The Proprietary Medicines Association of Australia Inc

CODE OF PRACTICE

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REVISED	

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PREFACE

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

This authorisation applies to:

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

The Commission further required that:

- the public and healthcare professionals be advised of the existence of the Code and the complaint process;
- the Executive Director circulate to the Complaints Panel and to the Marketing & Ethics Subcommittee monthly summaries of all complaints received and their disposition.

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

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

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

NOTE: This preface 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, or in the spoken word, or in any other way.

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

- **"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 Proprietary Medicines Association of Australia Incorporated.

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

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

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

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

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

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

- **"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 proprietary medicines.

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

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

- **"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.

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

  - preventing, diagnosing or alleviating a disease, ailment, defect or injury in man;
  - influencing, inhibiting or modifying a physiological process in man;
  - testing for a physiologic condition or the susceptibility of man to a disease or ailment; or
  - destroying or inhibiting micro-organisms that may be harmful to man.

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

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

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

2. INTRODUCTION

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

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

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

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

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

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

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

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

3. OBJECTIVES OF THE CODE

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

Specifically, the Code seeks to assist Members to:

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

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.

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

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

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

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

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

5. ADVERTISING

5.1 GENERAL PRINCIPLES— ALL PROPRIETARY MEDICINES

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

5.1.2 Scope
Nothing in this Section of the Code of Practice shall be construed as replacing, diminishing or precluding requirements of The Therapeutic Goods Advertising Code in relation to consumer advertisements* of Proprietary Medicines. This section of the Code of Practice applies to all advertisements* for Proprietary Medicines, including comparative advertisements and advertisements for Schedule 3 items.

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

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.

5.1.5 No Member shall advertise an offer to return money to dissatisfied users of proprietary medicines.

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

5.2 COMPARATIVE ADVERTISING

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

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

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

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

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

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

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

5.3 ADVERTISING TO CONSUMERS

5.3.1 Compliance with advertising regulations

Members shall submit copy for advertising to consumers to the appropriate bodies (eg. PMAA 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 PMAA Code of Practice

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

5.4 ADVERTISING TO HEALTHCARE PROFESSIONALS

The intent of this Clause is to ensure that all promotion and advertising of proprietary medicines directed to healthcare professionals, encourages rational use of medicines, does not mislead and contributes to PMAA's overall aim of promoting responsible self medication.

Advertising material directed to healthcare professionals does not require prior approval by PMAA'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 PMAA's Complaints Handling Process outlined in Clause 9.

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 PMAA Code, as well as this Clause, 5.4.

Requirements for Advertising to Healthcare Professionals

Advertising for unscheduled, 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 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 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.

5.4.1 Advertising of Pharmacist Only Medicines (Schedule 3)

Background

With the introduction of the Therapeutic Goods Regulations adopted on 15/2/91, 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 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.

Requirements for Advertisements 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 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 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.

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

5.5 ADVERTISING OF PHARMACIST ONLY MEDICINES (SCHEDULE 3) TO CONSUMERS

5.5.1 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.

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

6.1.5 No Member will promote to the general public any prize competition which is conditional on the purchase of a Proprietary Medicine. 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 Proprietary Medicine which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

Techniques which may be considered inappropriate and contrary to the provisions of the Code 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 Proprietary Medicines, which may be likely to persuade consumers to purchase a proprietary medicine which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

- 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

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 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 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 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 Proprietary Medicine to children.

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

- Encouragement or support of the positioning of Proprietary Medicines where they are readily accessible to children.

- Direction of advertising of Proprietary Medicines to children.

- advertising of Proprietary Medicines in a manner which is likely to lead to its use by children without parental supervision.

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

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

7.3 Techniques considered inappropriate in provision of 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.

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

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.

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

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 (in the case of print advertisements in mainstream media) or The Minister for Communications, Information Technology and the Arts (in the case of advertisements in mainstream broadcast media). 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 PMAA 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, PMAA affords the parties opportunities to respond to each other's submissions.

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

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

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

9.2.9 The Complaints Panel shall consider all information provided before making any decision. Where the Complaints Panel is hearing a complaint about 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.

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

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

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

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

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

9.3 GUIDELINES FOR COMPLAINTS

These guidelines are intended to assist both complainants and Members against which complaints are made to ensure that a fair and full review is conducted. 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 PMAA, 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 PMAA to cover the administrative costs of the PMAA. 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 PMAA 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.

iii) 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.

iv) 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.

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

If these criteria are not met, the PMAA 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.

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.

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 Compliants 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 he 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 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 PMAA setting out the grounds for objection. When lodging an appeal, the appellant 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 PMAA to cover the administrative costs of the PMAA. Appellants other than industry appellants are not required to pay a lodgement fee. If the appeal is upheld, the subject company will be required to pay to the complainant an amount equivalent to the value of the lodgement fee. The Executive Members of the Committee of Management will be advised of the appeal lodgement within 7 working days.

11.2.2 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.

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

11.2.4 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.

11.2.5 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.

11.2.6 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.

11.2.7 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.

11.2.8 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).

11.2.9 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.

11.2.10 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.

PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA

PROPOSED AMENDMENTS TO THE PMAA CODE OF PRACTICE
Adopted at the August 1999 AGM
For consideration by ACCC

RATIONALE DOCUMENT

Preface

- The third bullet point under the requirements of the TPC is no longer relevant as the issue of penalties had been addressed.

Section 1 Definitions

- **Insert definition of CMI**

  At the Annual Code Review in December 1998 it was agreed that the Marketing and Ethics Subcommittee consider inserting a definition for Consumer Medicines Information into Section1 of the Code. The purpose is to clarify the distinction between this form of communication and advertising/promotional tools.

- **Delete the definitions of Professional Advertisements, including Full Disclosure, Abridged Disclosure and Short Advertisements from Section 1**

  Full Disclosure Advertisement had never been a requirement for Pharmacist Only Medicines (Schedule 3).

  Recent amendments to the APMA Code of Practice resulted in inconsistencies between the PMAA and the APMA Codes in relation to the requirements for advertisements directed to healthcare professionals.

  The Marketing and Ethics Subcommittee was requested to formulate proposals for amendments to the PMAA Code to address these inconsistencies. The proposals are reflected under the heading ***"Requirements for Advertisements of Pharmacist Only Medicines to Healthcare Professionals"*** . The insertion of the appropriate definitions in this section obviates the need for the definitions in Section 1.

Section 4 Principles of Practice

- **Clause 4.3**

  The references to the Media Council of Australia and the Advertising Code of Ethics are no longer relevant. The proposal is to clarify this clause by rephrasing it and introducing subheadings.

Section 5 Advertising

- **Clause 5.1.2 Scope**

  Delete inappropriate references.

- **Clause 5.1.3 Claims**

  Amend the reference to the Commonwealth Dept. of Health and Aged Care to reflect the current name.

- **Clause 5.3 Advertising in non-broadcast media and Clause 5.4 Advertising in Consumer Print, Outdoor and Cinema Media**

  The proposal is to delete both clauses and rephrase the content under two subheadings, ***5.3.1*** and ***5.3.2*** under the heading ***5.3 Advertising to Consumers***. The amendment will reflect the regulatory changes in relation to the delegations (under the Therapeutic Goods Regulations and the Broadcasting Services Act) for the approval of advertisements in mainstream media. It will also further clarify the requirements for PMAA Members to ensure compliance of advertising with the PMAA Code of Practice.

- **Clause 5.5 Advertising to Healthcare Professionals**

  Proposals for some minor amendments to this clause will reflect current terminology, (e.g. ***approval*** in stead of ***preclearance and Pharmacy Medicine*** for Schedule 2's. The requirements of this clause are extended to include ***Pharmacist Only Medicine*** (Schedule 3). A revised heading is introduced to make referencing easier.

- **5.5.1 Advertising of Schedule Three Items**

  Proposed amendments to this clause reflect the regulatory changes in relation to the prohibition on branded advertising of Schedule 3 substances. Requirements for the branded advertising of those Schedule 3 substances published in Appendix H of the SUSDP are introduced.

  Revision of the section on **Requirements for Professional Advertisements** are proposed to ensure that compliance with the revised requirements of the PMAA Code will avoid any inconsistencies with the APMA Code.

- **Clause 5.6 Indirect Advertising of Schedule 3 Products to Consumers**

  This clause is updated and reformatted to clarify the distinctions between Schedule 3 branded advertising and indirect advertising of Schedule 3 products to consumers.

  To reflect the purpose of this particular requirement an amendment is proposed to extend the prohibition on incentive programs for pharmacists or pharmacy

assistants to the entire category of healthcare professionals as defined in the Therapeutic Goods Regulations.

Section 6 Promotion

- **Clause 6.1.3**

  The amendment to this clause will ensure consistency with the Therapeutic Goods Regulations and also reflect current terminology.

- **Clause 6.1.5**

  The Marketing and Ethics Subcommittee considered a request by a Member to extend the exemptions in relation to the prohibition on prize competitions, to apply to those disinfectants not making antiseptic claims. The Committee considered an amendment to this effect appropriate for the product category.

- **Clause 6.2 Scheduled Substances and Internal Analgesics**

  A new clause 6.2.1 is proposed to accommodate the changes in relation to Schedule 3 substances in Appendix H of the SUSDP. This clause will make provision for the promotion of these S3's to consumers by way of empty packs. It also reiterates the requirements in relation to the display to the general public and promotion to healthcare professionals applicable to all other S3's.

Section 7 Consumer Product Information

The proposed amendments will reflect the current terminology - ***CMI*** in stead of CPI and the ***Chemicals and Non-Prescription Medicines Branch*** of the TGA in stead the Compliance Branch.

Section 8 Administration of the Code

- **Clause 8.2**

  The issue of confidentiality of documents submitted to the Complaints Panel is an important issue. The Complaints Panel should be able to consider materials in confidence but to publish its final determination. The amendments to this clause have been made to clarify that determinations of the Complaints Panel will be published in certain circumstances.

- **Clauses 8.6 and 9.3.4**

  A new clause has been inserted to indicate that PMAA may make available to members the determinations of the Complaints Panel. An amendment has also been made to clause 9.3 to reflect this. It is proposed that the PMAA will develop a database of decisions which can be accessed by members and people involved in complaints.

Section 9 Complaint Procedure

- **Clause 9.2.3**

  Sometimes situations have arisen where the same advertisement is being held in two different forums such as by the APMA and PMAA Complaint Panels. It was recognised that in some instances a similar complaint may result in an inconsistent decision by two different bodies. However, this could arise because of the fact that the two different bodies are looking at different aspects of the complaint and considering it from a slightly different perspective. Despite the disadvantages with this scenario it was recognised that all complaints should be dealt with except those that were being considered by a court. For this reason, some of the provisions have been deleted from clause 9.2.3.

- **Clauses 9.2.3 and 9.3**

  Changes were made to these clauses to require parties to a complaint to notify the PMAA rather than the PMAA to have to make inquiries to check that a complaint was not the subject of court proceedings.

  Consideration was given to the possible overlap of decisions of the APMA and PMAA but it was decided that the only complaints which the PMAA should not hear are those which are pending before a court. It is possible that a decision of the APMA and PMAA could be inconsistent but there may be a legitimate reason for this arising for example, from the fact that the advertisement was addressed to different audiences.

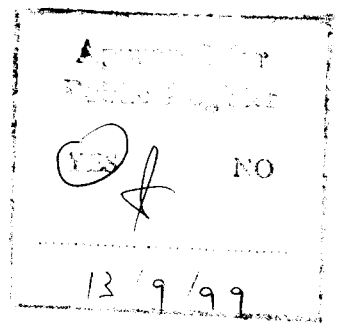
- **Clauses 9.3.2 and 11.2.1**

  The changes made to this clause have been made to clarify that the fee for the hearing of a complaint is an administrative fee which is designed to cover the administrative costs of the PMAA. This fee is in addition to any fines that may be payable if a breach of the Code is found by the Complaints Panel. Similar changes have been made to the fee for lodging an appeal in clause 11.2.1.

Section 10 Sanctions

This section has been reordered and amended to make it clearer how it applies and in particular, to clarify that the Complaints Panel can impose one or more of the sanctions including a fine.

The Complaints Panel does not have to apply sanctions in all cases. In most cases, if a breach of the Code is established, a sanction would be imposed but there may be circumstances where it is not appropriate. For example, if a company put out an advertisement which contained a misprint and the company did everything it could to retract the advertisement by withdrawing it and advertising that the advertisement had contained an error, there may be no need for a sanction to be imposed.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