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 medicine which may not be needed or a larger quantity of medicine 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 health professional, of prize competitions which are in any way related to sales to consumers of such products
- 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, eg. 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 therapeutic products where they are readily accessible to children
- Direction of advertising of therapeutic products to children
- Advertising of therapeutic products in a manner which is likely to lead to its use by children without parental supervision.

PART B: MANAGEMENT OF THE CODE

7. ADMINISTRATION OF THE CODE

- 7.1 The administration of the Code shall be co-ordinated by the Executive Director of the Association and supervised by the Executive Sub-Committee.
- 7.2 The Executive Sub-Committee will nominate a Code of Practice Complaints Panel to participate as and when necessary in the administration of the Code, and in accordance with Sections 8, 9 and 10 of the Code.
- 7.3 The Executive Sub-Committee 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 will be comprised of a Trade Practices lawyer; a nominee from the RACGP, a community pharmacist nominated by the PSA; three members of the Committee of Management (on a rotating membership); and the Executive Director.
 - 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. The Complaints Panel will only be convened to hear and make recommendations 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 Executive Sub-Committee shall regularly (and at minimum annually) review the Code. The Executive Sub-Committee, 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 Committee of Management.

8. <u>COMPLAINT PROCEDURE</u>

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 1 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 Media Council of Australia is made aware of the complaint. However, the Association will retain the right to consider the complaint in relation to this 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 company which is the subject of the complaint; and
 - the Executive Sub-Committee.
- 8.2.6 The member company that is the subject of the complaint shall be given full details of the nature of the complaint. The member company 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 shall refer 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 Sub-Committee.
- 8.2.9 If the Executive Director considers that no breach may have occurred, he/she shall so advise the complainant of the relevant appeal procedures contained in Section 10 of this Code.
- 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, that 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 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 days.
- 8.2.17 The parties to the complaint shall be advised of the relevant appeal procedures open to him/her/it as 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 product
 - (b) Brief description of complaint itemising the specific claims at issue with complete rationale for alleged breach to be included as an attachment
 - (c) Section of 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 an 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, then the Association may return the complaint to the complainant for further information.

8.3.3 Response by Subject Member

When a complaint has been accepted for evaluation, the subject 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 subject member should include:

- details of attempts to resolve the matter with the complainant;
- a brief summary of the response to each alleged breach;
- substantiating 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.

Page 17

9. 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 company 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 Executive Sub-Committee and/or 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 company 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 2)
 - 9.2.1.2 The expulsion of the member from the Association, under the provisions of the Rules of the Association. (Refer Appendix 2)

- **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.

10. RIGHT OF APPEAL

(refer Appendix 3 for diagrammatic representation of Appeal mechanism)

10.1 COMPLIANCE WITH SANCTIONS

In the event of a member being required 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 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.

10.2 APPEAL AGAINST SANCTIONS BY COMPLAINTS PANEL

- 10.2.1 A disciplined member may lodge a written appeal to the Committee of Management setting out the grounds for objection to the sanction/s proposed by the Complaints Panel.
- 10.2.2 The appeal shall be considered at a meeting of the Committee of Management held not later than 28 days after receipt of the written appeal.
- 10.2.3 The disciplined member shall be advised of the date, time and place of that meeting and that the member may, either in person and/or through its legal representative, do either or both of the following:
 - (i) attend and speak at that meeting;
 - (ii) submit to the Committee of Management at or prior to the date of that meeting written representations relating to the appeal.
- 10.2.4 At the meeting of the Committee of Management held as referred to in 10.2.3 above, the Committee shall:
 - give the member the opportunity to make oral representations;
 - give due consideration to any written representations submitted to the Committee of Management by the member at or prior to the meeting; and
 - by resolution determine whether to confirm, modify, or revoke the sanctions applied by the Complaints Panel.
 - 10.2.5 Where the Committee of Management confirms the sanctions applied by the Complaints Panel, the Executive Director shall, as soon as practicable, inform the member in writing of the Committee of Management decision.

10.3 APPEAL AGAINST SANCTIONS RECOMMENDED BY COMPLAINTS PANEL AND IMPOSED BY THE COMMITTEE OF MANAGEMENT

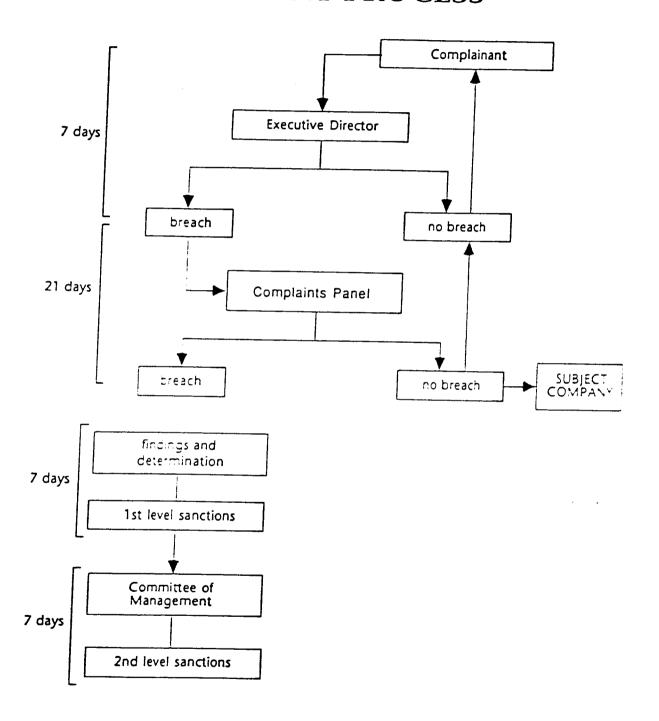
- An appeal against suspension shall proceed in the same manner as an appeal against sanctions by the Complaints Panel, as described in sub-section 10.2 (10.2.1 to 10.2.5 inclusive).
- 10.3.2 Where the Committee of Management confirms a suspension, the Executive Director shall, as soon as practicable, inform the member in writing of the decision.
- 10.3.3 An appeal against expulsion shall proceed in accordance with the Association's Rules. (Refer Appendix 2).

10.4 APPEAL BY COMPLAINANT

- 10.4.1 A complainant, on being informed by the Executive Director that no breach of the Code is considered to have occurred, may appeal against this decision.
- 10.4.2 The complainant may request adjudication of the matter by the Complaints Panel. The Executive Director shall advise the member that is the subject of the complaint and the Complaints Panel accordingly.
- The Complaints Panel shall consider all information provided. Parties to the complaint shall be given the opportunity to provide further information and/or make submissions to the Complaints Panel.
- 10.4.4 If the Complaints Panel, after considering all information provided and making such further inquiry as is necessary, forms the opinion that a breach of the Code has occurred, it shall impose sanctions in accordance with Section 9.1 of this Code or recommend to the Committee of Management appropriate sanctions as provided for under Section 9.2 of this Code.
- 10.4.5 Should the Complaints Panel consider that no breach of the Code has occurred, it shall so advise the Executive Director.
- 10.4.6 The Complaints Panel shall provide to the Executive Director written reasons for its opinion.

APPENDIX 1

COMPLAINT PROCESS



Note: The Code allows for the Executive Subcommittee to be notified at each stage of the above process

18

EXTRACT FROM RULES OF THE ASSOCIATION

RULE 11 - DISCIPLINING OF MEMBERS

- 11.1 Where the committee of Management is of the opinion that an Ordinary Member or Associate Member:
 - (a) has persistently refused or neglected to comply with a provision or provisions of the Association's rules, or
 - (b) has persistently and wilfully acted in a manner prejudicial to the interests of the Association,

the Committee may, by resolution -

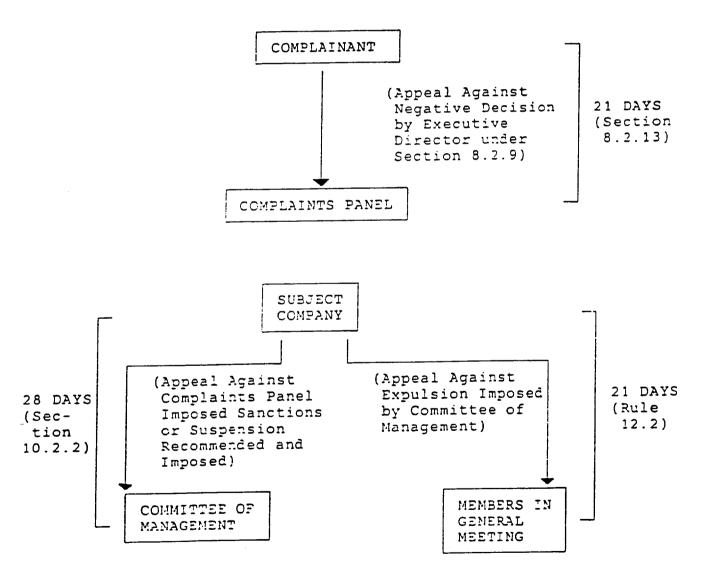
- (c) suspend the member from membership of the Association for a specified period; or
- (d) expel the member from the Association.
- A resolution of the Committee of Management under rule 11.1 (d) is of no effect unless the Committee at a meeting held not earlier than 14 days and not later than 28 days after service on the member of a notice under rule 11.3, confirms the resolution in accordance with this rule.
- Where the Committee of Management passes a resolution under rule 11.1

 (d) above the Secretary shall, as soon as practicable, cause a notice in writing to be served on the member -
 - (a) setting out the resolution of the Committee and the grounds on which it is based:
 - (b) stating that the member 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 that the member may, either in person and/or through its legal representative, do either or both of the following:
 - (i) attend and speak at that meeting;
 - (ii) submit to the Committee at or prior to the date of that meeting written representations relating to the resolution.
 - 11.4 At a meeting of the Committee of Management held as referred to in rule 11.3, the Committee shall:
 - (a) give to the member an opportunity to make oral representations;
 - (b) give due consideration to any written representations submitted to the Committee by the member at or prior to the meeting; and
 - (c) by resolution determine whether to confirm or to revoke the resolution.

RULE 12 - RIGHT OF APPEAL OF DISCIPLINED MEMBER

- 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 11.4 within 7 days after notice of the resolution is served on the member, by lodging with the Executive Director a notice to that effect.
- Upon receipt of a notice from a member under rule 12.1, 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.
- 12.3 At a general meeting of the Association convened under rule 12.2 -
 - (a) no business other than the question of the appeal shall be transacted;
 - (b) the Committee of Management and the member shall be given the opportunity to state their respective cases orally or in writing, or both; and
 - (c) the members present shall, in writing and on the form specified in Appendix IV of the Association's Rules, vote by secret ballot, and in accordance with rule 32 of the Association's Rules, on the question of whether or not the special resolution should be confirmed.
- 12.4 If at the general meeting the Association passes a special resolution in favour of the confirmation of the resolution, the resolution is confirmed. If no such special resolution is passed, the resolution is revoked with effect from the date of the general meeting.

APPEAL MECHANISM



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J M Philip - General Manager, Chemicals Division
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Dr Choo Hoffmann - Dir of Clinical Research A/sia

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Stephen Nicholson - Plant Manager

Ron Harman - External Affairs Manager

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5

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