

7. CONSUMER MEDICINES INFORMATION

7.1 Background

E.N.

Since 1 July 1995 all new Pharmacist Only Medicines (Schedule 3) are required to develop Consumer Medicines Information (CMI).

Existing Pharmacist Only Medicines (Schedule 3) as at 1 July 1995 will be required to have CMI available by 1 January 2004. Companies will be encouraged to progressively develop CMI during the interim period.

7.2 CMI Content

6.1.

Members shall ensure that all CMI's 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 CMI is:

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

Delete

CMI 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 Storage conditions
- Where case of over-dosages
- to go for further information

E.N.

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 CMI

E.N.

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

6.1.

7.4 Complaint Handling—CMI

If on initial review of the complaint, the Executive Director believes that Schedule 13 has been breached, the complaint will be referred to the Chemicals and Non-Prescription Medicines 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 Complaints Panel is to hear a complaint concerning a CMI, an ad hoc observer will be coopted onto the panel to provide expertise in the area in the area of writing CMI.

For details on the complaint procedure with regard to CMI, 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 Executive Subcommittee*
 - ▶ ☐ coordinated 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.

As a condition of appointment all members of the Complaints Panel must enter into a confidentiality agreement regarding the deliberations of the Complaints Panel in the form determined by the Marketing & Ethics Subcommittee. This confidentiality agreement will not apply to the determinations of the Complaints Panel.

- 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 nominee from a broad-based representative consumer/community organisation and, as a non-voting observer, a representative from the Department of Health and Aged Care.

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.

When the Complaint concerns CMI, the Complaints Panel will include a non-voting observer with expertise in the writing of CMI.

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.

- 8.6** To ensure that parties to complaints are aware of complaint procedures and previous decisions about complaints, the Executive Director may make determinations of the Complaints Panel available to members.
- 8.7** Because the integrity of the complaints handling mechanism depends on the Complaints Panel and the Arbiter operating independently of the Association, it is inappropriate for the Executive Director and staff (who provide administrative support) to comment on their decisions.

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 – GENERAL

- 9.2.1** A complainant is not precluded from resorting to litigation but the Complaints Panel must not consider a complaint while its substance is the subject of pending court proceedings.
- 9.2.2** A party to a complaint must notify the Executive Director immediately upon becoming aware of any court proceedings concerning the substance of the complaint.
- 9.2.3** Upon receiving a complaint concerning the advertising or promotion by a Member of a non-prescription healthcare product, the Executive Director must
 - (a) notify the Executive Subcommittee; and
 - (b) if the complaint is in writing, consider whether the Therapeutic Goods Advertising Code may have been breached. Where this likelihood exists, the Executive Director must ascertain whether the complainant has approached the Complaints Resolution Panel. If not, the Executive Director must ensure that the relevant authority is made aware of the complaint. However, ASMI retains the right to consider the complaint in relation to the ASMI Code and to apply sanctions, where appropriate.
- 9.2.4** The Executive Director must ensure all complaints are acknowledged in writing within seven working days of receipt and are handled as expeditiously as possible.
- 9.2.5** The Executive Director must ensure that details of the complaint are notified to the Chief Executive of the Member whose conduct is the subject of the complaint.
- 9.2.6** The Executive Director may, from time to time, make available for the guidance of Members, copies of previous determinations of the Complaints Panel and of the Arbiter (excluding confidential matters). Complaints Panel members and the Arbiter may receive such material to assist them in making their determinations. Non-members proposing to make complaints or responding to complaints may receive such material for the purposes of their conduct of the complaint or of their response to the complaint.

9.3 COMPLAINTS FROM CONSUMERS AND OTHER PERSONS OUTSIDE THE INDUSTRY

- 9.3.1** Complainants are encouraged to contact the Member concerned prior to lodging a complaint as a satisfactory solution may be immediately available.
- 9.3.2** Where a complaint is made by a consumer or other person outside the industry, the complainant may simply state the nature of the conduct to which objection is taken and give the reason(s) for the objection. Where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review.
- 9.3.3** The Member whose conduct is the subject of the complaint must be given full details of the complaint. The Member must provide such references and information as the Executive Director may require. The Member must respond to the complaint within 10 working days.
- 9.3.4** ASMI will provide to the complainant a copy of the Member's response. The complainant may deliver to ASMI within 5 working days any reply it wishes to make. ASMI will send a copy of the reply to the Member.
- 9.3.5** All material provided by the parties in accordance with the provisions of this Code will be considered by the Complaints Panel.

9.4 INDUSTRY-GENERATED COMPLAINTS

9.4.1 Informal procedures

- 9.4.1.1** Members are encouraged to seek to resolve their differences informally both before invoking the formal procedures described below and at any time before final determination of a formal complaint. No informal communications may be sent to ASMI nor communicated to the Panel or the Arbiter.
- 9.4.1.2** If the complaint is resolved by agreement after the initiation of the formal complaint process and before final determination of the complaint (whether by the Complaints Panel or by the Arbiter), the complainant (or, in the case of an appeal, the appellant) must inform the Executive Director immediately and the complaint will be treated as withdrawn.

9.4.2 Formal procedures

- 9.4.2.1** Industry-generated complaints should not be used simply as a competitive tool.
- 9.4.2.2** The unsuccessful party to an industry-generated complaint must reimburse ASMI its out-of-pocket expenses associated with the determination of the complaint (such as fees payable to the Panel Chair) unless the Panel determines that each party should contribute a specified proportion, in which case each party must contribute that proportion. This payment is separate

from and in addition to any fine payable to ASMI in accord with the schedule of fines outlined in Clause 10.2.3.

9.4.2.3 If the complaint is resolved by agreement after the initiation of the formal complaint process and before determination of the complaint by the Complaints Panel, the parties must bear ASMI's out-of pocket expenses associated with the complaint in such proportions as they may agree or, failing agreement, in equal shares.

9.4.2.4 Industry-generated complaints must be initiated by letter from the complainant to the respondent stating that it is a formal complaint under the ASMI Code of Practice. Everything on which the complainant proposes to rely should be included because generally there will be no opportunity to add anything later. Therefore the formal complaint should:

- include a copy of the advertisement or promotional material in question;
- include copies of any studies relied on;
- explain why it is said this Code has been contravened;
- specify the section or sections of this Code said to have been contravened;
- identify the category of breach; and
- identify the sanctions the complainant considers the Panel should impose if the matter were to proceed to a hearing.

The formal complaint should not be sent to ASMI at this stage.

9.4.2.5 Any formal response which the respondent wishes to make to the formal complaint must be delivered to the complainant within 10 working days of receipt of the formal complaint or within such further time as the complainant, acting reasonably, may allow. The formal response must state that it is a formal response under the ASMI Code of Practice. The formal response should contain everything on which the respondent wishes to rely because generally there will be no opportunity to add anything later. The formal response should not be sent to ASMI at this stage.

9.4.2.6 If the complainant is not satisfied with the formal response, the complainant may invoke the ASMI complaints resolution procedure by sending to ASMI 10 copies of both the formal complaint and any formal response and state that it wishes the Panel to resolve the complaint. The complainant must also send one copy of this material to the respondent.

9.4.2.7 Neither the complainant nor the respondent may send to ASMI or to any member of the Panel any informal correspondence between the parties.

9.4.2.8 If a formal response was delivered out of time, the complainant must nevertheless include copies of the response in the material provided to ASMI, and, if it objects to the Panel

considering the response, must so state, with its reasons. In such a case, the Executive Director must ask the respondent to show cause why the Panel should take the response into account. If and only if the Executive Director decides that the complainant unreasonably refused a reasonable request for additional time or granted unreasonably short additional time, the Executive Director must ensure the response is placed before the Panel for its consideration. The decision of the Executive Director on this issue shall be final.

9.4.2.9 Unless the Executive Director has decided to place a late response before the Panel, the Panel must determine the complaint without regard to a late response.

9.4.2.10 The Panel must determine the complaint solely with regard to the formal complaint and any formal response that was made within time or placed before the Panel upon a decision of the Executive Director pursuant to the previous paragraph. In exceptional cases, the Panel or the Panel Chair may allow further material to be put before the Panel and may allow an opportunity to respond to it. The question whether a late response should be taken into account cannot be considered an exceptional circumstance.

9.5 PANEL PROCEDURES FOR ALL COMPLAINTS

9.5.1 Should a complaint concern a Member represented by a person who is a member of the Complaints Panel, the person shall, for that complaint, disqualify himself or herself and another Industry member shall act as a member of the Complaints Panel.

9.5.2 The Complaints Panel shall consider all information provided in accordance with the provisions of this Code before making any decision. Where the Complaints Panel is hearing a complaint about CMI, the Complaints Panel may elect to refer an issue to the CMI Quality Assurance Reference Group for comments, prior to the Complaints Panel completing its deliberations.

9.5.3 Should the Complaints Panel consider that no breach of the Code has occurred, it shall so advise the Executive Director, with reasons.

9.5.4 Should the Complaints Panel consider that a breach of the Code has occurred, it shall determine appropriate sanctions as provided for under Section 10 of this Code and advise the Executive Director of its findings and determinations, with reasons.

9.5.5 Within seven working days, the Executive Director must notify the parties to the complaint and the ASMI Executive Subcommittee of the Complaints Panel's findings and determinations, with its reasons.

9.5.6 If the Complaints Panel identifies a possible breach of the Code not raised by the complainant, the Complaints Panel may draw the possible breach to the attention of the Member (with sufficient particularity for the Member to understand the respect(s) in which a breach may be established) and may request a response from the Member. If the Complaints Panel finds a breach

established, after having considered the Member's response in light of all other material before it, the Complaints Panel may classify the breach and impose sanctions pursuant to section 10 of this Code.

- 9.5.7** The Executive Director must ensure that the parties to the complaint are advised of the appeal procedures contained in Section 11 of this Code.

9.6 ANNUAL 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 BREACHES

10.1.1 Where a breach of the Code has been established, the Complaints Panel must first classify what kind of breach has occurred, in accordance with the classification set out below:

Minor Breach:	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
Moderate Breach	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.
Severe Breach	a breach of the Code that has safety implications or will have a major impact on how consumers or healthcare professionals view the product or competitor products
Repeat Breach	when the same or 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.

10.1.2 After classifying the breach, the Complaints Panel must consider whether or not it will impose any sanctions. The Complaints Panel is not obliged to impose a sanction where breaches of the Code have been established.

In determining whether or not to impose a sanction and, if so, what that sanction should be, the Complaints Panel will consider all the circumstances of the case, including whether:

- ▶ ☐ publication has ceased;
- ▶ ☐ steps have been taken to withdraw the material published;
- ▶ ☐ corrective statements have been made;
- ▶ ☐ the breach was deliberate or inadvertent;
- ▶ ☐ the Member that is the subject of the complaint has previously breached the Code;
- ▶ ☐ there were or are safety implications; and
- ▶ ☐ the perceptions of healthcare professionals or consumers have been or will be affected.

10.2 SANCTIONS ABLE TO BE APPLIED BY THE COMPLAINTS PANEL.

10.2.1 Undertaking to discontinue advertising

The Complaints Panel may require the Member to 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 Panel may require the undertaking to oblige the Member to cease publication in any media (until they can be supported) of an advertisement or of a particular claim or claims which, in the advertisement before the Panel, have been determined to constitute a breach of the Code.

Where a breach of 5.1.4 involving failure to provide substantiation is found, the Panel may direct the Member to provide substantiation to the complainant, within such time as the Panel may specify.

10.2.2 Retraction and/or corrective statements

The Complaints Panel may require the Member to issue retraction statements and/or corrective statements or advertisements and/or to use its best endeavours to retrieve advertisements found to be in breach on such conditions as the Complaints Panel specifies, as appropriate. The format, size, wording, mode of publication and method of distribution of such statements/advertisements shall be specified by the Complaints Panel in its determination and will in general conform to the original statement/advertisement. This does not preclude the party that is the subject of the complaint from suggesting minor amendments to the retraction or corrective statements. However, the Complaints Panel through its Chair may set a time limit on any such suggestions and is under no obligation to accept the amendments. Subject to the appeal process set out in the Code, the decision of the Complaints Panel is final. The time for lodging an appeal is unaffected.

10.2.3 Fines

The Complaints Panel may issue a fine to the subject company in accordance with the schedule of fines, detailed below. 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.

BREACH	FINES
Minor Breach	NIL
Moderate Breach	Maximum: \$20,000
Severe Breach	Maximum: \$40,000
Repeat Breach	Maximum: \$50,000

10.2.4 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 10.2.1 , 10.2.2 and 10.2.3.

10.2.5 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.

10.2.6 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.

10.2.6.1 That the Member discontinue immediately distribution of the CMI.

10.2.6.2 That corrective measures be taken to redraft the CMI in accordance with the findings of the Complaints Panel.

10.2.6.3 That the Member issue retraction and/or corrective statements, as appropriate, flagging the redrafted CMI.

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

10.2.7 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 Complaints Panel may request the complainant to show cause why the Complaints Panel should not impose a charge of \$2,000 for vexatious use of the Code.

10.3 SANCTIONS ABLE TO BE APPLIED BY COMMITTEE OF MANAGEMENT

10.3.1 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.

10.3.1.1 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.

10.3.1.2 The expulsion of the Member from the Association, under the provisions of the Rules of the Association.

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

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

11. RIGHT OF APPEAL

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

The appeal process will be conducted following the principles of fairness and equity for both parties to the appeal process. The appeal will have regard to section 9.3 and 9.4 of the Code of Practice.

- 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 ASMI setting out the grounds for objection.
- 11.2.2** The unsuccessful party to an industry generated appeal must reimburse ASMI its out-of-pocket expenses associated with the determination of the appeal (such as fees payable to the Arbiter) unless the Arbiter determines that each party should contribute a specified proportion, in which case each party must contribute that proportion. This payment is separate from and in addition to any fines payable to ASMI in accord with the schedule of fines outlined in clause 10.2.3
- 11.2.3** If the complaint is resolved by agreement after the initiation of the formal complaint process and before determination of the complaint by the Arbiter, the parties must bear ASMI's out-of pocket expenses associated with the complaint in such proportions as they may agree or, failing agreement, in equal shares.
- 11.2.4** The Executive Members of the Committee of Management will be advised of the appeal lodgement within 7 working days.
- 11.2.5** The appeal shall be held not later than 28 days after receipt of the written appeal. The parties shall be advised of the date, time and place of the appeal meeting and any adjournment thereof.
- 11.2.6** The appeal shall be determined by an independent person (the "Arbiter") appointed by the Marketing & Ethics Subcommittee with appropriate legal and trade practice expertise and not involved in any previous hearing of the particular complaint, sitting alone on an at-call basis. Parties to the appeal shall not introduce medical expertise to assist the Arbiter in deliberating the scientific or medical aspects of the appeal. The arbiter can request that the

ASMI Executive Director appoint an independent scientific or medical expert to advise the arbiter in their deliberation.

11.2.7 Three copies of the written appeal shall be received by the Executive Director and a copy will be provided to both the company which lodged the original complaint and the Arbiter. The responding company will have 10 working days within which to provide three copies of any written response to the appeal to the Executive Director, should it so wish. The written response will be forwarded to the appellant company and to the Arbiter.

11.2.8 To avoid the appeal becoming a new hearing on fresh material, the materials to be considered by the Arbiter shall be confined to the evidence that was before the Complaints Panel; the determination and reasons of the Complaint Panel and any written submissions of the parties. In exceptional circumstances the Arbiter may decide to accept material that was not available when the complaint was heard by the Complaint Panel, such as new published material or changes to product registration.

11.2.9 The parties will indicate in writing whether they wish to attend and speak at the meeting. The party may appear in person or through representatives or both. The names and positions of the nominated persons are to be notified to the Executive Director prior to the date of the appeal meeting who will then inform the Arbiter prior to the meeting.

11.2.10 At the appeal meeting referred to in 11.2.2 and 11.2.6 above, the Arbiter shall ensure proper consideration of the appeal, whilst not being bound by the rules of evidence. The Arbiter shall;

- i) give the parties the opportunity to make oral representations. In the event of an oral representation, the following procedures shall apply;
 - the party bringing the appeal will be heard first and that party shall be entitled to reply to any oral representations made on behalf of the other party;
 - with the consent of the Arbiter proceedings may be adjourned for a short time between oral submissions;
 - neither party may intervene during the other party's oral presentation, or direct questions to the other party;
 - the Arbiter may ask questions of either party and may (but shall not be obliged to) ask a question of a party at the suggestion of the other party.
- ii) The Arbiter shall give due consideration to any written representations submitted by the parties prior to the meeting.

11.2.11 The Arbiter in reaching a determination may confirm, revoke or modify the decision of the Complaints Panel. The Arbiter may request the Complaint Panel to reconvene to reconsider the complaint in the event that;

- i) a procedural error is identified by the Arbiter;
- ii) new technical or scientific information is presented.

The procedures of the Complaints Panel under these circumstances will be determined by the Chair of the Complaints Panel in consultation with the

Executive Director. Upon such reconsideration the Complaints Panel may confirm, revoke or vary its previous determination(s).

11.2.12 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.

11.2.13 The Executive Director shall, as soon as practicable, inform the parties in writing of the Arbiter's decision, and shall also so inform the Committee of Management where the Arbiter recommends suspension or expulsion of a Member. The Executive Director shall not comment or engage in correspondence in relation to the substance of the decision or reasoning of the Arbiter.

12. MONITORING OF ADVERTISING

12.1 OBJECTIVES

To support compliance with the ASMI Code of Practice, the Promotional Monitoring Committee will pro-actively monitor selected promotional material of Members on a regular and ongoing basis.

12.2 AIMS OF THE MONITORING PROCESS

- To encourage compliance with the ASMI Code of Practice
- To provide comment on compliance issues where requested
- To provide an ongoing mechanism for the identification of trends in health matters, marketing activities or changes in technology which may indicate the potential need for amendments to the Code of Practice
- To provide and publish statistical data on the rate of compliance.

12.3 SCOPE

All forms of promotional material which are not subject to the formal approval process may be reviewed by the Committee.

12.4 PROTOCOL FOR THE ACTIVITIES OF THE PROMOTIONAL MONITORING COMMITTEE

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

12.5 MEMBERSHIP OF THE PROMOTIONAL MONITORING COMMITTEE

The Marketing and Ethics Subcommittee will determine the composition of the Promotional Monitoring Committee which will include adequate representation from the medical and pharmacy profession, patient/consumer groups and Industry.

The Chairperson of the Promotional Monitoring Committee will be independent of the Australian Self-Medication Industry and its member companies.