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3 October 1996

Mr J P O'Neill
Senior Assistant Commissioner Adjudication
Australian Competition & Consumer Commission
PO Box 19
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Dear John

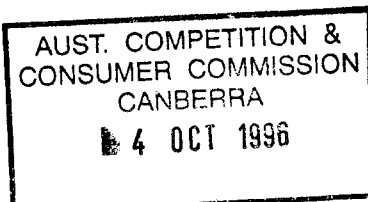
PMAA Code of Practice - Authorisation A90549 (1994) ATPR (Com) 50-141

On 27 September 1996 the Media Council of Australia announced its decision to disband the current system of Advertising Codes and structures with effect from 31 December 1996. One of those codes is the Therapeutic Goods Advertising Code ("TGAC"), which the PMAA Code of Practice requires its members to observe (4.3).

PMAA considers that it is essential that a co-regulatory approach to the advertising of therapeutic goods continue and, to that end, proposes to incorporate directly into its Code of Practice the provisions of the TGAC, so far as relevant having regard to the decision of the MCA to cease its administration of that code. This will ensure that PMAA is able, through consultation with interested parties, to amend the TGAC from time to time, something it cannot do at present.

PMAA has hitherto referred complaints of breach of the TGAC to the Advertising Standards Council, while retaining the right to adjudicate itself where a PMAA member is involved. One consequence of the MCAs decision will be the disbandment of the ASC, so the PMAA Code will be amended to reflect this.

As delegate for the Secretary of the Department of Health and Family Services under the Broadcasting Services Act, PMAA approves all radio and television advertisements to the public for medicines, whether proposed for members or non-members. The direct incorporation of the TGAC into the PMAA code will enable PMAA to continue to carry out this important function. PMAA sees this as paving the way for it to assume responsibility for the protection of consumers in relation to non-broadcast forms of therapeutic goods advertising by non-members, as it already does in relation to members.



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SYDNEY MELBOURNE BRISBANE CANBERRA GOLD COAST LONDON HONG KONG BEIJING
ASSOCIATED OFFICES ADELAIDE PERTH AUCKLAND WELLINGTON JAKARTA SINGAPORE

PMAA proposes that its complaints panel replace the MCA mechanism for handling complaints under the TGAC, whether involving members or not. It is accordingly proposed in due course to expand and modify the complaints panel, so as to ensure that non-members of PMAA have no reason to believe that TGAC issues before the panel will be dealt with by processes merely internal to PMAA. In particular, persons with knowledge of and experience relating to alternative or nutritional medicine will be included. No language for this aspect of the proposal has yet been developed and this will be provided in due course.

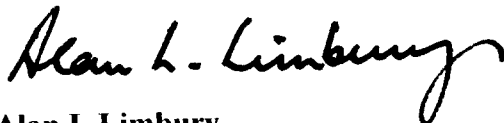
For the present PMAA seeks approval of the amendments submitted herewith, on the footing that these initial amendments are a first step towards the achievement of PMAA's intentions, namely :-

- * total industry coverage under a single advertising code for therapeutic goods;
- * appeals and complaints mechanisms which are open, transparent and at arms length from the codes administrators; and
- * uniformity in advertising approval processes and standards across print and broadcast media.

Accordingly I enclose a copy of the proposed revised code (showing all changes in bold italics). This is based on the document supplied to you under cover of my letter of 18 September and it proceeds on the assumption that the amendments which are the subject of that letter are accepted and implemented.

PMAA now seeks the Commission's approval of the further changes embodied in the enclosed document in terms of paragraph 7.2 of the current authorisation determination, namely that they are not significant (in competition terms) and that they will not materially alter the circumstances of the authorisation which came into force on 18 February 1994.

Yours sincerely



Alan L Limbury,
Special Counsel - Trade Practices

The Proprietary Medicines Association of Australia Inc

**CODE OF
PRACTICE**

Adopted:	8 October 1991
Revised:	28 May 1992 15 October 1992
Authorised by TPC:	27 January 1994
Revised to meet conditions of authorisation:	12 May 1994
Revised:	April 1995
Revised:	September 1996

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4. THERAPEUTIC GOODS ADVERTISING CODE

PREFACE

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

This authorisation applies to:

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

The Commission further required that:

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

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

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

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

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

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, leaflets, booklets, letter (whether circular or addressed to a particular person) or other document, or by means of any packaging materials (including all labels, cartons, direction folders, and other packaging components bearing printed matter), or by words inscribed on any article, or by exhibition of a photograph or film, or by way of sound recording, radio or television, or in the spoken word, or in any other way.
- **"Consumer Advertisement"** *means an advertisement in consumer media as defined and covered by the Therapeutic Goods Advertising Code.*
- **"Professional Advertisements"** means one of the three categories of advertisements defined below and directed at healthcare professionals:
 - Full Disclosure Advertisements** - the effect of which is to communicate the full text of product information as required by any applicable conditions of registration;
 - Abridged Disclosure Advertisements** - the effect of which is to remind the reader of the name of the Proprietary Medicine, its indication(s) for use, including safety related statements, and some elementary commercial information;
 - Short Advertisements** - the effect of which is to communicate commercial information only, such as details of packaging, pricing, trading terms or marketing incentives.
- **"The Association"** means the Proprietary Medicines Association of Australia Incorporated.
- **"Code"** means the PMAA Code of Practice, *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 PMAA Code of Practice Complaints Panel.
- **"Discredit"** means injure the reputation of or destroy confidence in the product/industry.
- **"Executive Subcommittee"** means the committee appointed by the Committee of Management* and comprising, but not limited to, the Association's President, two Vice Presidents and Immediate Past President.
- **"External Use"** in relation to any medicine or related product means for application to the anal canal, ear, eye, mucosa of the mouth, nose, skin, teeth, throat or vagina, where local action only is required and where extensive systemic absorption will not occur, but this shall not apply to nasal drops, nasal inhalations, nasal sprays, teething applications, throat lozenges, throat pastilles, throat sprays or throat tablets.

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

- **"Healthcare professionals"** means persons designated under Regulation 4 (1), (2) and (2A) of the Therapeutic Goods Regulations (refer Appendix 1).
- The **"industry"** means the basic manufacture and/or formulation and/or importation and/or basic or applied research into and/or the registration and/or marketing of Proprietary Medicines.
- **"Marketing & Ethics Subcommittee"** means the committee appointed by the Committee of Management to, *inter alia*, monitor and review the PMAA Code of Practice.
- **"Member"** means any Ordinary or Associate member as defined by the PMAA Rules. For the purposes of this Code, "Member" also includes any consenting non-member company which has agreed to be bound by all or part of the provisions of the Code.
- **"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.
- ***"Therapeutic Goods Advertising Code" means the Code set out in Appendix 4.***
- **"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:
- *the Therapeutic Goods Advertising Code;*
 - the Code of Good Manufacturing Practice; and
 - such other Codes as are from time to time developed and/or endorsed by the Association.
- 4.4 A Member shall ensure that all relevant persons, including representatives, employed by the Member are aware of the requirements of this Code and the responsibilities inherent in membership of the Association.
- 4.5 Members will cooperate with the Association in the investigation of problems which may from time to time arise with respect to the safe use of Proprietary Medicines.
- 4.6 Members will cooperate to whatever extent they are reasonably able in programs conducted by the Association, either on its own or in collaboration with Government authorities, which are aimed to educate the user or the consumer in the safe and proper use of Proprietary Medicines.
- 4.7 Members will assist the Association and/or Government authorities to the full extent that they are able in consideration of any existing regulations or voluntary schemes, or any which may be proposed, having in mind both their responsibilities under this Code and the needs and legitimate interests of the industry.
- 4.8 Members will draw to the attention of the Association any information which may lead to improvement in standards of correct and safe use of Proprietary Medicines.

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.
- 5.1.4** Furthermore, information and claims must, when made, be capable of substantiation, such substantiation being provided without delay upon receipt of bona fide requests.
- 5.1.5** Information that may be considered false or misleading includes the following examples:
- literature references, or quotations or claims that are more favourable than has been demonstrated by the body of clinical evidence or experience;
 - information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions;
 - citing of data previously valid but made obsolete or false by subsequent findings;
 - suggestions or representations of uses, dosages, or indications not approved by the Commonwealth Department of Human Services and Health.
- 5.1.6** No Member shall advertise an offer to return money to dissatisfied users of Proprietary Medicines.
- 5.1.7** Members may, by virtue of belonging to other industry associations, be required also to conform to codes of practice of such other associations.

5.2 COMPARATIVE ADVERTISING

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

- Comparative advertisements should not be misleading, or likely to be misleading, either about the Proprietary Medicine advertised or that with which it is compared.
- Points of comparison should be based on facts which have been previously substantiated and reflect the body of scientific evidence or experience at the time the advertisement is published.

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

- It should be clear with what the advertised Proprietary Medicine is being compared and upon what basis.
- Claims of superior or superlative status should be expressed in terms which accurately reflect the extent and the nature of the evidence available to substantiate them.
- Advertisements should not describe or show the Proprietary Medicines of a competitor as broken or defaced, inoperative or ineffective. The only exception is where the description or depiction is based upon the outcome of fair comparative tests to which the advertiser's Proprietary Medicine also has been subjected and the results of such tests are stated.

5.3 ADVERTISING IN BROADCAST AND NON-BROADCAST ELECTRONIC MEDIA

All Members shall submit **all** electronic media advertising to PMAA for **approval to ensure compliance with the Therapeutic Goods Advertising Code as defined in Appendix 4**. In addition to broadcast electronic media **approval**, Members shall obtain **approval** of advertising through closed circuit video or audio networks in locations such as pharmacies, retail stores or doctors' surgeries.

5.4 ADVERTISING IN CONSUMER PRINT, OUTDOOR AND CINEMA MEDIA

All Members shall submit copy for consumer print/outdoor/cinema advertising to PMAA for preclearance to ensure compliance with the Therapeutic Goods Advertising Code.

5.5 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.

5.5 ADVERTISING TO HEALTHCARE PROFESSIONALS (CONTINUED)

Advertising material directed to healthcare professionals does not require prior approval by PMAA's *approval* service. ***Approval is only required for consumer advertising in consumer media as detailed in Clause 5.3 and 5.4. 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, 5.5.

Information in Advertising

Advertising for unscheduled and Schedule 2 OTC Medicines 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.

5.5.1 Advertising of Schedule Three Items

Background

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

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

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

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. Schedule 3 Proprietary Medicines must be stored in pharmacy in areas to which the public does not generally have access. Promotional or advertising material relating to Schedule 3 Proprietary Medicines must not be visible to the public.

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

Requirements for Professional Advertisements

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

Abridged Disclosure Advertisements

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

- the brand name of the Proprietary Medicine;
- the Australian Approved Name(s) of the active ingredient(s);
- approved indication(s) for use;
- clinically significant contra-indications, warnings/precautions, interactions and diverse effects;
- content of active ingredient(s) per dosage form or regimen;
- dosage forms, regimens and routes of administration;
- dependence potential of clinical significance;
- reference to special groups of patients (including Australian pregnancy categorisation if issued);
- the name of the supplier and the city, town or locality of the registered office;
- and
- a statement to the effect that full product information (if more extensive than the above) is available on request from the manufacturer.

Short Advertisements

A short advertisement for S3 Proprietary Medicines shall contain:-

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

Short advertisements shall not contain therapeutic claims.

5.6. INDIRECT ADVERTISING OF SCHEDULE 3 PRODUCTS TO CONSUMERS

Background

It is in consumers' interest to be better informed about the availability of some Schedule 3 treatments. Indirect advertising of these treatments 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 Schedule 3 products

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

- Inform consumers of the availability of Schedule 3 treatments.
- 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 Schedule 3 treatment for a particular condition or symptoms, 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 Schedule 3 treatment 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 Schedule 3 treatments. 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 Schedule 3 treatments 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 Schedule 3 Products

- 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 Schedule 3 products may detail the condition, conditions or class of condition where Schedule 3 treatments have become available or where new indications for Schedule 3 treatments are allowed.
- Claims must focus on building consumer awareness that certain treatments are available.
- Indirect advertisements for Schedule 3 products 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 labelled instructions"

Or words to the same effect.

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

No forms of incentive programs for pharmacists or pharmacy assistants are to be initiated for Schedule 3 products.

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 his or her own doctor.
- 6.1.4 Requests for information on Proprietary Medicines must be answered in a balanced way to avoid the risks of raising unfounded hopes or fears in the public mind as to the results of the use of such medicines.
- 6.1.5 No Member will promote to the general public any prize competition which is conditional on the purchase of a Proprietary Medicine. Unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use* are exempted from this clause.
- 6.1.6 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 Schedule 2 or Schedule 3 substances 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.

6.3 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 PRODUCT INFORMATION

7.1 Background

Since 1 July 1995 all new Schedule 3 products are required to develop Consumer Product Information (CPI).

Existing Schedule 3 products as at 1 July 1995 will be required to have CPI available by 1 January 2004. Companies will be encouraged to progressively develop CPI during the interim period.

7.2 CPI Content

Members shall ensure that all CPIs 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 CPI is:

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

CPI 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 Useability Guidelines and Glossary of Terms provide additional guidance.

7.3 Techniques considered inappropriate in provision of CPI

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

7.4 Complaint Handling—CPI

If on initial review of the complaint, the Executive Director believes that Schedule 13 has been breached, the complaint will be referred to the Compliance 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 Panel is to hear a complaint concerning a CPI, an ad hoc observer will be coopted onto the panel to provide expertise in the area in the area of writing CPI.

For details on the complaint procedure with regard to CPI, 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* (refer Appendix 3, Rule 5.1)
- 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.

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 representative from a broad-based representative consumer/community organisation and, as an observer, a representative from the Department of Human Services and Health*.

The Chair of the Complaints Panel shall be the lawyer with trade practices experience or his/her alternate, also a lawyer with trade practices experience.

The Marketing & Ethics Subcommittee may appoint an alternate to officiate in the absence of a member.

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

When the Complaint concerns CPI, the Panel will include an observer with expertise in the writing of CPI.

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.

* ***Composition to be revised***

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

(refer Appendix 2 for diagrammatic representation of Complaint Process)

- 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 make enquiries to ascertain whether the subject matter of the complaint is also the subject matter of pending litigation. Since it would be inappropriate for PMAA to pre-empt a court adjudication, the Executive Director shall advise the complainant that PMAA will not consider the complaint until the disposition of any such proceedings.***
- 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 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 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 CPI, the Panel may elect to refer an issue to the CPI Quality Assurance Reference Group for comments, prior to the 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 Panel identifies a breach of the Code not raised by the complainant, the 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. 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.

PMAA will not consider any complaint that is the subject of pending or ongoing litigation. PMAA will defer hearing the complaint, until the litigation has been completed or discontinued.

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 a lodgement fee of \$1000 to have the complaint heard. If the complaint is upheld, the subject company will be required to reimburse the complainant to the value of the lodgement fee, in addition to being subject to a fine (in accord with the schedule of fines outlined in Clause 10.1.1.4.) if the Complaints Panel determines it appropriate.

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.

- A summary page containing:
 - (a) subject Proprietary Medicine;
 - (b) brief description of complaint itemising the specific claims at issue with complete rationale for the alleged breach to be included as an attachment;
 - (c) section of the Code alleged to be breached;
 - (d) details of attempts to resolve matter with the Member concerned.
- Medically based complaints - supporting data cross referenced to specific claims at issue and rationale for challenge.
- Marketing based complaints - alleged consequences (damage to

complainant where appropriate) with supporting data if available.

In addition, complainants should note that:

- when challenging a claim on medical/scientific grounds, it is not sufficient simply to state that the claim is not supported. Evidence should be provided to support the complainant's case;
- if these criteria are not met, the Association may return the complaint to the complainant for further information.
- 10 copies of all material must be lodged with PMAA and one copy delivered at the same time to the other party.

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: details of attempts to resolve the matter with the complainant;

- a brief summary of the response to each alleged breach;
- substantiation of the specific claims at issue with full supporting data.

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.