MINTER ELLISON
LAWYERS

CONTACT Alan L Limbury (02) 9210 4809

OUR REFERENCE sall 10097131
YOUR REFERENCE CA 93/4 JK:HL

MINTER ELLISON BUILDING
44 MARTIN PLACE SYDNEY NSW

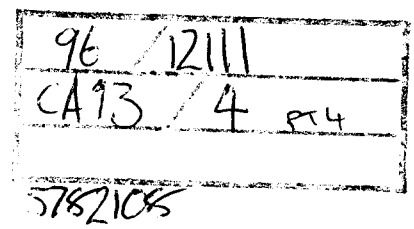
TELEPHONE (02) 9210 4444
INTERNATIONAL +61 2 9210 4444
FACSIMILE (02) 9235 2711

POSTAL ADDRESS
GPO BOX 521
SYDNEY NSW 2001
AUSTRALIA

DX 117 SYDNEY

18 September 1996

Mr J P O'Neill
Senior Assistant Commissioner Adjudication
Australian Competition & Consumer Commission
PO Box 19
BELCONNEN ACT 2616



Dear John

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

Following the 1996 annual review of its Code of Practice by the Marketing and Ethics Subcommittee and its Committee of Management, the Proprietary Medicines Association of Australia Inc ("PMAA"), at its annual general meeting held in Canberra on 11 September 1996, adopted proposed amendments to the Code, subject to the Commission considering 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.

Accordingly I enclose a copy of the proposed revised code (showing all changes in bold italics); background notes made available to members at the meeting by way of explanation of the changes, and a copy of the Annual Report of PMAA, which contains an account of the administration of the Code and of the handling of complaints.

The only proposed deletion from the Code is Clause 6.1.6, which reads:

> " Competition prizes and other goods or services provided in connection with the promotion of Proprietary Medicines should not be of a nature or economic value which might bring *discredit* upon the industry or the recipient."

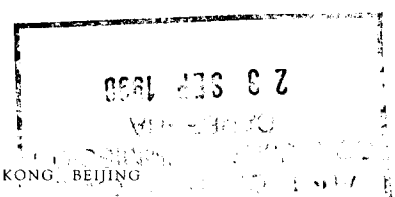
You will note in particular the proposed introduction of pecuniary penalties (a topic mentioned in the TPC's reasons for its determination) and of fees payable (by industry members only) towards the costs of administering the Code.

PMAA now seeks the Commission's approval of these changes in terms of paragraph 7.2 of the determination.

Yours sincerely

Alan L. Limbury

Alan L Limbury, Special Counsel - Trade Practices



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PMAA ANNUAL GENERAL MEETING SEPTEMBER 11, 1996

PMAA CODE OF PRACTICE AMENDMENTS

NOTE: All changes to the Code are in bold italics. Explanatory notes providing the rationale for the changes are detailed below.

BACKGROUND NOTES

Clause 1- Definitions

Introduction of a definition of "off-site", as referred to in Clause 6.2

Clause 5.5 -Advertising to Healthcare Professionals - Information in Advertising

At the annual Code review, the TGA expressed concern regarding the inconsistency between PMAA's Code of Practice, re minimum requirements for advertising directed to healthcare professionals, and other self-regulatory codes.

The revision now requires all advertising for unscheduled and schedule 2 medicines to comply with minimum information requirements, which include the product name, indication for use and AAN of the active ingredient. Multi-ingredient products are required to provide as a minimum, a reference to the principal active ingredient.

Trade advertising which contains only purchasing information and no product claims or benefits is exempted from this requirement.

Clause 5.6 - Indirect Advertising of Schedule 3 Products to Consumers

In late 1995, PMAA and the PSA (Pharmaceutical Society of Australia) developed a joint guideline document for indirect advertising for Schedule 3

products to consumers. These guidelines were approved by APAC (Australian Pharmaceutical Advisory Committee) and PMAA was required to implement these guidelines into the PMAA Code of Practice.

PMAA proposes the creation of a new Clause in the Code - Clause 5.6.

When Government makes a determination regarding the recommendations of the IC inquiry for direct advertising of schedule 3 products, this Clause may need to be changed to reflect the outcomes.

Clause 6.1 - Promotion - General Principles - All Proprietary Medicines

Clause 6.1.6 has been deleted.

Clause 6.2- Promotion- Scheduled Substances and Internal Analgesics

Clause 6.2 of the PMAA Code of Practice has undergone major revision, to provide greater clarity of interpretation to the membership of the intent of the Clause. The cited examples of inappropriate promotional techniques, have been clarified and a reference to the basic test of Clause 6.2, is cited in each example. The pre-existing analgesic guideline document "Guideline for the promotion of analgesics in non-pharmacy outlets" has been abandoned, as they were outside the provisions of the Code and were therefore unable to be adjudicated upon by the Complaints Panel. Aspects of the guideline document have been adopted into the revised Clause 6.2 to illustrate potentially unacceptable promotional techniques, particularly with regard to ticketing.

Clause 8 - Administration of the Code

Clause 8.4 has been revised to expand the available pool of senior executives available to sit on the Complaints Panel. This had been previously limited to members of the Committee of Management.

Clause 9- Complaint Procedure

PMAA is proposing to fundamentally change the manner in which it hears complaints. The proposed revision to the Code has all complaints that are referred to PMAA being heard by the Complaints Panel. This is a change from the current process, where the Executive Director refers complaints to the Complaints Panel that are unable to be resolved satisfactorily by the Executive Director. (9.2.6. to 9.2.14) The revision also defines that PMAA will

not accept intercompany complaints unless the two parties show that they have attempted to resolve the matter between themselves.(9.3.2)

The revisions also include provision of timeframes for responses to complaints, as well as clearly setting out the complaint handling process. (9.2.6. 9.3.3)

The proposed changes clarify the limitations imposed on PMAA and the Complaints Panel in hearing complaints that are related to matters that are subject to legal action. (Clause 9.2.3 & 9.3)

When the TPC authorised the PMAA Code in 1994, the TPC recommended that PMAA consider the application of pecuniary fines at its next Code review. PMAA's Committee of Management has considered this issue and now recommends the adoption of pecuniary fines as well as lodgement fees, appeal fees and potential fines for vexatious abuse of the Code. The pecuniary fines have application on complaints lodged from all sources, however the lodgement and appeal fees are only applicable for industry generated complaints.(9.3.2.10.1.1.3-10.1.1.6, 10.1.3, 11.2.1)

Clause 10- Sanctions

The details of the proposed pecuniary fines are outlined in the new Clauses 10.1.1.3. 10.1.1.4. as well as the proposed new Clause 10.1.3 concerning vexatious abuse of the Code.

Clause 11 Right of Appeal

Clause 11.2.1 now requires that if an Industry party wish to lodge an appeal against a determination of the Complaints Panel a lodgement fee is required.

Appendix 2

Revision to reflect the changes to the Complaints process.

PMAA CODE OF PRACTICE REVISED AMENDMENTS

Clause 5.5 Advertising To Healthcare Professionals

The proposed amendment to Clause 5.5 that was sent to Members as part of the AGM papers has been resisted by the TGA.

A further revision has been endorsed by PMAA Committee of Management to reflect further discussions with the TGA regarding the disclosure of active ingredients in advertising directed to healthcare professionals.

Committee of Management recommends to the PMAA Membership that the attached printed words be substituted for those words in the Clause 5.5. amendment already provided.

Members are advised that the rationale for any revision to Clause 5.5, allowing minimum disclosure of active ingredients within advertising, was to help address the logistical problems experienced by advertisers of multi-ingredient products such as multi-vitamins. The Clause was not intended to encourage advertisers of orthodox medicines with only two or three ingredients to meet only the minimum requirement by listing the first label ingredient.

However, the TGA had concerns that if advertisers elected to exercise the minimum requirements, the information provided could be misleading.

Committee of Management has now recommended a final proposal to address these concerns of TGA by bringing the requirements of Clause 5.5 in line with TGO48, which determines the requirements for active ingredient disclosure on the front label.

Accordingly, the proposed revision to Clause 5.5 for Membership approval is as follows (with changes in **bold**):

Information in Advertising

Advertising for unscheduled and Schedule 2 OTC Medicines where 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 conveys 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 a brand name reminder is such that it is demonstrably and obviously impractical to display legibly the information required, the advertisment must be accompanied by a document that contains the required information.

Clause 6.1 Promotion - General Principles

At a recent meeting of the Complaints Panel, the Panel sought consideration of a Code review from the PMAA Marketing & Ethics Subcommittee. The subject of a complaint was a novel promotion that was not subject to any application of the Code.

The promotion concerned unsolicited distribution to households by letterbox of a placebo sample of a replica of an internally ingested therapeutic good.

Marketing & Ethics agreed with the view of the Panel that unsolicited sampling of a placebo medicine sends a confusing message to children and consumers at large about the difference between medicines and confectionary.

Committee of Management has endorsed the recommendation of the Marketing & Ethics Subcommittee for an additional Clause be added to Clause 6.1:

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

Committee of Management seeks the approval of the Membership for this proposal.

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:	**August 1996**

LEVEL 4, 140 ARTHUR ST, NORTH SYDNEY, NSW 2060
POSTAL ADDRESS: PRIVATE BAG 938, NORTH SYDNEY 2059
TELEPHONE: (02) 9922 5111 FAX: (02) 9959 3693

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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 of the Media Council of Australia.

- **"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.

- **"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.

- **"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 relevant Advertising Codes of the Media Council of Australia, including the Advertising Code of Ethics and 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 relevant Advertising Codes of the Media Council of Australia (including the Advertising Code of Ethics and 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.

5.2 Comparative Advertising (Contd)

- 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 NON-BROADCAST ELECTRONIC MEDIA

All Members shall submit electronic media advertising to PMAA for preclearance. In addition to broadcast electronic media preclearance, Members shall obtain preclearance 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. On receiving PMAA approval, companies shall submit advertising copy to the Australian Publishers' Bureau, Outdoor Advertising Association of Australia or Australian Cinema Advertising Council, as appropriate, for final clearance and provision of clearance number.

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.

Advertising material directed to healthcare professionals does not require prior approval by PMAA's preclearance service. Preclearance is only required for consumer advertising in broadcast media, and other 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.

Advertising to Healthcare Professionals (Cont'd)

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.

♦ 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 adverse 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].

Indirect Advertising of Schedule 3 Products to Consumers (Cont'd)

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"

Indirect Advertising of Schedule 3 Products to Consumers (Cont'd)

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, eg, 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.