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23 March 1994

Mr J P O'Neill
Senior Assistant Commissioner
Adjudication Branch
Trade Practices Commission
P O Box 19
BELCONNEN ACT 2616

Dear Mr O'Neill

PMAA Code of Practice
Authorisation No A90549

We enclose a revised Code of Practice designed to comply with the conditions of the Commission's determination of 27 January 1994. Amendments of an editorial nature have also been made. All the amendments to the version for which authorisation was sought appear in italics.

The revision will be submitted to members in general meeting for adoption on 12 May 1994.

We draw your attention to the following points:

Page 9 - advertising of s3 products. This section is now consistent with the APMA and WHO Codes but has been modified to take into account the particular circumstances of s3 products. Some are required by their terms of registration to make certain disclosures. Some are not. The revision covers both situations.

Page 20 - appeals. Section 10.2 has been amended in light of paragraphs 4.26 and 4.31 of the Commission's determination. This has led to proposed changes to the Association's Rules. On 12 May 1994 the PMAA membership will be asked to amend the rules in the respects indicated on page 26.

In accordance with the procedures specified in your letter of 27 January 1994, we will treat the absence of any expression of concern on the part of the Commission within 10 working days of its receipt of these amendments as advice that they are not significant and that, accordingly, they are covered by the authorisation which came into effect on 18 February 1994.

Yours faithfully
MINTER ELLISON MORRIS FLETCHER

Alan L. Limbury

Alan L Limbury

enclosure

The Proprietary Medicines Association of Australia

CODE OF PRACTICE

Adopted:	8 October 1991
Revised:	28 May 1992 15 October 1992
Authorised by TPC:	27 January 1994
Revised to meet conditions of authorisation:	*12 May 1994*

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PREFACE

Authorisation of the PMAA Code of Practice by the Trade Practices Commission (TPC) was granted on 27 January, 1994 and came into force on 18 February, 1994.

This authorisation applies to:

- *PMAA and its members from time to time;*
- *all future proposed amendments to these arrangements which PMAA provides to the Commission and which the Commission considers are not significant and will not materially alter the circumstances of any authorisation granted in respect of these arrangements.*

The Commission further required that:

- *the public and healthcare professionals be advised of the existence of the Code and the complaint process;*
- *the Executive Director circulate to the Complaints Panel and to the Marketing & Ethics Subcommittee monthly summaries of all complaints received and their disposition;*
- *as requested by the Commission, the issue of pecuniary penalties will be considered when the Code is next reviewed.*

The Commission will adopt the following procedures with respect to future amendments of the Code:

- *PMAA will notify the Commission of amendments it proposes to make to the Code;*
- *within 10 working days of the Commission receiving these, the Commission will advise PMAA if it considers the proposed amendments are significant and would materially alter the circumstances of any authorisation granted by the Commission. Failure to do so will constitute advice that the amendments are not significant;*
- *both the proposed amendments and the Commission's advice to PMAA concerning those amendments will be placed on the public register of authorisation applications maintained by the Commission, subject to the Commission's power to, on request, exclude material from the public register.*

The Commission has agreed that no time limit be imposed on the authorisation, subject to regular PMAA reviews of the Code.

NOTE: This preface and the flow charts for the complaints and appeal processes do not form part of the Code.

DEFINITIONS

In this Code of Practice:

- **"Advertisement"** includes every form of communication whether in a publication, or by display or any notice, or by means of any catalogue, price list, leaflets, booklets, letter (whether circular or addressed to a particular person) or other document, or by means of any packaging materials (including all labels, cartons, direction folders, and other packaging components bearing printed matter), or by words inscribed on any article, or by exhibition of a photograph or film, or by way of sound recording, radio or television, or in the spoken word, or in any other way.

- **"Consumer Advertisement"** means an advertisement in consumer media as defined and covered by the Therapeutic Goods Advertising Code of the Media Council of Australia.

- **"Professional Advertisements"** means one of the three ***categories*** of advertisements defined below and ***directed at healthcare professionals:***

  Full Disclosure **Advertisements** - the effect of which is to communicate ***the full text of product*** information ***as required by any applicable conditions of registration;***

  Abridged Disclosure **Advertisements** - the effect of which is to remind the reader of the name of the ***Proprietary Medicine***, its ***indication(s) for use, including safety related statements***, and some elementary commercial information;

  Short Advertisements - the effect of which is to communicate commercial information ***only***, such as details of packaging, pricing, trading terms or marketing incentives.

- "The Association" means the Proprietary Medicines Association of Australia Incorporated.

- ***"Code" means the PMAA Code of Practice.***

- **"Committee of Management"** means the Committee as specified in Part IV of the Rules* of the Association, which has been elected to control and manage the affairs of the Association.

- ***"Complaints Panel" means the PMAA Code of Practice Complaints Panel.***

- **"Discredit"** means injure the reputation of or destroy confidence in the product/industry.

- **"Executive Subcommittee"** means the committee ***appointed by the Committee of Management* and*** comprising, ***but not limited to***, the Association's President, two Vice Presidents and Immediate Past President.

- "External Use" in relation to any medicine or related product means for application to the anal canal, ear, eye, mucosa of the mouth, nose, skin, teeth, throat or vagina, where local action only is required and where extensive systemic absorption will not occur, but this shall not apply to nasal drops, nasal inhalations, nasal sprays, teething applications, throat lozenges, throat pastilles, throat sprays or throat tablets.

Note: The first use of a defined term is underlined and marked with an asterisk(*).

- ***"Healthcare professionals" means persons designated under Regulation 4 (1), (2) and (2A) of the Therapeutic Goods Regulations (refer Appendix 1).***

- The **"industry"** means the basic manufacture and/or formulation and/or importation and/or basic or applied research into and/or the registration and/or marketing of Proprietary Medicines.

- ***"Marketing & Ethics Subcommittee" means the committee appointed by the Committee of Management to, inter alia, monitor and review the PMAA Code of Practice.***

- ***"Member" means any Ordinary or Associate member as defined by the PMAA Rules. For the purposes of this Code, "Member" also includes any consenting non-member company which has agreed to be bound by all or part of the provisions of the Code.***

- ***"Parties" means, for the purpose of the complaint and appeal processes, both the complainant and the company which is the subject of a complaint.***

- **"Proprietary Medicines"** means products for ***health/personal*** care that may be purchased directly by consumers. These include, but are not limited to, products which are available to the public without medical prescription and which are used for the purpose of or in connection with:

  - preventing, diagnosing or alleviating a disease, ailment, defect or injury in man;

  - influencing, inhibiting or modifying a physiological process in man;

  - testing for a physiologic condition or the susceptibility of man to a disease or ailment; or

  - destroying or inhibiting micro-organisms that may be harmful to man.

- **"Rules"** means the Rules of the Association for the time being in force.

- **"Unfair"** means not equitable or honest or impartial or according to the Rules.

Note: The first use of a defined term is underlined and marked with an asterisk(*).

INTRODUCTION

2.1 The Association* is the corporate representative and advocate for manufacturers of Proprietary Medicines*.

2.2 As an integral part of Australia's healthcare system, the Association, through its Members*, is committed to positively encouraging and extending the use of self-medication in Australia and to making available to the public, quality ***Proprietary Medicines*** which are both safe and effective when used as directed.

2.3 In this commitment, the Association's Members recognise that, whilst ***Proprietary Medicines*** can bring substantial social and economic benefits to the community, the advertising and promotion of Proprietary Medicines should be responsible and balanced.

2.4 For these reasons, the Association has developed and promulgated this Code of Practice which requires Members to submit to its provisions as an act of self-discipline.

2.5 Recognising that the conduct of an individual Member can reflect upon both the industry* and the Association's membership as a whole, the Code* sets out to address what are deemed to be appropriate standards of commercial conduct generally and of advertising and promotional practices in particular.

2.6 Acceptance and observance of its provisions are binding and a condition of membership of the Association.

2.7 *Members* also acknowledge that the Code itself is to be applied in spirit, as well as in the letter, so that high ethical standards are followed throughout the industry.

2.8 Members shall ensure that all agents acting on their behalf are fully conversant with the provisions of this Code. Proprietary Medicines manufacturing companies outside the Association are invited to accept and observe this Code.

OBJECTIVES OF THE CODE

This Code is intended to establish the basic parameters which guide ***Members*** in the conduct of their business and particularly in matters of advertising and promotion of Proprietary Medicines.

Specifically, the Code seeks to assist ***Members*** to:

- responsibly inform consumers about Proprietary Medicines which are available;
- uphold a high standard in the communication of information about Proprietary Medicines;
- ensure that all claims made for Proprietary Medicines are accurate, balanced and based on sound and objective scientific considerations;
- ensure that such information is communicated in a way which promotes the responsible use of Proprietary Medicines.

\RT A: THE CODE AND ITS APPLICATION

4. PRINCIPLES OF PRACTICE

4.1 Members shall not engage in any unfair* or unconscionable conduct or commercial practice.

4.2 Members shall at all times ensure that they are familiar with, and comply with, the relevant provisions of Commonwealth and/or State Acts, Regulations or other legal instruments which pertain to the functions and operations in the industry.

4.3 Members shall at all times comply with provisions of:

- the relevant Advertising Codes of the Media Council of Australia, including the Advertising Code of Ethics and the Therapeutic Goods Advertising Code;
- the Code of Good Manufacturing Practice; and
- such other Codes as are from time to time developed and/or endorsed by the Association.

4.4 A Member shall ensure that all relevant persons, including representatives, employed by the Member are aware of the requirements of this Code and the responsibilities inherent in membership of the Association.

4.5 Members will cooperate with the Association in the investigation of problems which may from time to time arise with respect to the safe use of Proprietary Medicines.

4.6 Members will cooperate to whatever extent they are reasonably able in programs conducted by the Association, either on its own or in collaboration with Government authorities, which are aimed to educate the user or the consumer in the safe and proper use of Proprietary Medicines.

4.7 Members will assist the Association and/or Government authorities to the full extent that they are able in consideration of any existing regulations or voluntary schemes, or any which may be proposed, having in mind both their responsibilities under this Code and the needs and legitimate interests of the industry.

4.8 Members will draw to the attention of the Association any information which may lead to improvement in standards of correct and safe use of Proprietary Medicines.

ADVERTISING

5.1 GENERAL PRINCIPLES - ALL *PROPRIETARY MEDICINES*

5.1.1 Section 5 of this Code applies to ***Members*** whose ***Proprietary Medicines*** are promoted to ***healthcare professionals**, consumers, or both.*

5.1.2 Scope

Nothing in this Section of the Code of Practice shall be construed as replacing, diminishing or precluding requirements of the relevant Advertising Codes of the Media Council of Australia (including the Advertising Code of Ethics and the Therapeutic Goods Advertising Code) in relation to ***consumer advertisements** of* Proprietary Medicines. ***This section of the Code of Practice applies to all advertisements** for Proprietary Medicines, including comparative advertisements and advertisements for Schedule 3 items.*

5.1.3 Claims

Information and medical claims about Proprietary Medicines must be current, accurate, balanced, and must not mislead either directly, by implication, or by omission.

5.1.4 Furthermore, information and claims must, when made, be capable of substantiation, such substantiation being provided without delay upon receipt of bona fide requests.

5.1.5 Information that may be considered false or misleading includes the following examples:

- literature references, or quotations or claims that are more favourable than has been demonstrated by the body of clinical evidence or experience;
- information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions;
- citing of data previously valid but made obsolete or false by subsequent findings;
- suggestions or representations of uses, dosages, or indications not approved by the Commonwealth ***Department of Human Services and Health.***

5.1.6 No Member shall advertise an offer to return money to dissatisfied users of Proprietary Medicines.

5.1.7 Members may, by virtue of belonging to other industry associations, be required also to conform to codes of practice of such other associations.

5.2 COMPARATIVE ADVERTISING

Advertisements containing comparison with other advertisers, or other ***Proprietary Medicines***, shall comply with the terms of this section.

- ***Comparative advertisements should not be misleading, or likely to be misleading, either about the Proprietary Medicine advertised or that with which it is compared.***

- Points of comparison should be based on facts which have been previously substantiated and reflect the body of scientific evidence or experience at the time the advertisement is published.

Techniques which may be considered inappropriate and contrary to the provisions of this Code include the following examples:

- It should be clear with what the advertised ***Proprietary Medicine*** is being compared and upon what basis.

- Claims of superior or superlative status should be expressed in terms which accurately reflect the extent and the nature of the evidence available to substantiate them.

- Advertisements should not describe or show the ***Proprietary Medicines*** of a competitor as broken or defaced, inoperative or ineffective. The only exception is where the description or depiction is based upon the outcome of fair comparative tests to which the advertiser's ***Proprietary Medicine*** also has been subjected and the results of such tests are stated.

5.3 ADVERTISING OF SCHEDULE THREE ITEMS

5.3.1 Background

With the introduction of the Therapeutic Goods Regulations adopted on 15/2/91, ***Proprietary Medicines*** classified as Schedule 3 cannot legally be advertised directly to the general public throughout Australia.

Schedule 3 ***Proprietary Medicines*** are described in the Standard for Uniform Scheduling of Drugs & Poisons as:

> "Schedule 3 - Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental or veterinary practitioners."

(Substances so listed in the current issue of the Standard are covered by this Section of the Code).

Consequently their sale to the general public requires the involvement of the pharmacist personally to ensure the ***Proprietary Medicine*** is suitable for the customer and that the customer is informed on the correct method of use. Schedule 3 ***Proprietary Medicines*** must be stored in pharmacy in areas to which the public does not generally have access. Promotional or advertising material relating to Schedule 3 ***Proprietary Medicines*** must not be visible to the public.

With this background, it is clear that the advertising of such ***Proprietary Medicines*** should be informative where possible, should be directed to ***healthcare professionals*** only and must not be directed to pharmacy assistants or other non-qualified personnel. Since only Professional Advertisements* are permitted, Schedule 3 ***Proprietary Medicines*** do not strictly fall within the ambit of the Therapeutic Goods Advertising Code of the Media Council of Australia. However, as set out in clause 5.1.2, this Code picks up and extends the provisions of the Therapeutic Goods Advertising Code.

5.3.2 Requirements for Professional Advertisements

Advertisements for Schedule 3 Proprietary Medicines shall comply with any applicable conditions of registration. This may require a full disclosure advertisement*, meaning full disclosure of product information as approved for the purposes of registration.

5.3.3 Abridged Disclosure Advertisements

Abridged disclosure advertisements* for S3 ***Proprietary Medicines*** shall contain the following information as a minimum requirement, save that ***where the product information does not include items under these headings, such items are not required to be included in the advertisement.***

- the brand name of the ***Proprietary Medicine;***
- the Australian Approved Name(s) of the active ingredient(s);
- ***approved indication(s) for use;***
- ***clinically significant contra-indications, warnings/precautions, interactions and adverse effects;***

- *content of active ingredient(s) per dosage form or regimen;*
- *dosage forms, regimens and routes of administration;*
- *dependence potential of clinical significance;*
- *reference to special groups of patients (including Australian pregnancy categorisation if issued);*
- *the name of the supplier and the city, town or locality of the registered office; and*
- *a statement to the effect that full product information (if more extensive than the above) is available on request from the manufacturer.*

5.3.4 Short Advertisements

A short advertisement for S3 Proprietary Medicines shall contain:-

- *the brand name of the Proprietary Medicine;*
- *the Australian Approved Name(s) of the active ingredient(s);*
- *the name of the supplier and the city, town or locality of the registered office; and*
- *a statement to the effect that further information is available on request from the manufacturer.*

Short advertisements shall not contain therapeutic claims.

5.4 ADVERTISING IN NON-BROADCAST ELECTRONIC MEDIA

All *Members* shall submit electronic media advertising to PMAA for preclearance. In addition to broadcast electronic media preclearance, *Members* shall obtain preclearance of advertising through closed circuit video or audio networks in locations such as pharmacies, retail stores or doctors' surgeries.

5.5 ADVERTISING IN CONSUMER PRINT, OUTDOOR AND CINEMA MEDIA

All *Members* shall submit copy for consumer print/outdoor/cinema advertising to PMAA for preclearance to ensure compliance with the Therapeutic Goods Advertising Code. On receiving PMAA approval, companies shall submit advertising copy to the Australian Publishers' Bureau, Outdoor Advertising Association of Australia or Australian Cinema Advertising Council, as appropriate, for final clearance and provision of clearance number.

6.1 GENERAL PRINCIPLES - ALL *PROPRIETARY MEDICINES*

6.1.1 All methods of communicating promotional information must be carried out in accordance with the requirements of this Code.

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

6.1.3 Requests from individual members of the public for advice of a diagnostic nature must always be refused and the enquirer recommended to consult his or her own doctor.

6.1.4 Requests for information on Proprietary Medicines must be answered in a balanced way to avoid the risks of raising unfounded hopes or fears in the public mind as to the results of the use of such medicines.

6.1.5 No Member will promote to the general public any prize competition which is conditional on the purchase of a Proprietary Medicine. Unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use* are exempted from this clause.

6.1.6 Competition prizes and other goods or services provided in connection with the promotion of Proprietary Medicines should not be of a nature or economic value which might bring discredit* upon the industry or the recipient.

6.2 SCHEDULED SUBSTANCES AND INTERNAL ANALGESICS

Promotional techniques for Schedule 2 or Schedule 3 substances and internal analgesics should be such that they cannot be construed as persuading consumers to purchase a ***Proprietary Medicine*** which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

Techniques which may be considered inappropriate and contrary to the provisions of the Code include the following examples:

- Promotion to sales assistants, or to any healthcare professional, of prize competitions which are in any way related to sales to consumers of such ***Proprietary Medicines.***
- Distribution of samples to the public or issue of any coupon or voucher in connection with the distribution of samples.
- Initiation of advertising of recommended 'cut price' deals to the general public which may stimulate increased volume of purchase.
- Initiation of cooperative retail press advertisements where recommended prices are featured in a manner which may stimulate increased volume of purchase.
- Encouragement or support of promotional displays in off-site locations within reach of the public which may stimulate increased volume of purchase, e.g. dump bins/gondola ends/dispensers/impulse bars at check-outs or other points of sale.

6.3 CHILDREN

No Member shall promote any Proprietary Medicine to children.

Techniques which may be considered inappropriate and contrary to the provisions of the Code include the following examples:

- Encouragement or support of the positioning of ***Proprietary Medicines*** where they are readily accessible to children.
- Direction of advertising of ***Proprietary Medicines*** to children.
- Advertising of ***Proprietary Medicines*** in a manner which is likely to lead to its use by children without parental supervision.

ART B: MANAGEMENT OF THE CODE

7. ADMINISTRATION OF THE CODE

7.1 The administration of the Code shall be:

- ***supervised by the Executive Subcommittee* (refer Appendix 3, Rule 5.1)***

- ***co-ordinated by the Executive Director, and***

- ***monitored and reviewed by the Marketing & Ethics Subcommittee*.***

7.2 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 8, 9 and 10 of the Code. ***Members of the Complaints Panel shall hold office for one year and shall be eligible for re-appointment.***

7.3 The ***Marketing & Ethics*** Subcommittee shall ensure that the external members of the Complaints Panel nominated 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.

7.4 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 members of the Committee of Management (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, after consultation and agreement, 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.

Where Code complaints are heard, any Committee of Management member sitting on the Complaints Panel will be excluded if a conflict of interest or confidentiality arises, and shall be replaced by another member of the Committee of Management, ***failing whom another representative of a Member of the Association co-opted by the President.*** The Complaints Panel will only be convened 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.

7.5 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.***

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").

8.1 POLICY

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

8.2 COMPLAINT HANDLING

(refer Appendix 2 for diagrammatic representation of Complaint Process)

8.2.1 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.***

8.2.2 The Executive Director shall ensure that written notification is given to the Association of all complaints against a ***Member.***

8.2.3 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.

8.2.4 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.

8.2.5 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.

8.2.6 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 whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be considered necessary.

8.2.7 If the Executive Director, after considering all information provided and making such further inquiry as necessary, forms the opinion that a breach of the Code may have occurred, he/she ***may notify*** the complaint to the Complaints Panel.

8.2.8 Upon resolution of the complaint, the Executive Director shall confirm in writing to the Chief Executive of the ***Member*** which was the subject of the complaint, the finding and actions agreed on to resolve the matter. The Executive Director shall also so notify the complainant and the Executive Subcommittee.

8.2 Complaint Handling continued:

8.2.9 If the Executive Director considers that no breach may have occurred, he/she shall so advise the complainant. ***If the complainant is dissatisfied, the complainant may nevertheless require the Executive Director to convene a meeting of the Complaints Panel to hear the complaint. The Executive Director shall so inform the complainant.***

8.2.10 If the Executive Director is unable to achieve a satisfactory resolution and/or compliance with the Code, he/she shall convene a meeting of the Complaints Panel to consider all information and responses to date and to make such further inquiry as is necessary or desirable. The Executive Director shall keep the Parties* to the complaint informed as to the stage of the complaint investigation procedure.

8.2.11 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 the President shall co-opt another member of the Committee of Management to act as a pro-tempore member of the Complaints Panel.

8.2.12 The Complaints Panel shall consider all information provided before making any decision. Parties to the complaint shall be given the opportunity to provide further information and/or make submissions to the Complaints Panel.

8.2.13 Upon completion of the Complaints Panel's investigations, which shall be completed within 21 working days of the Executive Director convening a Panel meeting, the Executive Director will notify the parties to the complaint of the Complaints Panel's findings and determinations.

8.2.14 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.

8.2.15 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 9 of this Code and so inform the Executive Director.

8.2.16 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.

8.2.17 The parties to the complaint shall be advised of the appeal procedures contained in Section 10 of this Code.

8.3 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.

8.3.1 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.

8.3.2 Industry generated complaints

Intercompany complaints should not be used simply as a competitive tool. Complaints from one ***Member*** against another should include the following information to ensure a complete review.

- 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:

- dialogue with the ***Member*** concerned is not absolutely essential, but unless adequate reason for not undertaking dialogue is given, then the complaint may not be accepted for evaluation until such attempts are made;

- 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.

8.3 Guidelines for Complaints continued:

8.3.3 Response by *Member*

When a complaint has been accepted for evaluation, the ***Member*** 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 ***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.

8.4 ANNUAL REPORT

The Executive Director shall publish annually a report of all matters arising under Sections 8, 9 and 10 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.

SANCTIONS

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

9.1.1 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.

9.1.1.1 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.

9.1.1.2 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.

9.1.1.3 Failure of the offending ***Member*** to comply with either or both 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 9.1.1.1 and 9.1.1.2.

9.1.1.4 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.

9.2. SANCTIONS ABLE TO BE APPLIED BY COMMITTEE OF MANAGEMENT

9.2.1 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 8 of the Code.

9.2.1.1 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).

9.2.1.2 The expulsion of the ***Member*** from the Association, under the provisions of the Rules of the Association (refer Appendix 3).

9.2.1.3 Notification, wherever applicable, to the overseas parent company of the offending ***Member*** of its expulsion from the Association.

9.2.1.4 Notification of the offending ***Member's*** suspension and/or expulsion from the Association to the editors of all trade journals.

). 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").

10.1 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.

10.2 APPEAL AGAINST DETERMINATIONS OF THE COMPLAINTS PANEL

10.2.1 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.

10.2.2 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.

10.2.3 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.

10.2.4 At the ***appeal*** meeting held as referred to in 10.2.3 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***.

10.2.5 ***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).***

10.2.6 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.

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, pharmacists, physiotherapists, dietitians, 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.

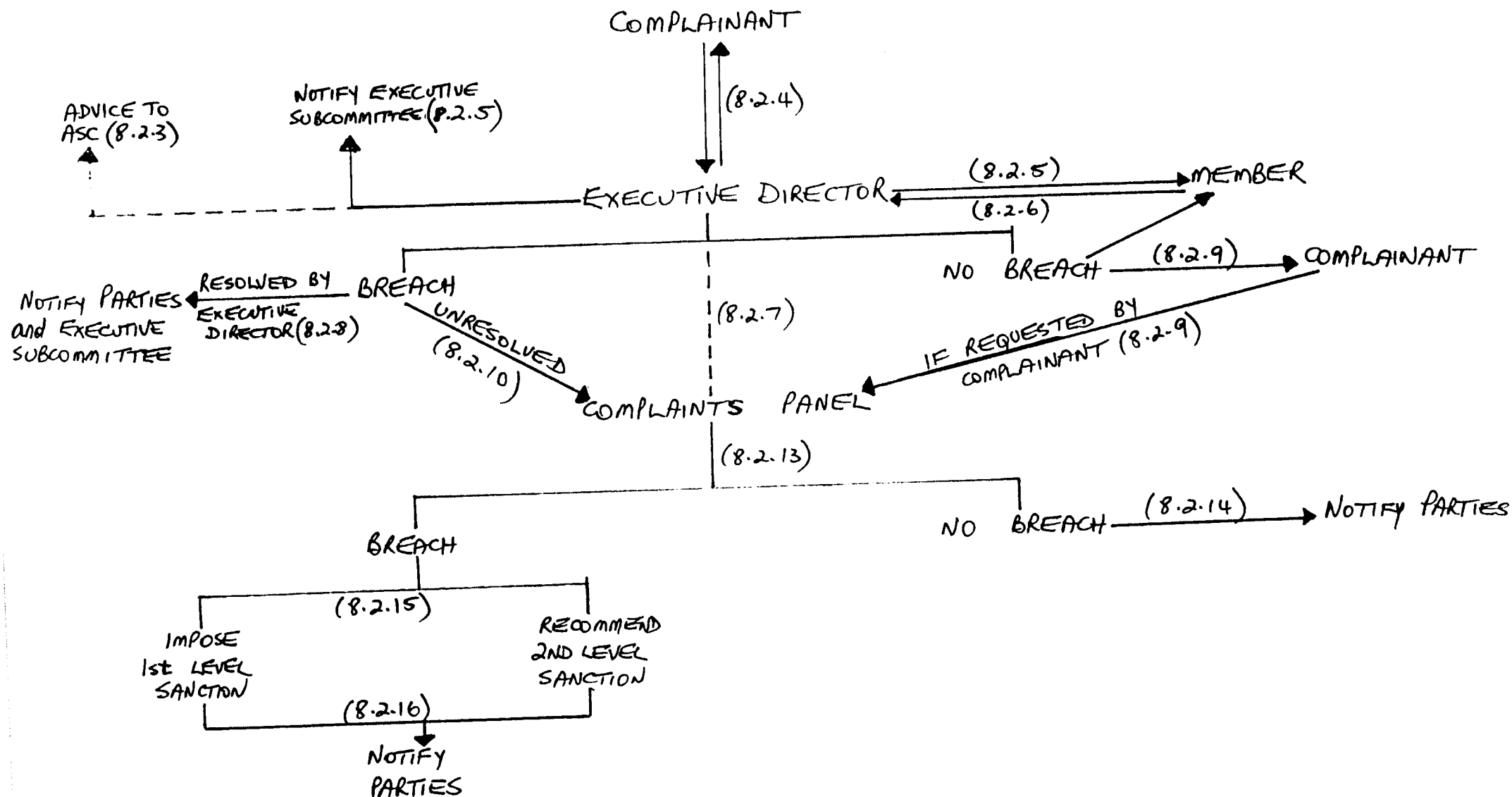
SCHEDULE 1

Subregulation 4 (2)

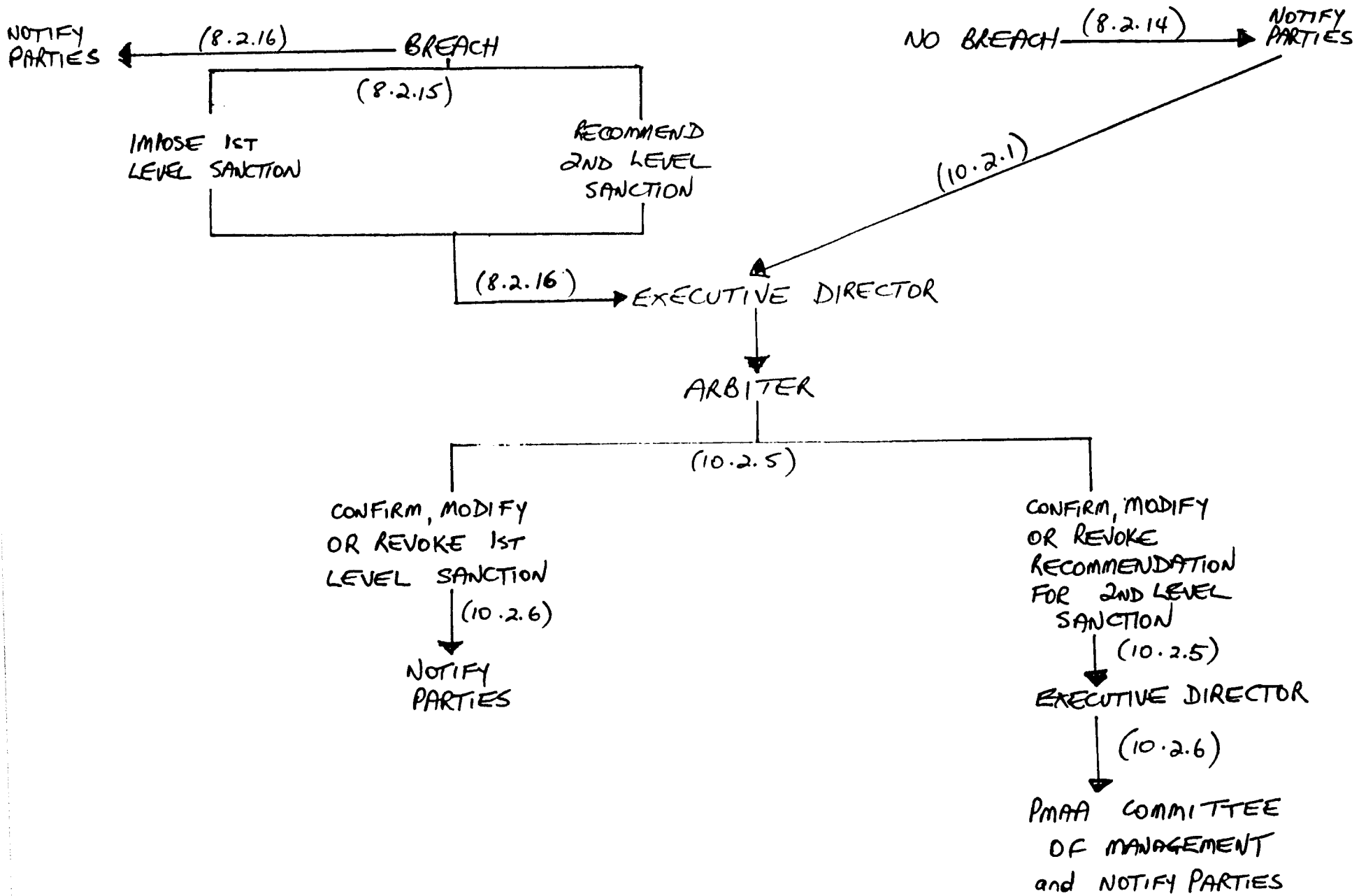
PART 2 DOES NOT APPLY TO MEMBERS OF AN AUSTRALIAN BRANCH OF ONE OF THESE BODIES

Column 1 Item No.	Column 2 Body
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

COMPLAINT PROCESS

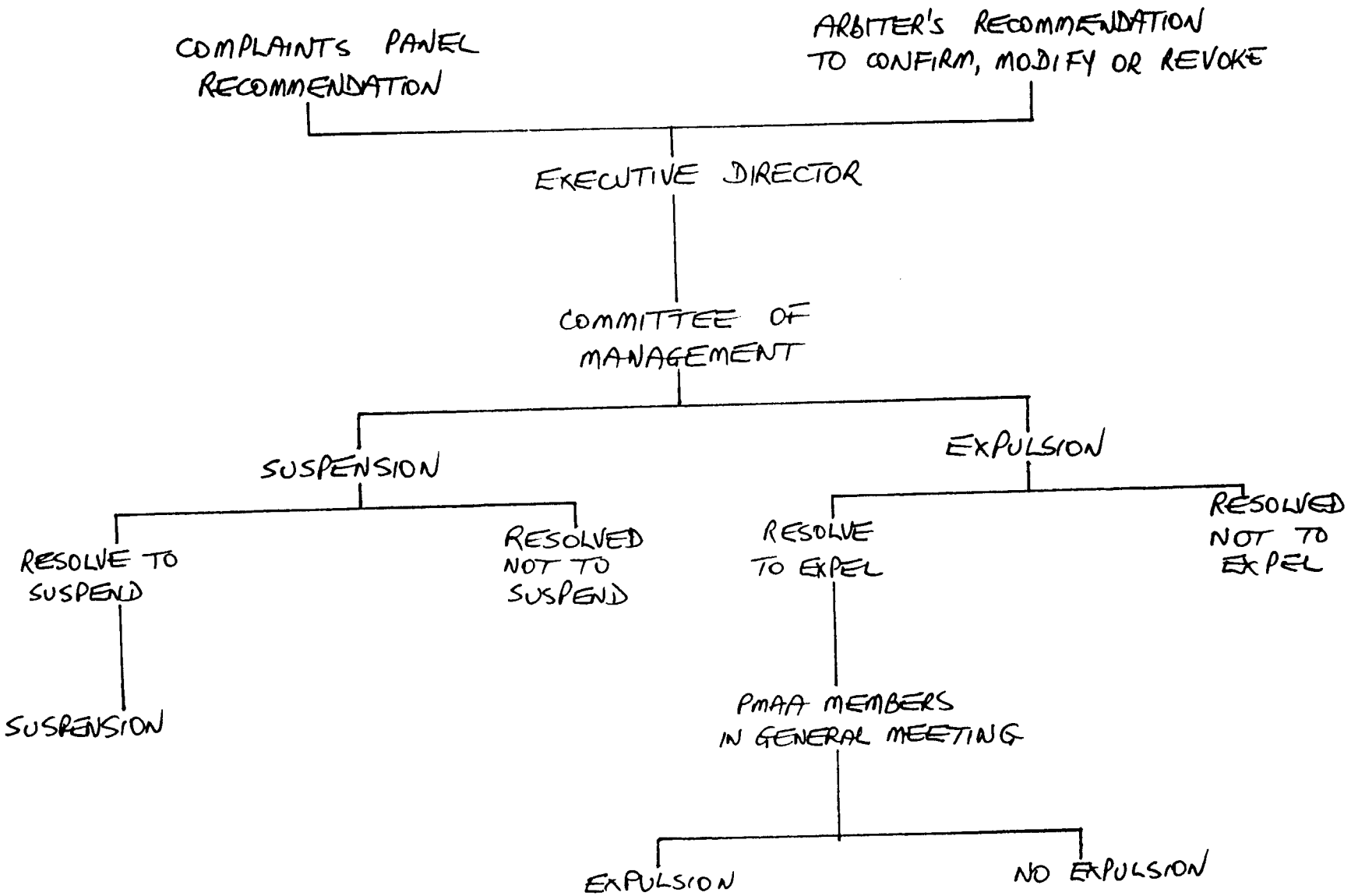


APPEAL PROCESS



APPEAL PROCESS (CONTINUED)

2ND LEVEL SANCTIONS



:TRACT 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 Sucommittees] of these Rules.

ıle 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.***

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.

.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.