively develop CPI during the interim period.

7.2 CPI Content

Members shall ensure that all CPIs developed for their products comply with Schedule 13 of the Therapeutic Goods Regulations and the Australian Guidelines for the Registration of Drugs Vol.2. Non-Prescription Drug Products (AGRD2).

Schedule 13 requires that CPI is:

- written in English
- clearly legible
- written in language that will easily be understood by patients
- consistent with product information about the product

CPI must include the following:

Identification

What the product is used for and how it works

Advice before using the product

How to use the product properly

Further information

Unwanted effects

In case of overdosages

Storage conditions

Where to go for further information

Further details of the information required can be found in Schedule 13 and AGRD2. The Usability Guidelines and Glossary of Terms provide additional guidance.

7.3 Techniques considered inappropriate in provision of CPI

CPI is not an advertising or promotional tool and as such should be confined to factual information concerning the product and its use.

As a consequence, the following techniques are considered contrary to the provisions of the Code:

- inclusion in CPI of any form of comparison with other product(s), unless such comparision is consistent with approved PI;
- attempts to use CPI as a direct/indirect form of advertising for the product.

7.4 Complaint Handling - CPI

If on initial review of the complaint, the Executive Director believes that Schedule 13 has been breached, the complaint will be referred to the Compliance Branch, TGA, for resolution.

If however, the breach relates to Clause 7.3 above, the Executive Director will refer it to the Complaints Panel. Where the Panel is to hear a complaint concerning a CPI, an ad hoc observer will be co-opted onto the panel to provide expertise in the area in the area of writing CPI.

For details on the complaint procedure with regard to CPI, refer to Clause 9.

PART B: MANAGEMENT OF THE CODE

8. ADMINISTRATION OF THE CODE

- **8.1** The administration of the Code shall be:
 - supervised by the <u>Executive Subcommittee</u>* (refer Appendix 3, Rule 5.1)
 - co-ordinated by the Executive Director, and
 - monitored and reviewed by the Marketing & Ethics Subcommittee*.
- 8.2 The Marketing & Ethics Subcommittee will appoint a Code of Practice Complaints Panel to participate as and when necessary in the administration of the Code in accordance with Sections 9, 10 and 11 of the Code. Members of the Complaints Panel shall hold office for one year and shall be eligible for re-appointment.
- 8.3 The Marketing & Ethics Subcommittee shall ensure that the external members of the Complaints Panel are independent of the Association and its Members, of high public standing and with demonstrated experience and ability in the respective areas of expertise they bring to the Complaints Panel.
- 8.4 The Complaints Panel shall comprise a lawyer with trade practices experience; a practising member of the RACGP; a community pharmacist, being a member of the PSA; Three Industry members, being members of Committee of Management or Chief Executive Officers of Member companies or their nominee on a rotating membership; a representative from a broad-based representative consumer/community organisation and, as an observer, a representative from the Department of Human Services and Health.

The Chair of the Complaints Panel shall be the lawyer with trade practices experience or his/her alternate, also a lawyer with trade practices experience.

The Marketing & Ethics Subcommittee may appoint an alternate to officiate in the absence of a member.

The Executive Director and other representatives of the PMAA Secretariat shall be entitled to attend meetings of the Complaints Panel as advisers.

When the Complaint concerns CPI, the Panel will include an observer with expertise in the writing of CPI.

A member of the Complaints Panel having an interest in the subject matter of a complaint or likely to have a conflict of confidentiality in hearing the complaint may not sit to hear that complaint but shall be replaced by an alternate having the same qualifications for appointment as the member. The Complaints Panel will be convened only to hear and make findings and determinations on complaints/disputes. The quorum for the Complaints Panel shall be five, two of whom shall be external members.

8.5 To ensure that the Code accurately reflects current community standards and values, the Marketing & Ethics Subcommittee shall regularly (and at minimum annually) review the Code. The Marketing & Ethics Subcommittee, in consultation with the external members of the Complaints Panel, shall consider ways in which the Code should be amended and/or updated and shall formulate recommendations to the Executive Subcommittee.

9. COMPLAINT PROCEDURE

For the purposes of the Complaint Procedure, "Member" includes non-member companies agreeing to be bound by the Code (refer definition of "Member").

9.1 POLICY

It is the policy of the Association that all complaint procedures will be administered in accordance with general principles of fairness.

9.2 **COMPLAINT HANDLING PROCEDURE**

(refer Appendix 2 for diagrammatic representation of Complaint Process)

- 9.2.1 The following procedure shall apply in the event of the Association receiving a complaint concerning the advertising and/or promotion of Proprietary Medicines by a Member.
- 9.2.2 The Executive Director shall ensure that written notification is given to the Association of all complaints against a Member.
- 9.2.3 The Executive Director shall on receipt of written notification of the complaint consider whether the Advertising Codes of the Media Council of Australia may have been breached. Where this likelihood exists, the Executive Director shall determine whether the complainant has independently approached the Advertising Standards Council and/or the Media Council of Australia. If not, the Executive Director will ensure that the Advertising Standards Council is made aware of the complaint. However, the Association will retain the right to consider the complaint in relation to the PMAA Code and to apply sanctions, where appropriate.

The Executive Director shall make enquiries to ascertain whether the subject matter of the complaint is also the subject matter of pending litigation. Since it would be inappropriate for PMAA to preempt a court adjudication, the Executive Director shall advise the complainant that PMAA will not consider the complaint until the disposition of any such proceedings.

9.2.4 The Executive Director shall ensure all complaints are acknowledged in writing within seven working days of receipt and are dealt with as expeditiously as possible.

- 9.2.5 The Executive Director shall ensure that the details of the complaint are notified to:
 - the Chief Executive of the Member which is the subject of the complaint; and
 - the Executive Subcommittee.
 - 9.2.6 The Member that is the subject of the complaint shall be given full details of the nature of the complaint. The Member will provide references/information as deemed by the Executive Director to be necessary. The Member shall also 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 considered necessary. To ensure procedural fairness and to provide to the Panel the benefit of comprehensive submissions so that it may complete its deliberations, if possible, in one sitting, PMAA affords the parties opportunities to respond to each other's submissions.

Upon receipt, PMAA will provide to the complainant a copy of the subject company's response to the complaint. The complainant must deliver to PMAA and to the subject company within 5 working days copies of any reply it wishes to make. The subject company then has 5 working days to provide any final response.

9.2.7 The information provided by both parties (one or two submissions) shall be provided to the Complaints Panel.

- 9.2.8 Should a complaint concern a Member represented by a person who is a member of the Complaints Panel, the person shall, for that investigation, disqualify himself or herself and another Industry member shall act as a member of the Panel.
- 9.2.9. The Complaints Panel shall consider all information provided before making any decision. Where the Complaints Panel is hearing a complaint about CPI, the Panel may elect to refer an issue to the CPI Quality Assurance Reference Group for comments, prior to the Panel completing its deliberations.
- 9.2.10 Upon completion of the Complaints Panel's investigations, the Executive Director will notify the parties to the complaint and the PMAA Executive Subcommittee, of the Complaints Panel's findings and determinations. If the Panel identifies a breach of the Code not raised by the complainant, the Panel may request the Executive Director to draw the matter to the attention of the party in breach.
- 9.2.11 Should the Complaints Panel consider that no breach of the Code has occurred, it shall so advise the Executive Director. The Complaints Panel shall provide to the Executive Director in writing, reasons for its opinion.
- 9.2.12 If the Complaints Panel, after considering all information provided, forms the opinion that a breach of the Code has occurred, it shall determine appropriate sanctions as provided for under Section 10 of this Code and so inform the Executive Director.
- 9.2.13 In the case where a breach of the Code has occurred, the Complaints Panel will advise the Executive Director of its findings and determination.

 The Executive Director shall notify the parties to the complaint within seven working days.
- **9.2.14** The parties to the complaint shall be advised of the appeal procedures contained in Section 11 of this Code.

9.3 GUIDELINES FOR COMPLAINTS

These guidelines are intended to assist both complainants and Members against which complaints are made 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.

PMAA will not consider any complaint that is the subject of pending or ongoing litigation. PMAA will defer hearing the complaint, until the litigation has been completed or discontinued.

9.3.1 Externally generated complaints

Complainants are encouraged to contact the Member concerned prior to lodging a complaint as a satisfactory 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. Where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review.

9.3.2 Industry generated complaints

Intercompany complaints should not be used simply as a competitive tool. Complainants are strongly encouraged to take up any complaint firstly with the subject company. Unless the complainant can demonstrate adequate reasons for not taking the matter up with the subject company before bringing the matter to PMAA, the complaint will not be accepted for evaluation.

When lodging a complaint, the complainant will be required to pay a lodgement fee of \$1000 to have their complaint heard. If the complaint is upheld, the subject company will be required to reimburse the complainant to the value of the lodgement fee, in addition to being subject to a fine (in accord with the schedule of fines outlined in Clause 10.1.1.4.) if the Complaints Panel determines it appropriate.

Complaints from one Member against another *must* include the following information to ensure a complete review. Consideration of a complaint will not be undertaken until the necessary information is provided.

- A summary page containing:
 - (a) subject Proprietary Medicine;
 - (b) brief description of complaint itemising the specific claims at issue with complete rationale for the alleged breach to be included as an attachment;
 - (c) section of the Code alleged to be breached;
 - (d) details of attempts to resolve matter with the Member concerned.
- Medically based complaints supporting data cross referenced to specific claims at issue and rationale for challenge.
- Marketing based complaints alleged consequences (damage to complainant where appropriate) with supporting data if available.

In addition, complainants should note that:

- when challenging a claim on medical/scientific grounds, it is not sufficient simply to state that the claim is not supported. Evidence should be provided to support the complainant's case;
- if these criteria are not met, the Association may return the complaint to the complainant for further information.
- 10 copies of all material must be lodged with PMAA and one copy delivered at the same time to the other party.

9.3.3 Response by Member

When a complaint has been accepted for evaluation, the Member that is the subject of the complaint (subject company) will be requested 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.

When providing this information, the Member should include:

- details of attempts to resolve the matter with the complainant;
- a brief summary of the response to each alleged breach;
- substantiation of the specific claims at issue with full supporting data.

9.4ANNUAL REPORT

The Executive Director shall publish annually a report of all matters arising under Sections 9, 10 and 11 of this Code, including the names of the parties, the nature of the complaint, the stage reached and what sanctions, if any, have been imposed.

10. SANCTIONS

10.1 SANCTIONS ABLE TO BE APPLIED BY CODE OF PRACTICE COMPLAINTS PANEL

- 10.1.1 One or more of the following sanctions against a Member may be applied by the Complaints Panel where breaches of the Code have been established.
- 10.1.1.1 The requirement, notified in writing, that the Member give an undertaking in writing to discontinue any practice which has been determined to constitute a breach of the Code on or before a date determined by the Complaints Panel, such date being determined in line with the severity of the breach of this Code.
- The requirement, notified in writing, that the Member issue retraction statements and/or corrective statements or advertisements, as appropriate. The format, size, wording, mode of publication and method of distribution of such statements/advertisements shall be subject to the approval of the Complaints Panel prior to release and will in general conform to the original statement/advertisement.
- 10.1.1.3. The issuing of a fine by the Panel to the subject company in accordance with the schedule of fines, detailed in 10.1.1.4. The fine to be paid within 30 days of being advised subject to any appeal that may be lodged under Clause 11.2 of the Code.

10.1.1.4. Proposed Schedule of Fines

BREACH	FINES	
Minor Breach†	NIL	
Less Severe Breach*	Minimum: Maximum:	\$2000.00 \$5000.00
Severe Breach	Minimum: Maximum:	\$5000.00 \$20000.00
Repeat of Previous Breach ²	Minimum: Maximum:	\$10000.00 \$20000.00

- + a breach of the Code that has no safety implications and will have no effect on how consumers or healthcare professionals view the product or its competitors
- ♠ a breach of the code with no safety implications but will impact on the perceptions of the consumer or healthcare professionals regarding the product or competitor product.
- a breach of the Code that has safety implications and/or will also have a major impact on how consumers or healthcare professionals view the product or competitor products
- when a similar breach is repeated in the promotion of either a particular product, or any product of a company, which had been found to be in breach of the Code within the preceding 24 months. (This clause does not apply to minor breaches).

(OLD 10.1.1.3)

10.1.1.5.

Failure of the offending Member to comply with *any* of the above sanctions shall entitle the Complaints Panel to direct the Association to publish in the next edition of the Association's Newsletter details of the breach of the Code and the Association's consequent requirements for remedial action as described in 10.1.1.1, 10.1.1.2 *and* 10.1.1.3.

(OLD 10.1.1.4)

10.1.1.6.

- Continued refusal by the offending Member to undertake the required remedial action/s shall entitle the Complaints Panel to direct the Association to publish details in the trade press of the Member's breach of the Code, the Association's requirements for remedial action/s and the prospect of suspension or expulsion from the Association in the event of the continued failure by the Member to comply, and notify the ACCC if deemed necessary.
- 10.1.2 One or more of the following sanctions against a Member notified in writing may be applied by the Complaints Panel where breaches of Clause 7.3 of the Code have been established.
- 10.1.2.1 That the Member discontinue immediately distribution of the CPI.
- 10.1.2.2 That corrective measures be taken to redraft the CPI in accordance with the findings of the Panel.
- That the Member issue retraction and/or corrective statements, as appropriate, flagging the redrafted CPI.

10.1.2.4

That the matter be referred to TGA as a breach of Schedule 13.

10.1.3. Abuse of the Code

If in the course of hearing a complaint lodged by an Industry member, the Complaints Panel considers that the complaint has been submitted as a competitive tool and for vexatious reasons, the Panel may request the complainant to show cause why the Panel should not impose a charge of \$2,000 for vexatious use of the Code.

10.2. SANCTIONS ABLE TO BE APPLIED BY COMMITTEE OF MANAGEMENT

- 10.2.1 The Complaints Panel may recommend to the Committee of Management application of further sanctions. Such further sanctions may consist of one or more of the following or any other action deemed appropriate by the Committee of Management, under the procedures laid down in Section 9 of the Code.
- Suspension of the Member from the Association for a period to be determined by the Committee of Management, under the provisions of the Rules of the Association (refer Appendix 3).
- 10.2.1.2 The expulsion of the Member from the Association, under the provisions of the Rules of the Association (refer Appendix 3).
- 10.2.1.3 Notification, wherever applicable, to the overseas parent company of the offending Member of its expulsion from the Association.
- 10.2.1.4 Notification of the offending Member's suspension and/or expulsion from the Association to the editors of all trade journals.

11. RIGHT OF APPEAL

(refer Appendix 2 for diagrammatic representation of Appeal mechanism)

For the purposes of the appeal procedure, "Member" includes non-member companies agreeing to be bound by the Code (refer definition of "Member").

11.1 COMPLIANCE WITH SANCTIONS

In the event of a Member being required by a determination of the Complaints Panel to cease or withdraw a promotional activity, the Member shall at once make every endeavour to comply with the ruling pending any appeal against the decision pursuant to this Code. A promotional activity thus suspended shall not be recommenced before the appeal process has been concluded, nor shall any similar promotional activity be commenced during the period in question.

11.2 APPEAL AGAINST DETERMINATIONS OF THE COMPLAINTS PANEL

- 11.2.1 A party dissatisfied with a determination of the Complaints Panel may, within 10 working days of being notified of the determination, lodge a written appeal to the Executive Director of the Association setting out the grounds for objection. If the party lodging the appeal is a member of industry a lodgement fee of \$1,000 will be required to have the appeal heard. If the appeal is upheld the lodgement fee will be reimbursed.
- 11.2.2 The appeal shall be considered by an independent person appointed by the Marketing & Ethics Subcommittee (the "Arbiter") with appropriate legal and/or technical expertise and not involved in any previous hearing of the particular complaint, sitting alone on an at-call basis. The appeal shall be held not later than 28 days after receipt of the written appeal.
- 11.2.3 The parties shall be advised of the date, time and place of the appeal meeting and any adjournment thereof, and may, either in person and/or through legal representatives, do either or both of the following:

- (i) attend and speak at that meeting;
- (ii) submit to the Arbiter at or prior to the date of that meeting written representations relating to the appeal.
- 11.2.4 At the appeal meeting held as referred to in 11.2.3 above, the Arbiter shall:
 - give the parties the opportunity to make oral representations; and
 - give due consideration to any written representations submitted by the parties.
- 11.2.5 Within 10 working days following the conclusion of the appeal meeting, the Arbiter shall determine whether to confirm, modify or revoke any determination made or sanction applied or recommended by the Complaints Panel and shall notify the Executive Director in writing of the determination and of the reasons for it. The determination of the Arbiter shall be final, except where the Arbiter recommends suspension or expulsion of a Member (refer Appendix 2).
- 11.2.6 The Executive Director shall, as soon as practicable, inform the parties in writing of the Arbiter's decision and reasons, and shall also so inform the Committee of Management where the Arbiter recommends suspension or expulsion of a Member.

EXTRACT FROM THE THERAPEUTIC GOODS REGULATIONS

APPENDIX 1

PART 2 - ADVERTISEMENTS

This Part not to apply to advertisements directed at health professionals etc.

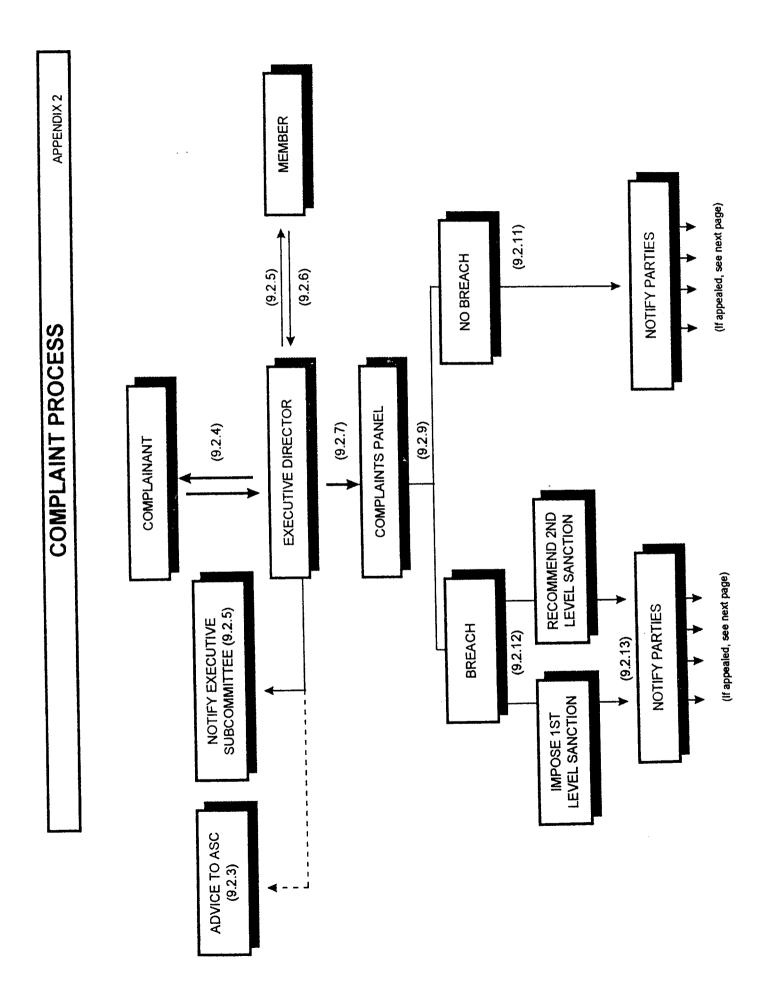
- **4.** (1) This Part does not apply to advertisements directed exclusively to:
 - (a) medical practitioners, psychologists, dentists, veterinary surgeons, dietitians, pharmacists, physiotherapists, scientists working in medical laboratories or nurses; or
 - (b) persons who are:
 - (i) engaged in the business of wholesaling therapeutic goods; or
 - (ii) purchasing officers in hospitals; or
 - (c) herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine or osteopaths registered under a law of a State or Territory.
 - (2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies referred to in Schedule 1.
 - (2A) For the purposes of subregulation (2), a person is taken to be a member of an Australian branch of one of those bodies if, and only if, the person has the qualifications and training that are necessary or appropriate for membership of the relevant body.

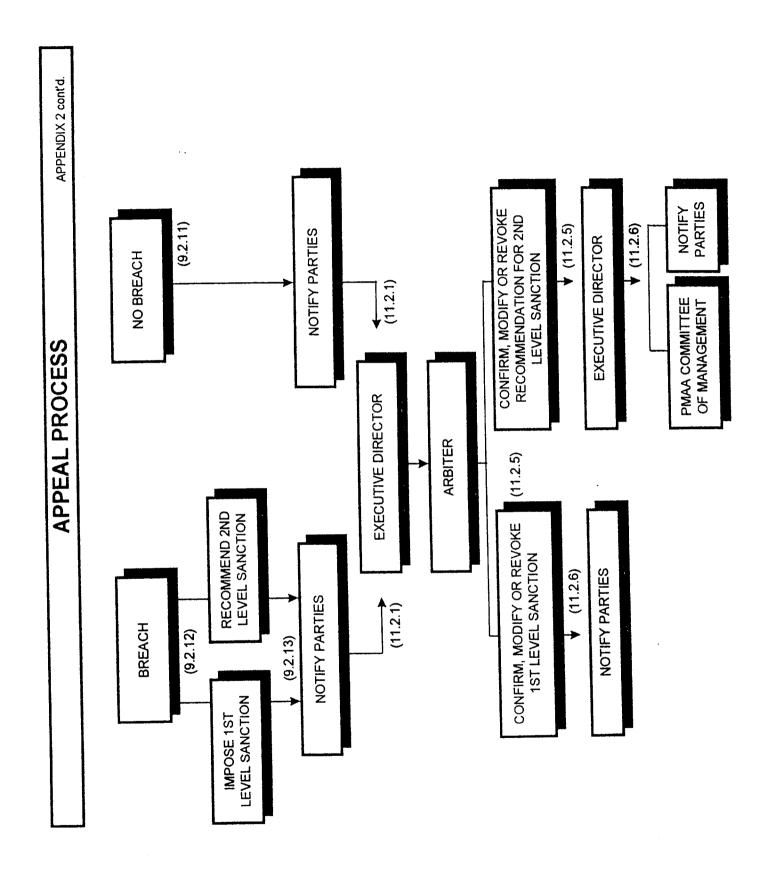
SCHEDULE 1

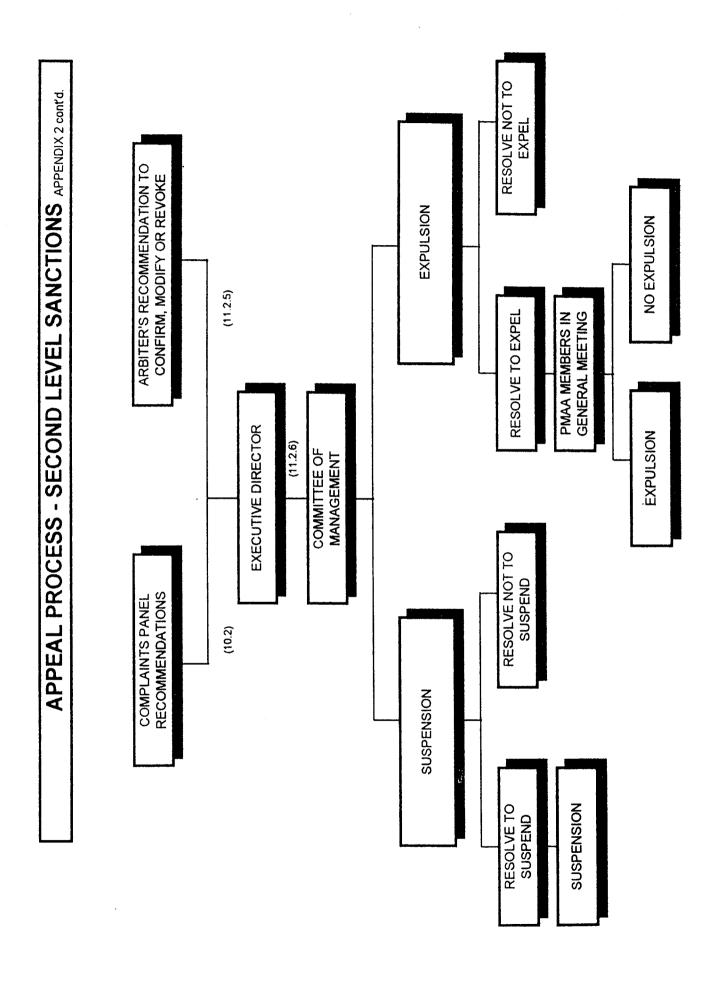
Subregulation 4 (2)

PART 2 DOES NOT APPLY TO MEMBERS OF AN AUSTRALIAN BRANCH OF ONE OF THESE BODIES

Colum Item N	
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
3	Association of Natural Health Practitioners
4	Australasian Federation of Natural Therapy Associations Inc.
5	Australian Acupuncture Association Inc.
6	Australian Association of Professional Homoeopaths
7	Australian Committee of Natural Therapies Inc. (SA)
8	Australian Council of Natural Therapies Inc.
9	Australian Federation of Homoeopaths
10	Australian Natural Therapists Association Ltd
11	Australian Naturopathic Practitioners and Chiropractors Association
12	Australian Traditional Chinese Herbalists Association (Qld)
13	Australian Traditional Chinese Medicine Association Inc.
14	Australian Traditional Medicine Society
15	Chinese Medicine Association Pty Ltd
16	Complementary Medicine Association
17	Homoeopathic Education and Research Association
18	National Herbalists Association of Australia
19	Queensland Naturopathic Association
20	Register of Acupuncture and Traditional Chinese Medicine
21	Society of Natural Therapists and Researchers Inc.
22	Society of Classical Homoeopathy Ltd
23	Traditional Medicine of China Society Australia
24	Society of Chinese Medicine and Acupuncture (Vic) Inc.
25	Naturopathic Practitioners Association Inc.
26	The Acupuncture Association of Australia, New Zealand and Asia
27	The New South Wales Research Association of Traditional Chinese Medicine







EXTRACT FROM RULES OF THE ASSOCIATION

APPENDIX 3

Rule 5 Membership Obligations

5.1 Code of Practice

The Association shall establish and maintain a Code of Practice which:

- (a) shall be adopted and/or amended as from time to time recommended by the Committee of Management, by Ordinary members in general meetings;
- (b) upon such adoption shall become binding upon all Ordinary and Associate Members as a condition of membership of the Association; and
- (c) shall be administered by an Executive Subcommittee constituted in accordance with rule 23 [relating to Delegation by the Committee of Management to Subcommittees] of these Rules.

Rule 12 - Disciplining of Members

- 12.1 The Committee of Management may, by resolution:
 - (a) expel; or
 - (b) suspend for a specified period

from membership of the Association an Ordinary Member or Associate Member

- (i) upon recommendation by the Code of Practice Complaints Panel or the Arbiter in accordance with the Code of Practice, or
- (ii) where the Committee of Management is of the opinion that the Member
 - (A) has persistently refused or neglected to comply with
 - (I) a provision or provisions of these Rules or of the Code of Practice;
 - (II) a sanction imposed by the Code of Practice Complaints Panel or the Arbiter in accordance with the Code of Practice; or
 - (B) has persistently and wilfully acted in a manner prejudicial to the interests of the Association.

Rule 12 - Disciplining of Members (Contd)

- 12.2 A resolution of the Committee of Management under rule 12.1(a) is of no effect unless the Committee at a meeting held not earlier than 14 days and not later than 28 days after service on the member company of a notice under rule 12.3, confirms the resolution in accordance with this rule.
- 12.3 Where the Committee of Management passes a resolution under rule 12.1(a) the Secretary shall, as soon as practicable, cause a notice in writing to be served on the member company:
 - (a) setting out the resolution of the Committee and the grounds on which it is based;
 - (b) stating that a delegate of the member company may address the Committee at a meeting to be held not earlier than 14 days and not later than 28 days after service of the notice;
 - (c) stating the date, place and time of that meeting; and
 - (d) informing the member company that the delegate of the member company may do either or both of the following:
 - (i) attend and speak at the meeting;
 - (ii) submit to the Committee at or prior to the date of that meeting written representations relating to the resolution.
- 12.4 At a meeting of the Committee of Management held as referred to in rule 12.3, the Committee shall:
 - (a) give a delegate of the member company an opportunity to make oral representations;
 - (b) give due consideration to any written representations submitted to the Committee by the member company at or prior to the meeting; and
 - (c) by resolution determine whether to confirm or to revoke the resolution.
- 12.5 Where the Committee of Management confirms a resolution under rule 12.4, the secretary shall, within 7 days after that confirmation, by notice in writing inform the member company of the fact and of the member's right of appeal under rule 13.

- 12.6 A resolution confirmed by the Committee of Management under rule 12.4 does not take effect:
 - (a) until the expiration of the period within which the member company is entitled to appeal against the resolution where the member company does not exercise the right of appeal within that period; or
 - (b) where within that period the member company exercises the right of appeal unless and until the Association confirms the resolution pursuant to rule 13.4.

Rule 13 - Right of Appeal of Disciplined Member Company

- 13.1 An Ordinary Member or Associate Member may appeal to the Association in general meeting against a resolution of the Committee of Management which is confirmed under rule 12.4 within 7 days after notice of the resolution is served on the member company, by lodging with the Executive Director a notice to that effect.
- 13.2 Upon receipt of a notice from a member company under rule 13.1, the secretary shall notify the Committee of Management which shall convene a general meeting of the Association to be held within 21 days after the date on which the secretary received the notice.
- 13.3 At a general meeting of the Association convened under rule 13.2:
 - (a) no business other than the question of the appeal shall be transacted;
 - (b) the Committee of Management and the member company shall be given the opportunity to state their respective cases orally or in writing, or both; and
 - (c) the member companies present shall, in writing and on the form specified in Appendix IV to these rules, vote by secret ballot, but in accordance with rule 33 of these rules, on the question of whether the resolution should be confirmed or revoked.
- 13.4 If at the general meeting the Association passes a special resolution in favour of the confirmation of the resolution, the resolution is confirmed.