AUSTRALIAN SELF-MEDICATION INDUSTRY
BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

4 December 2000

The General Manager
ACCC
PO Box 1199
Dickson ACT 2602

Proposed amendments to PMAA Code of Practice
Authorization A90549, 27 January 1994.

The Commission will recall that it was a condition of the above mentioned authorization that the PMAA Code of Practice be regularly reviewed.

As we indicated in our letter of 9 June 2000 a name change for the PMAA had been adopted unanimously by members at the 8 June 2000 Special General Meeting. The Code has been amended to reflect the new name: *Australian Self-Medication Industry.*

The Annual Code Review Committee adopted further proposals to amend the Code at the Annual Code Review meeting on 5 September 2000. The proposed amendments were subsequently endorsed by the Committee of Management and unanimously adopted by members at the Annual General Meeting held in Sydney on 23 November 2000.

Find attached the rationale document and the proposed amendments highlighted for your convenience. I also include a copy of the Code – **Revised November 2000**.

Please let me know if the Commission has any queries arising out of its consideration of the attached proposed amendments.

Yours sincerely

Deon Schoombie
Advertising Services Manager

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PROPOSED AMENDMENTS TO THE ASMI CODE OF PRACTICE

Recommended by the Annual Code Review Committee (ACRC)

RATIONALE DOCUMENT

CLAUSE 1 DEFINITIONS

- **"Advertisement" – insert Internet**

  Members agreed at the AGM in 1999 to include the Internet in the definition of an advertisement. This arrangement is consistent with new advertising arrangements following the recent major review of the TGAC. There was also agreement that promotional material inserted on the Internet will not be subject to formal approval. The proposed amendment will clarify the requirement that advertisements and promotional material inserted on the Internet must comply with the TGAC and the ASMI Code of Practice.

- **"Proprietary Medicines" – replace with "Non-prescription consumer healthcare products"**

  The existing term is obsolete – it does not reflect current terminology and it does not embrace the concept of complementary healthcare products. The proposed term is current and the description in the definition clearly indicates the range of products to be included in the new term. The outdated references to "in man" in the bullet points are replaced with "in humans".

CLAUSE 5.1.4 – clarify requirements for provision of substantiating evidence

The ASMI Complaints Panel recommended a review of the requirements under this clause in the context of a recent complaint. The proposed amendment seeks to clarify Members' responsibility to provide substantiating evidence.

The existing requirement is that information and claims, when made, "be capable of substantiation". This is inconsistent with the Therapeutic Goods Advertising Code (TGAC) which requires that all claims used by sponsors in advertisements must have been verified at the time the claims are made.

A further proposal is to delete the reference to "bone fide requests" because it has the potential of inviting a dispute whether a request is bone fide or not, while the focus should rather be on whether a claim is justified or not.

CLAUSE 5.1.5 – delete

The prohibition on "money back guarantees" had been discussed at several meetings of the Marketing and Ethics Subcommittee and the TGA was also asked for its interpretation of this type of guarantee. The TGA expressed the view that guarantees of satisfaction would not necessarily breach the TGAC.
"*Money back guarantee*" or "*Money back guarantee if not completely satisfied*" were considered acceptable and not an absolute claim as it is implying that the sponsor is aware that some consumers may not be satisfied with the product and under those circumstances a refund would be available. The claim, "*Guaranteed satisfaction*" was discussed at a TGACC Meeting and the members agreed that the claim does not necessarily mean guaranteed efficacy.

Historically, no rationale for this prohibition could be established. There was agreement that the deletion of the clause would not permit any guarantees in relation to efficacy as these are expressly prohibited in the TGAC.

CLAUSES 5.4 & 5.5 – clarify the requirements under these clauses and establish consistency with those requirements for S3's which are similar to S2's. Also ensure consistency with the requirements under the APMA Code of Practice

The requirements for advertising of unscheduled and S2 products to healthcare professionals differ from the requirements for the advertising of S3's and are listed under a separate heading under clause 5.5. The reference to S3's in clause 5.4 is therefore inappropriate and leads to confusion.

Members also reported problems with the interpretation and requirements for "trade advertising" and "brand name advertising" as described in this clause.

The proposal is to restructure the section to clarify the distinction between "trade advertising" which conveys only purchasing or commercial information and other forms of advertising which contain product claims and information. As the section is about advertising to healthcare professionals only, it was agreed to delete the reference to "trade".

CLAUSE 6.2 – reviewed at request of ASMI Member

An ASMI Member requested the Annual Code Review Committee to review this clause with a view to relaxing the restrictions. The principles underpinning the requirements under this clause were discussed at length by the Review Committee. The consumers representative on the Committee drew attention to the National Medicines Policy and one of its major objectives, i.e. Quality Use of Medicines. She indicated that CHF would be reluctant to support any amendments which could result in conflict with these principles. The representative from PSA/PGA indicated that both bodies support the principles underpinning promotional activities in the Code. Any proposals to amend these will require further consideration by PGA and PSA.

There was agreement that ASMI wants to be responsible and would like its Members to be seen to act responsibly. As there is no certainty as to what benefits could be achieved from rel ing current requirements, the Committee decided not to recommend amendments to this effect.

The Review Committee also considered the requirements under this clause as a result of concern expressed by the Chairman of APAC in relation to an incentive scheme (by an ASMI Member) directed to pharmacy assistants. The promotion raised the issue of "interference" with the recommendation process. While it is normal practice for sponsors to implement promotional techniques which would lead to brand switching, promotional techniques should not be likely to lead to inappropriate recommendations. It was agreed to propose a further requirement under clause 6.2 to address the issue of potential inappropriate product recommendations to consumers under incentive schemes.

SECTION 9 – COMPLAINT PROCEDURE – review entire procedure

Several ASMI Members have expressed the view that the complaints procedures are complicated and cumbersome and as a result, discourage sponsors to complain. They regarded the process to be slow and requiring considerable resource allocation.

It also became apparent during recent Complaints Panel hearings that parties to complaints were not consistently attempting to resolve complaints amongst themselves as required under clause 9.3.2 before resorting to the lodgement of a formal complaint.

Proposed Clause 9.2 General

This reproduces existing provisions in a more logical order.

Proposed Clause 9.3 External complaints

This preserves the existing procedure for external complaints, which do not have to be formal and which are not required to be paid for by the complainant.

Proposed Clause 9.4 Industry-generated complaints

At present the parties engage in correspondence before a complaint is made and then exchange formal complaint and response, followed by a reply and often a rejoinder. The prior correspondence is included in the material before the Panel because it is necessary to provide details of attempts to resolve the matter before the complaint is made. Often the complaint and response cover the same ground as was covered in the earlier correspondence but often also with differences. This is cumbersome and time consuming and it adds to the cost of handling the complaint because of the additional volume of material before the Panel.

The proposed amendments will replace the present process by encouraging attempts between the parties to resolve their differences informally while limiting the material put before the Complaints Panel to formal documents. Further, as a result of the recent high costs of two complaints (far exceeding the administrative lodgement fee under 9.3.2)

specific provision is proposed for the payment of ASMI's expenses by the unsuccessful party.

The proposals involve:-

- A formal complaint from the complainant to the advertiser (not to ASMI), containing everything on which the complainant wishes to rely;
- A formal reply (which must be delivered to the complainant, not to ASMI, within 10 working days or an agreed extended time) containing everything on which the advertiser (subject company) wishes to rely;
- If the complainant is not satisfied, it sends copies of both formal letters to ASMI asking the Panel to resolve the complaint;
- A late response must be sent to ASMI by the complainant. Only if the Executive Director decides that the complainant unreasonably refused a reasonable request for additional time, or granted unreasonably short additional time, will the Panel consider a late response;
- The Panel determines the complaint solely with regard to the formal complaint and any formal response that was made within time. In exceptional cases, the Panel or the Panel Chair may allow further material to be put before the Panel and an opportunity to respond to it.
- Proposed section 9.4.2.2 provides for the unsuccessful party to reimburse ASMI's expenses associated with the determination of industry-generated complaints (such as the fees payable to the Panel Chair) unless the Panel determines that each party should contribute a specified proportion. A similar provision (9.4.2.3) covers the situation where a complaint is settled before determination but after expenses have been incurred.

Proposed Clause 9.5 Procedure for all complaints

This incorporates existing provisions, but adds a provision, clause 9.5.6, permitting the Complaints Panel to impose sanctions for a breach not identified by the complainant, after giving the advertiser an opportunity to respond.

CLAUSE 10.2 SANCTIONS

- **Sanctions in relation to advertising campaigns**

  The present division of responsibility between the ASMI Panel and the CRP makes it desirable for the ASMI complaints mechanism to deal with advertising campaigns across a range of media, so as to avoid the need for complainants to invoke both jurisdictions or to go to court. This can be achieved by giving the ASMI Panel power to require a member to cease publication (until it can be supported) in **any** media of an advertisement or of a particular claim, once that advertisement or claim has been found in breach of the Code in the particular advertisement before the Panel.

- **Breaches of clause 5.1.4**

  At present, the only available sanction for failing to provide substantiation without delay upon receipt of bona fide requests (5.1.4) is to require the member to undertake to discontinue the practice of failing to provide the substantiation (10.2.1). This is cumbersome. A proposed addition to 10.2.1 gives the Panel specific power to require a member to provide substantiation to the person making the request where the Panel has found breach of 5.1.4.

SECTION 11 Appeals – cost recovery

Proposed clause 11.2.2 provides for the unsuccessful party to reimburse ASMI's expenses associated with the determination of industry-generated appeals (such as the fees payable to the Arbiter) unless the Arbiter determines that each party should contribute a specified proportion. A similar provision (11.2.3) covers the situation where an appeal is settled before determination but after expenses have been incurred.

PROPOSED SECTION 12 MONITORING OF ADVERTISING

The Marketing and Ethics Subcommittee, in collaboration with John Baker from the APMA, developed a proposal for the implementation of a monitoring system for advertising. The proposal was adopted in principle by COM. The Annual Code Review Committee discussed the detail and recommended the amendments under the new Section 12 of the ASMI Code of Practice.

The proposed system will cover promotional material which is not subject to the formal approval process and thus complement the co-regulatory system which applies to mainstream advertising.

The protocol for the system will be developed by the Marketing and Ethics Subcommittee. The importance of the membership of the Monitoring committee in relation to expertise, consistency and continuity was highlighted. The system will be accommodated within current budget arrangements and there will be no extra cost to Members.

It was noted that material found to be compliant with the Code by the Monitoring Committee, does not preclude the material from becoming the subject of a complaint and being found to be in breach by the Complaints Panel.

Membership of any Complaints Panel convened to hear a complaint resulting from the monitoring process, will exclude parties who had previously reviewed the material on the Monitoring Committee.

Australian
Self-Medication Industry

Code of Practice

Adopted:	*8 October 1991*
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	15 October 1992
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Revised	*September 1999*

REVISED: **JULY 2000**

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CONTENTS

PART A: THE CODE AND ITS APPLICATION

PART B: MANAGEMENT OF THE CODE

PREFACE

Authorisation of the then 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:

- ASMI (formerly PMAA) and its members from time to time;
- all future proposed amendments to these arrangements which ASMI 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.

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

- ASMI 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 ASMI if it considers the proposed amendments are significant and would materially alter the circumstances of any authorisation granted by the Commission.
- both the proposed amendments and the Commission's advice to ASMI 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 ASMI reviews of the Code.

NOTE: This preface does not form part of the Code.

1. 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, leaflet, booklet, 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, ***Internet,*** 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.

- **"Consumer Medicines Information (CMI)"** is confined to factual information concerning all Pharmacist Only Medicines (Schedule 3) and their use. The purpose is to help consumers use medicines appropriately and supplement and support the counseling activities of doctors, pharmacists and other caregivers. CMI is not an advertising or promotional tool. CMI must comply with Schedule 13 of the Therapeutic Goods Regulations and must be consistent with product information (within the meaning of section 32 of the Therapeutic Goods Act).

- **"The Association"** means the Australian Self-medication Industry Incorporated.

- **"Code"** means the ASMI Code of Practice, and includes (unless the context requires otherwise) the Therapeutic Goods Advertising Code.

- **"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 ASMI 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.

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

- 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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~.

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

- **"Member"** means any Ordinary or Associate member as defined by the ASMI 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.

- ***"Non-prescription consumer healthcare products"*** ~~**"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 ***humans*** ~~man~~;
  - influencing, inhibiting or modifying a physiological process in ***humans*** ~~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 ***humans*** ~~man~~.

- **"Off Site Location"** means any area of a retail outlet that is not the normal shelf placement site for therapeutic goods. Within grocery outlets, off site locations are defined as anywhere in the store that is beyond the Health & Beauty section. In Pharmacy, off site is defined as anywhere outside the store. For other distribution channels, promotional displays that appear other than in the routine placement area for therapeutic goods would be defined as off site.

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

- **"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 (*).

2. INTRODUCTION

2.1 The Association* is a ~~the~~ corporate representative and advocate for manufacturers of ***non-prescription consumer healthcare products*** ~~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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ which are both safe and effective when used as directed.

2.3 In this commitment, the Association's Members recognise that, whilst ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ can bring substantial social and economic benefits to the community, the advertising and promotion of ***these products*** ~~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 ***of non-prescription consumer healthcare products*** 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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~.

Specifically, ***in relation to non-prescription consumer healthcare products,*** the Code seeks to assist Members to:

- responsibly inform consumers about ***the products*** ~~Proprietary Medicines~~ which are available;
- uphold a high standard in the communication of information about ***the products*** ~~Proprietary Medicines~~;
- ensure that all claims made for ***the products s*** ~~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 ***the products*** ~~Proprietary Medicines~~.

PART 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:

4.3.1 the Therapeutic Goods Advertising Code;

4.3.2 the Code of Good Manufacturing Practice

and such other Codes as are from time to time developed and/or endorsed by the Association.

4.3 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.

4.4 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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~.

4.5 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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~.

4.6 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.

4.7 Members will draw to the attention of the Association any information which may lead to improvement in standards of correct and safe use of ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~.

5. ADVERTISING

5.1 GENERAL PRINCIPLES— ALL ~~PROPRIETARY MEDICINES~~ NON-PRESCRIPTION CONSUMER HEALTHCARE PRODUCTS

5.1.1 Section 5 of this Code applies to Members whose ***non-prescription consumer healthcare products*** ~~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 Therapeutic Goods Advertising Code in relation to consumer advertisements* of ***non-prescription consumer healthcare products*** ~~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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ must be current, accurate, balanced, and must not mislead either directly, by implication, or by omission.

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

- literature references, or quotations or claims that are more favorable 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 Health and Aged Care.

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.~~
Furthermore, information and claims must, when made, have been substantiated, such substantiation being provided without delay upon request. A member unable or unwilling to provide a reference in substantiation of a claim, should refrain from citing it. An abstract or summary of unpublished data should be identified as such when cited.

~~**5.1.5** No Member shall advertise an offer to return money to dissatisfied users of Proprietary Medicines.~~

5.1.5 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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ shall comply with the terms of this section.

- Comparative advertisements should not be misleading, or likely to be misleading, either about the ***products*** ~~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 ***non-prescription consumer healthcare products*** ~~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 ***non-prescription consumer healthcare products*** ~~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 ***product*** ~~Proprietary Medicine~~ also has been subjected and the results of such tests are stated.

5.3 ADVERTISING TO CONSUMERS

5.3.1 Compliance with advertising regulations

Members shall submit copy for advertising to consumers to the appropriate bodies (eg. ASMI and CHCA) for approval in accordance with the delegations under the Therapeutic Goods Regulations and the Broadcasting Services Act. On approval Members shall submit advertising copy to the Federation of Commercial Television Stations (FACTS), the Federation of Australian Radio Broadcasters or the Australian Cinema Advertising Council where applicable.

5.3.2 Compliance with the ASMI Code of Practice

In addition to the requirements in 5.3.1, Members shall submit all mainstream advertising material directed to consumers to the ASMI for approval to ensure compliance with the ASMI Code of Practice.

5.4 ADVERTISING TO HEALTHCARE PROFESSIONALS

The intent of this Clause is to ensure that all promotion and advertising of ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ directed to healthcare professionals, encourages rational use of medicines, does not mislead and contributes to ASMI's overall aim of promoting responsible self medication.

Advertising material directed to healthcare professionals does not require prior approval by ASMI's approval service. Approval is only required for consumer advertising in broadcast media, and other consumer media as detailed in Clauses 5.3.1. Companies must therefore satisfy themselves that any material they produce aimed at healthcare professionals complies with the Code.

Complaints regarding advertising or promotion of any OTC medicines directed to healthcare professionals will be adjudicated through ASMI's Complaints Handling Process outlined in Clause

Excluded from the scope of this Code are advertising and promotional activities relating to prescription (Schedule 4) products. These activities fall under the APMA Code of Conduct.

Advertising for OTC medicines, directed to healthcare professionals must comply with the body of the ASMI Code, as well as this Clause, 5.4.

Requirements for Advertising *of Unscheduled and Pharmacy Medicines (Schedule 2) to Healthcare Professionals*

Minimum requirements

Advertising for unscheduled ***and*** Pharmacy Medicines (Schedule 2) ~~and Pharmacist Only Medicines (Schedule 3)~~ where it is directed to healthcare professionals, shall contain the following information as a minimum:

- the brand name of the ***products*** ~~Proprietary Medicines~~
- the Australian Approved Name(s) of the active ingredient(s)
- a statement of the indication for use of the goods
- For multi-ingredient products, the advertisement shall contain reference to at least the first four principal active ingredients and the statement "For full active ingredients, see the label".

~~Trade advertising which conveys only purchasing details/information for the pharmacist and which communicates no claims or benefits of the goods shall be exempted from this requirement.~~

Brand name reminder advertising

Brand name reminder advertising i.e. conveying no claims or promotional statements, shall contain the following minimum information:

- the brand name of the product
- the Australian Approved Name(s) of the active ingredient(s)
- For multi-ingredient products, the advertisement shall contain reference to at least the first four principal active ingredients and a statement "For full active ingredients, see the label".

Where the nature of the brand name reminder is such that it is demonstrably and obviously impractical to display legibly the information required, the advertisement must be accompanied by a document that contains the required information.

Advertising which conveys only purchasing details/information for the pharmacist and which communicates no claims or benefits of the goods shall be exempted from the above requirements.

5.5 ADVERTISING OF PHARMACIST ONLY MEDICINES (SCHEDULE 3)

Background

With the introduction of the Therapeutic Goods Regulations adopted on 15/2/91, ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ classified as Pharmacist Only Medicines (Schedule 3) could not legally be advertised directly to the general public throughout Australia.

A review into advertising in 1997 produced a report "*Further Review of the Brand Advertising of Schedule 3 Medicines*", which recommended that Pharmacist Only Medicine (Schedule 3) branded advertising direct to the consumer be permitted subject to certain conditions. As a result the NDPSC will determine which Pharmacist Only Medicine (Schedule 3) substances are permitted to be brand advertised to the general public and for what indications, in accordance with the nationally agreed guidelines. These substances are published in Appendix H of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Pharmacist Only Medicines (Schedule 3) are described in the Standard for Uniform Scheduling of Drugs & Poisons as:

"Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription".

Consequently their sale to the general public requires the personal involvement of the pharmacist to ensure the ***product*** ~~Proprietary Medicine~~ is suitable for the customer and that the customer is informed on the correct method of use. Pharmacist Only Medicines (Schedule 3) must be stored in pharmacy in areas to which the public does not generally have access.

Except for those Pharmacist Only Medicines (Schedule 3 substances) for which direct to consumer advertising is permitted, promotional or advertising material relating to Pharmacist Only Medicines (Schedule 3) must not be visible to the public.

For those Pharmacist Only Medicines (Schedule 3 substances) for which direct to consumer brand advertising is permitted, promotional or advertising material must comply with the body of this Code as well as the requirements of the Therapeutic Goods Advertising Code.

For those Pharmacist Only Medicines (Schedule 3 substances) not permitted to be brand advertised to the general public, advertising should be directed to healthcare professionals only and must not be directed to pharmacy assistants or other non-qualified personnel.

5.5.1 Advertising of Pharmacist Only Medicines (S3) to Healthcare Professionals.

Advertisements for Pharmacist Only Medicines (S3) shall comply with any applicable conditions of registration.

Minimum ~~disclosure~~ requirements

~~Advertisements directed to healthcare professionals must include as a minimum, except for *brand reminder advertising:* a short advertisement:~~

- the brand name of the product
- the Australian Approved Name(s) of the active ingredient(s)

- the approved indication/s for use
- a succinct statement of the contra-indications, clinically significant precautions and side-effects
- dosage and method of use
- the name of the supplier and the city, town or locality of the registered office
- a clear and unambiguous statement for ***healthcare professionals*** ~~prescribers~~ to review the full PI (if more extensive than the above) before recommending, and alerting them to the availability of the full PI from the manufacturer on request.

~~**Short Advertisements**~~

~~*A short advertisement for Pharmacist Only Medicines (S3) are those advertisements intended to communicate commercial information only such as details of packaging, pricing, trading terms or marketing incentives. Short advertisements shall not contain therapeutic claims.*~~

Brand name reminder advertising

Brand name reminder advertising, i.e. conveying no claims or promotional statements, shall contain the following minimum information: ~~A short advertisement for Pharmacist Only Medicines (S3) shall contain:~~

- the brand name of the product
- 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

Where the nature of the brand name reminder is such that it is demonstrably and obviously impractical to display legibly the information required, the advertisement must be accompanied by a document that contains the required information.

Advertising which conveys only purchasing details/information for the pharmacist and which communicates no claims or benefits of the goods shall be exempted from the above requirements.

5.5.2 Advertising of Pharmacist Only Medicines (Schedule 3) To Consumers

5.5.2.1 Direct to Consumer Advertising

For those Pharmacist Only Medicines (Schedule 3) for which branded advertising is permitted, all advertising and promotional activity should comply with this Code and the Therapeutic Goods Advertising Code and advertising shall be submitted for approval as provided for in clause 5.3 of this Code.

5.5.5.2 Indirect Consumer Advertising

Indirect advertising of other Pharmacist Only Medicines (Schedule 3) can provide relevant information to consumers and enhance their awareness that the treatments are available without a doctor's prescription, and can direct them to seek further information from their doctor or pharmacist about those treatments.

Objectives of indirect advertisements for Pharmacist Only Medicines (Schedule 3)

The need to create such awareness may arise from the availability of new OTC treatments, or rescheduling which has enabled treatments which had been previously restricted to prescription only use, to be now available without a prescription.

- Inform consumers of the availability of Pharmacist Only Medicines (Schedule 3).
- Emphasise that such treatments may only be used on the recommendation of, or after consultation with, a pharmacist or medical practitioner.
- Convey information of an educational, rather than promotional nature.
- Refer consumers to their pharmacist or doctor for further information, thus promoting better communication between consumers and health professionals.

The Role of the Pharmacist

The role of the pharmacist as an adviser to the consumer is very important.

Once the consumer is aware of the availability of a Pharmacist Only Medicine (Schedule 3) for a particular condition or symptom, the suitability of available products, and the possible need for a doctor's diagnosis, will need to be assessed. If a suitable product is available, information about the product, its correct usage, dosage and precautions, will be required at the point of purchase when the patient is most receptive to this type of information.

Indirect advertising simply indicates availability of the Pharmacist Only Medicines (Schedule 3) for certain conditions and communicates basic information. Research on advertising has shown definitively that only essential information is understood and retained by consumers [Taylor Nelson, UK].
The role of the pharmacist as adviser at the point of purchase is crucial and will not be usurped by indirect advertising of Pharmacist Only Medicines (Schedule 3). Rather, it should be enhanced.

The requirements for indirect advertisements clearly limit the scope of allowable claims, ensuring no identification of brands, product, or classes of drugs.

The provision of information via indirect advertising to consumers on some Pharmacist Only Medicines (Schedule 3) provides a means of informing them of the availability of treatments and directing them to pharmacists and doctors for further discussion.

Requirements for Indirect Advertising for Pharmacist Only Medicines (Schedule 3)

- No reference to any pharmaceutical, or product, or any substance whatsoever by name, whether of brand, drug, chemical class, or therapeutic class. Reference to any such substance to be in terms of a treatment only.

- No sponsor company identification.

- Indirect advertising for Pharmacist Only Medicines (Schedule 3) may detail the condition, conditions or class of condition where Pharmacist Only Medicines (Schedule 3) have become available or where new indications for Pharmacist Only Medicines (Schedule 3) are allowed.

- Claims must focus on building consumer awareness that certain treatments are available.

- Indirect advertisements for Pharmacist Only Medicines (Schedule 3) must clearly emphasise the role of the pharmacist/medical practitioner in recommending actual products, and direct consumers to their pharmacist or doctor for further information.

- The indirect advertisement will contain one cautionary statement from each of the following categories:

  Category 1

  "Consult your pharmacist and/or doctor"
  "Seek your pharmacist's and/or doctor's advice"
  "Ask your pharmacist and/or doctor for advice about suitable products for you"

  Category 2

  "Always read the label"
  "Read label instructions carefully"
  "Make sure you understand the labeled instructions"

Or words to the same effect.

Companies sponsoring indirect advertising are encouraged to provide pharmacists with educational material.

No forms of incentive programs for healthcare professionals or pharmacy assistants are to be initiated for Pharmacist Only Medicines (Schedule 3).

6. PROMOTION

6.1 GENERAL PRINCIPLES - ALL *NON-PRESCRIPTION CONSUMER HEALTHCARE PRODUCTS* ~~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 inquirer recommended to consult an appropriate healthcare professional.

6.1.4 Requests for information on ***non-prescription consumer healthcare products*** ~~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 ***non-prescription consumer healthcare product*** ~~Proprietary Medicine~~. Disinfectants (not including those with antiseptic claims), unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use* are exempted from this clause.

6.1.6 Encouragement or support of unsolicited sampling of a placebo of therapeutic goods for internal use, by other than a healthcare professional, is prohibited.

6.2 SCHEDULED SUBSTANCES AND INTERNAL ANALGESICS

Promotional techniques for Pharmacy Medicines (Schedule 2) or Pharmacist Only Medicines (Schedule 3) or internal analgesics should be such that they are not likely to persuade consumers to purchase a ***non-prescription consumer healthcare product*** ~~Proprietary Medicine~~ which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

Promotional techniques should not offer incentives to recommend S2 and S3 products unless based entirely on suitability of the product for which it is required by the consumer.

Techniques which may be considered inappropriate and contrary to the provisions of the Code **if they fail the above test**, 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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~, which may be likely to persuade consumers to purchase a ***product*** ~~proprietary medicine~~ which may not be

needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

- Distribution of samples to the public or issue of any coupon or voucher in connection with the distribution of samples, which may be likely to persuade consumers to purchase a ***non-prescription consumer healthcare product*** ~~proprietary medicine~~ which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

- Encouragement or support of advertising of recommended "cut price" deals to the general public which may be likely to persuade consumers to purchase a ***non-prescription consumer healthcare product*** ~~Proprietary Medicine~~ in a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

Examples of ticketing which may constitute a breach of this Clause include:

"special"
temporary "value"
"discount"
"get it while it lasts"
or similar forms of ticketing.

This does not, however, preclude "every day low price" policies. Lowering of prices to meet competitive challenge may be implemented, but it must not be communicated to the general public via ticketing or similar promotional techniques.

- Encouragement or support of cooperative retail press advertisements where recommended prices are featured in a manner which may be likely to persuade consumers to purchase a ***non-prescription consumer healthcare product*** ~~Proprietary Medicine~~ in a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

Examples of ticketing which may constitute a breach of this Clause are detailed above.

- Encouragement or support of promotional displays in off-site locations within reach of the public which may be likely to persuade consumers to purchase a ***non-prescription consumer healthcare product*** ~~Proprietary Medicine~~ in a larger quantity than is sufficient to meet the reasonable needs of the purchaser, e.g. dump bins, gondola ends (shared or full), dispensers, impulse bars at check out or other known impulse areas. Free standing off location displays should only be placed in the appropriate category aisles, and should display stock as it is on shelf, that is neatly stacked not jumbled. Shelf extensions such as dispenser units may only be displayed in the appropriate category aisles.

6.2.1 Pharmacist Only Medicine (Schedule 3) branded advertising

Promotion of Pharmacist Only Medicines (Schedule 3 substances) listed in Appendix H of the SUSDP by way of empty packs does not constitute a breach of the requirements. Promotional material for Pharmacist Only Medicines (Schedule 3) not permitted to be brand advertised to the general public must not be visible to the general public and must be exclusively directed to healthcare professionals.

6.3 CHILDREN

No Member shall promote any ***non-prescription consumer healthcare product*** ~~Proprietary Medicine~~, other than the therapeutic goods listed in Appendix 5 of the Therapeutic Goods Advertising Code, to children.

For therapeutic goods not listed in Appendix 5, 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 ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ where they are readily accessible to children.
- Direction of advertising of ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ to children, except for those listed in Appendix 5 of the TGAC.
- Advertising of ***non-prescription consumer healthcare products*** ~~Proprietary Medicines~~ in a manner which is likely to lead to its use by children without parental supervision.

7. CONSUMER MEDICINES INFORMATION

7.1 Background

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

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

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

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

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.

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 Complains 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 COMPLAINTS BY MEMBERS ABOUT MEMBERS (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.

~~**9.2.1** The following procedure shall apply in the event of the Association receiving a complaint concerning the advertising and/or promotion of Proprietary Medicines by a Member.~~

~~**9.2.2** The Executive Director shall ensure that written notification is given to the Association of all complaints against a Member.~~

~~**9.2.3** The Executive Director shall, on receipt of written notification of the complaint, consider whether the Therapeutic Goods Advertising Code may have been breached. Where this likelihood exists, the Executive Director shall determine whether the complainant has independently approached the Complaints Resolution Panel. If not, the Executive Director will ensure that the relevant authority is made aware of the complaint. However, the Association will retain the right to consider the complaint in relation to the ASMI Code and to apply sanctions, where appropriate.~~

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

~~**9.2.5** The Executive Director shall ensure that the details of the complaint are notified to:~~

- the Chief Executive of the Member which is the subject of the complaint; and
- the Executive Subcommittee.

9.2.6 The Member that is the subject of the complaint shall be given full details of the nature of the complaint. The Member will provide references/information as deemed by the Executive Director to be necessary. The Member shall also be invited to state within 10 working days whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be considered necessary. To ensure procedural fairness and to provide to the Complaints Panel the benefit of comprehensive submissions so that it may complete its deliberations, if possible, in one sitting, ASMI affords the parties opportunities to respond to each other's submissions.

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

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

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

9.2.9 The Complaints Panel shall consider all information provided before making any decision.

9.2.10 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.

9.2.11 Upon completion of the Complaints Panel's investigations, the Executive Director will notify the parties to the complaint and the ASMI Executive Subcommittee, of the Complaints Panel's findings and determinations.

If the Complaints Panel identifies a breach of the Code not raised by the complainant, the Complaints Panel may request the Executive Director to draw the matter to the attention of the party in breach. The Executive Director shall not comment or engage in correspondence in relation to the substance of the decision or reasoning of the Complaints Panel.

9.2.12 Should the Complaints Panel consider that no breach of the Code has occurred, it shall so advise the Executive Director. The Complaints Panel shall provide to the Executive Director in writing, reasons for its opinion.

9.2.13 If the Complaints Panel, after considering all information provided, forms the opinion that a breach of the Code has occurred, it shall determine appropriate sanctions as provided for under Section 10 of this Code and so inform the Executive Director.

9.2.14 In the case where a breach of the Code has occurred, the Complaints Panel will advise the Executive Director of its findings and determination. The Executive Director shall notify the parties to the complaint within seven working days.

9.2.15 The parties to the complaint shall be advised of the appeal procedures contained in Section 11 of this Code.

9.3 GUIDELINES FOR COMPLAINTS

These guidelines are intended to assist both complainants and Members against which complaints are made to ensure that a fair and full review is conducted. Copies of previous determinations may be made available for this purpose under clause 9.3.4. 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.

A complainant is not precluded from resorting to litigation but the Complaints Panel must not consider a complaint while its subject matter is the subject of pending court proceedings.

A party to a complaint must notify the Executive Director immediately upon becoming aware of any court proceedings concerning the subject matter of the complaint.

9.3.1 Externally generated complaints

Complainants are encouraged to contact the Member concerned prior to lodging a complaint as a satisfactory solution may be immediately available.

Where a complaint is generated from sources external to the industry, the complainant can simply report what is perceived as a problem provided the complainant states the nature of the practice being complained about, and a simple explanation of the reason(s) for the objection. Where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review.

9.3.2 Industry generated complaints

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

When lodging a complaint, the complainant will be required to pay an administrative lodgement fee in an amount as determined from time to time by the Executive Subcommittee to be kept by the ASMI to cover the administrative costs of the ASMI. If the complaint is upheld, the subject company will be required to pay to the complainant an amount equivalent to the value of the lodgement fee. 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.

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

i) A summary page containing:

(a) subject proprietary medicine;
(b) brief description of complaint itemizing 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.
(e) 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.

ii) Complainants should note that when challenging a claim on medical/scientific grounds, it is not sufficient simply to state that the claim is not supported. Evidence should be provided to support the complainant's case.

iii) Complainants must specify the category of the alleged breach (with reference to clause 10.1.1) and the level of sanction/fine (with reference to clause 10.2) which they consider to be appropriate for the alleged breach and give reasons to support their argument.

iv) 10 copies of all material must be lodged with ASMI and one copy delivered at the same time to the other party.

If these criteria are not met, the ASMI may return the complaint to the complainant for further information.

9.3.3 Response by Member

When a complaint has been accepted for evaluation, the Member that is the subject of the complaint (subject company) will be requested to state within 10 working days whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

When providing this information, the Member should include:
i) details of attempts to resolve the matter with the complainant;
ii) a brief summary of the response to each alleged breach;
iii) substantiation of the specific claims at issue with full supporting data; and
iv) submissions on the issue of classification under clause 10.2.3.

9.3.4 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.

9.4 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.