MINTER ELLISON MORRIS FLETCHER

SOLICITORS, ATTORNEYS & NOTARIES

MINTER ELLISON BUILDING
44 MARTIN PLACE
SYDNEY NSW

Telephone (02) 210 4444

Facsimile (02) 235 2711
Telex AA24676

DX 117 SYDNEY

Postal address
GPO Box 521
SYDNEY NSW 2001
AUSTRALIA

OUR REFERENCE
MYC:ALL:10097131

YOUR REFERENCE

DIRECT LINE
(02) 210 4809

29 January 1993

93/522

Trade Practices Commission
Benjamin Offices
Chan Street
BELCONNEN ACT 2617

BY COURIER 5711750

Dear Sir

Attention: Mr J P O'Neill
Mergers & Adjudication Branch

The Proprietary Medicines Association of Australia Inc. ('PMAA')
Application for Authorisation

We enclose an application for authorisation in respect of the PMAA's Code of Practice.

Yours faithfully
MINTER ELLISON MORRIS FLETCHER

Alan L. Limbury

enclosure

TRADE PRACTICES COMMISSION
CANBERRA
1 - FEB 1993

MYC301804

COMMONWEALTH OF AUSTRALIA

A 90549

Trade Practices Act 1974—*Subsection* 88 (1)

57

Agreements Affecting Competition: Application For Authorization Form B

TO THE TRADE PRACTICES COMMISSION:

Application is hereby made under subsection 88 (1) of the Trade Practices Act 1974 for an authorization under that subsection—

* to make a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of that Act,

* to give effect to a provision of a contract, arrangement or understanding which provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45 of that Act.

* Strike out whichever is not applicable.

(PLEASE READ DIRECTIONS AND NOTICES ON BACK OF FORM)

1. (*a*) Name of applicant The Proprietary Medicines Association of Australia Inc
(See Direction 2 on the back of this Form)

(*b*) Short description of business carried on by applicant Corporate representative & advocate for manufacturers of proprietary medicines that can be sold without prescription

(*c*) Address in Australia for service of documents on the applicant C/o Alan L Limbury Minter Ellison Morris Fletcher, 44 Martin Place, Sydney 2000

2. (*a*) Brief description of contract, arrangement or understanding and, where already made, its date Code of Practice, Adopted 8 October 1991, Revised 28 May 1992 and 15 October 1992 (copy attached) subject to authorisation

(*b*) Names and addresses of other parties or proposed parties to contract, arrangement or understanding See attached list of members
(See Direction 4 on the back of this Form)

3. Names and addresses (where known) of parties and other persons on whose behalf application is made See attached list of members

4. (*a*) Grounds for grant of authorization Public benefit outweights any anti-competitive detriment that might result

(*b*) Facts and contentions relied upon in support of those grounds See attached submission
(See Notice 1 on the back of this Form)

5. This application for authorization may be expressed to be made also in relation to other contracts, arrangements or understandings or proposed contracts, arrangements or understandings, that are or will be in similar terms to the above-mentioned contract, arrangement or understanding.

(*a*) Is this application to be so expressed? No

(*b*) If so, the following information is to be furnished—

(i) the names of the parties to each other contract, arrangement or understanding

(ii) the names of the parties to each other proposed contract, arrangement or understanding which names are known at the date of this application
(See Direction 5 and Notice 2 on the back of this Form)

6. (*a*) Does this application deal with a matter relating to a joint venture (see section 4J of the Trade Practices Act 1974)? No

(*b*) If so, are any other applications being made simultaneously with this application in relation to that joint venture?

(*c*) If so, by whom or on whose behalf are those other applications being made?

7. Name and address of person authorized by the applicant to provide additional information in relation to this application Alan L Limbury, Minter Ellison Morris Fletcher, 44 Martin Place, Sydney 2000

ATTACHMENTS IN SUPPORT OF THE APPLICATION FOR AUTHORISATION OF THE PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA INC. CODE OF PRACTICE UNDER SECTION 88(1) OF THE TRADE PRACTICES ACT

MINTER ELLISON MORRIS FLETCHER
Solicitors
44 Martin Place
SYDNEY NSW 2000

DX 117 SYDNEY
Telephone (02) 210 4444
Facsimile (02) 235 2711

CONTENTS

THE PROPRIETARY MEDICINES ASSOCIATION
OF AUSTRALIA INC.

SUBMISSION IN SUPPORT OF APPLICATION FOR AUTHORISATION OF CODE OF PRACTICE UNDER SECTION 88(1) OF THE TRADE PRACTICES ACT

MINTER ELLISON MORRIS FLETCHER
Solicitors
44 Martin Place
SYDNEY NSW 2000

DX 117 SYDNEY
Telephone (02) 210 4444
Facsimile (02) 235 2711

CONTENTS

SUBMISSION IN SUPPORT OF APPLICATION FOR AUTHORISATION

HISTORY OF THE CODE

1. The PMAA has maintained a Code of Practice ('**Code**') for its members' advertising and promotion of over-the-counter ('**OTC**') products since 1977. The PMAA has reviewed the Code from time to time, and made amendments where appropriate. A major review was undertaken in 1989, and regular annual reviews have occurred since then.

2. A new draft Code was discussed with the TPC during the 1991 review process. The TPC's suggestions were carefully considered and the draft Code was amended in several significant respects. In addition, the PMAA established a Task Force to formalise its review process (the '**Task Force**'). The Task Force continues to liaise with the TPC on a regular basis in relation to the Code.

3. The new Code was adopted by PMAA members in October 1991, subject to TPC authorisation. Certain amendments advised by the Task Force were made in May and October 1992. These amendments:

   (a) update the Code to reflect certain changes in the law relating to unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use;

   (b) correct certain typographical errors;

   (c) clarify the appeals process; and

   (d) introduce a new service to PMAA members to pre-clear advertisements in the print, outdoor and cinema media (similar to the service currently provided to members to pre-clear advertisements to the non-broadcast electronic media).

4. Although the PMAA encourages members to comply with the new Code's objectives and principles, the PMAA cannot enforce the Code using the new complaints handling procedures until authorisation is granted.

5. The PMAA considers that full implementation of the Code will support the government's current initiatives in relation to promoting greater public awareness of the proper use of OTC products and greater public access to accurate information about them.

6. In addition, full implementation as soon as possible will provide the Task Force with experience on which to base its regular reviews of the Code, and on which to propose any future amendments.

RELEVANT TEST FOR AUTHORISATION

7. This application for authorisation may be granted only if the TPC is satisfied in all the circumstances that the provisions of the Code would result, or be likely to result, in a benefit to the public that would outweigh the

detriment to the public constituted by any lessening of competition that would result, or be likely to result, if the Code were implemented (see s90(6) of the *Trade Practices Act*).

8. In deciding whether to grant this application for authorisation the TPC must:

   (a) examine the anti-competitive aspects of the Code;

   (b) examine the public benefits or expected public benefits arising from the Code; and

   (c) weigh them to determine which is greater.

9. If the public benefits or expected public benefits outweigh any anti-competitive detriments, the TPC must grant the application.

RELEVANT MARKET

10. 'Prescription drugs' are drugs that cannot legally be sold to the general public without prescription from a medical practitioner.

11. OTC medicines (also known in the industry as 'proprietary medicines') are medicines that can be sold legally to the general public without prescription from a medical practitioner.

12. Given the Commonwealth and State drug approval processes, no new chemical entity can be given non-prescription status. Therefore, OTC medicines, as non-prescription medicines, will always have a long record of safety.

13. While the PMAA recognises that other definitions of the relevant market may be preferred, the PMAA is prepared to accept, for the purposes of this application for authorisation, that the relevant market is the proprietary medicines market in Australia.

14. Sales of proprietary medicines in Australia during the 1990-91 year were valued at about $420 million. Of that, Australian proprietary medicines manufacturers sold about 75%.

POSSIBLE EFFECTS ON COMPETITION

15. Prescription drugs cannot lawfully be advertised to the general public (with some limited exceptions). Prescription drugs can legally be advertised to health professionals (medical practitioners and pharmacists).

16. OTC medicines can lawfully be advertised to the general public and to health professionals (although the law applicable to advertisements to the general public and to health professionals is somewhat different).

17. Both prescription drugs and OTC medicines (together with certain other products) are sometimes classed as 'therapeutic goods'.

18. The Commonwealth *Therapeutic Goods Act 1989* and regulations under it regulate advertising of therapeutic goods, including OTC medicines. Among other things, this legislation regulates what sort of representations can and cannot be made and creates certain advertising offences. The regulations incorporate certain relevant sections of the Media Council of Australia's ('**MCA**') Therapeutic Goods Advertising Code ('**TGAC**').

19. Other Commonwealth legislation of general application is also applicable to therapeutic goods (such as the *Trade Practices Act*), as is specific and general State legislation.

20. To the extent the PMAA Code simply adopts these legislative requirements, it cannot lessen competition.

21. In addition to the applicable law, certain self-regulatory schemes are operated by therapeutic goods industry groups.

22. An example is the TGAC, which applies to broadcast and print advertisements about therapeutic goods to the general public by MCA members (essentially, commercial media proprietors).

23. In addition, as part of the regulations under the *Therapeutic Goods Act 1989*, the relevant sections of the TGAC apply to persons in addition to MCA members (eg, PMAA members).

24. Therefore, it is only to the extent that the PMAA Code goes beyond the applicable legal requirements that the Code could potentially have an anti-competitive effect.

25. The Code goes beyond the applicable legal requirements in 2 ways:

    (a) it governs members' advertising and promotional activity in all media to all audiences (not just to health professionals and to the general public in print and broadcast media); and

    (b) some provisions on advertising and promotion are more restrictive than the law.

26. An example is helpful. The TGAC, as a self-regulatory code, would apply to an advertisement for a nasal spray published by a member newspaper in its publication. The provisions of the TGAC relevant to the nasal spray print advertisement include a requirement that the advertisement 'not contain incorrect statements, or unverifiable claims'.

27. If a PMAA member displayed in a retail outlet using a 'shelf-talker' the same nasal spray referred to in paragraph 26 above the PMAA Code would regulate what could be included in the 'shelf-talker'.

28. Because the Code requires PMAA members to comply with the provisions of the TGAC, the 'shelf-talker' may 'not contain incorrect statements, or unverifiable claims'. In

addition, s5.1.4 of the Code states that 'information and claims must, when made, be capable of substantiation, such substantiation being provided without delay upon receipt of bona fide requests' (underlining added for emphasis).

29. In other words, the PMAA Code restricts members' freedom in this case by requiring that claim substantiation be prompt.

30. The Code consists of 10 sections. Only parts of sections 5 and 6, which deal with Advertising and Promotion respectively, restrict members' freedom and hence only these can potentially have any effect on competition.

31. The following table illustrates the extent to which these sections create new restrictions on advertising and promotion:

Section #	New Restriction
5.1.1	None
5.1.2	None
5.1.4	Provide claim substantiation promptly after request
5.1.5	None
5.1.6	No ads offering return of money if dissatisfied
5.1.7	None
5.2	No ads may unfairly denigrate/attack other goods/services
5.3	Information to be included in trade ads for S3 products
5.4	None
5.5	None
6.1.1	Promotion not to bring discredit on/reduce confidence in the industry
6.1.2	None
6.1.3	None
6.1.4	None
6.1.5	None
6.1.6	Prize competitions limited
6.1.7	Prize competitions limited
6.2	Ads for S2 and S3 products not to persuade consumers to buy unnecessary products or products in unnecessary quantities

6.3 No promotion to children (advertisements already prohibited by law).

THE PUBLIC BENEFITS

32. In the PMAA's submission, the additional restrictions and the wider application of the Code improve the quality of OTC advertising and promotion without restricting unduly members freedom to advertise and promote.

33. The Code's objectives and principles are designed to achieve important public benefits.

34. Adherence to the Code's objectives ensures that:

(a) members take a responsible approach to advertising and promotion of OTC products;

(b) members are, and can be seen to be, responsive to community concerns relating to OTC products; and

(c) consumers continue to have access to and be properly informed about quality OTC products that are safe and effective when used as directed.

35. In particular the Code's principles are designed to:

(a) ensure the general public is properly informed about OTC products;

(b) protect the general public from inducement to buy OTC products in excess of immediate requirements;

(c) reduce the likelihood of inappropriate or excessive consumption of scheduled substances or analgesics;

(d) reinforce responsible use and care of OTC products; and

(e) protect children from direct advertising and promotion of OTC products.

36. The Code seeks to achieve these public benefits in 4 ways:

(a) by its wider application than required by law, as described in paragraph 25(a), thereby promoting consistency between all forms of advertising and promotional activity in all media to all audiences;

(b) by ensuring that to the extent to which its requirements go beyond the law, they are consistent with government and community concerns about advertising and do not unduly restrict members' freedom to compete;

(c) by offering an efficient and fair complaints handling procedure; and

(d) by including features to promote the Code's acceptance by the public.

Complaints Procedures

37. The Code establishes easily accessible procedures for complainants (who may be members or non-members) and failure to comply with the Code can be efficiently enforced.

38. Provision is made for adequate and appropriately advised personnel to provide speedy resolution of complaints. The complaints and appeals processes are fair and non-discriminatory.

39. The PMAA has only ever received one complaint that was not capable of being resolved at first level by the Executive Director. On this basis, the PMAA expects that any claim that would need to be referred to the appellate Complaints Panel would involve a dispute about technical issues.

40. Accordingly, in structuring the composition of the Complaints Panel, the PMAA considers it essential:

    (a) that each appointee have relevant expertise and experience to contribute to the Complaints Panel's deliberations; and

    (b) that regard be had to existing complaints bodies available to potential complainants, in particular, the Advertising Standards Council ('**ASC**'). That is to say, since the TGAC is in effect the benchmark from which the PMAA Code operates, the PMAA has not sought to recreate the ASC in its Complaints Panel.

41. The Complaints Panel will comprise of member representatives and outsiders: a trade practices lawyer, a nominee of the Royal Australian College of General Practitioners and a community pharmacist nominated by the Pharmaceutical Society of Australia. The outside members are to bring to the Complaints Panel not only their technical expertise, but also their experience of consumers gained through their advisory and consulting roles and their own experience as consumers.

42. Selection of Complaints Panel members is to be coordinated by the PMAA's Marketing and Ethics Subcommittee. This consists of senior executives of a number of PMAA members and the PMAA proposes to invite a representative of the Department of Health, Housing and Community Services and a representative of a broadly based consumer group to participate in Subcommittee meetings relating to selection of Complaints Panel members and other issues in relation to the Complaints Panel and relating to the annual review of the Code. In seeking nominations for outside members from the Royal Australian College of General Practitioners and the Pharmaceutical Society of Australia, the Subcommittee will require that nominees have a demonstrated interest in community, including consumer, issues.

Provision of Information

43. In addition to the complaints procedures members are required to ensure that their personnel understand and comply with the Code. Members are provided with a copy of the Code as part of their handbooks. These handbooks also include the other relevant codes of conduct.

44. Non-members may request information about all potentially applicable Codes from the DHHCS or the ASC.

45. The PMAA holds regular seminars on how to improve knowledge of and compliance with the Code, the other relevant Codes and the pre-clearance procedures.

Acceptance by the Public

46. The PMAA recognises that the OTC products industry must be open and accessible to the public, that required information must be readily available and that its Code must be publicly accepted. The Code incorporates the following crucial features that promote public acceptance.

46.1 The Code clearly states its objects and principles (see ss2-6).

46.2 The Code is administered over time by a body including outside representation (s7.5 provides for at least annual review by the Executive Sub-Committee in consultation with the external Complaints Panel members).

46.3 The PMAA's membership covers a substantial proportion of the OTC products industry. The PMAA currently has 44 ordinary members (OTC product manufacturers) and 23 associate members (non-manufacturing members, eg, advertising agencies). The PMAA estimates that its ordinary members represent about 95% of the turnover of the OTC products industry.

46.4 The Code provides an independent complaints handling procedure to provide easily accessible, quick and inexpensive remedies for complainants. Section 8 of the Code provides for a very speedy process, which includes the possible involvement of the appellate Complaints Panel comprising representatives of members and outsiders to the OTC products industry (s7.4)).

46.5 The Code's appeals process allows complainants to appeal to the Complaints Panel (see s10.4.1).

46.6 Breach of the Code can result in commercially significant sanctions for Code breaches. Section 9 of the Code provides for sanctions ranging from undertakings not to engage in the conduct to expulsion from the PMAA.

46.7 The Complaints Panel can impose first level sanctions (see s8.2.15 and s9.1). Higher level

sanctions are imposed by the Committee of Management (see s9.2).

46.8 The complaints handling procedures apply to non-members with their consent (see s2.8).

46.9 Section 8.2.3 of the Code states that complaints about members may be referred to the MCA if appropriate. The Code does not require that complaints about non-members be referred to any third person, since any referral by the PMAA to any third person of a complaint involving a non-member would involve the possibility of defamation proceedings arising. However, it is the PMAA's practice, where appropriate, to inform complainants with complaints about non-members that they may complain to the MCA.

46.10 The PMAA provides information to members over time so that problem practices are understood. Section 8.4 provides for publication in the PMAA's Annual Report of all complaint, sanction and appeal matters. Since the PMAA Annual Report is publicly available, the PMAA's practices enable members, customers and the general public to assess the Code's effectiveness.

46.11 The PMAA monitors compliance with the Code as part of its rules of association.

46.12 The PMAA undertakes regular reviews to ensure the Code meets changing community concerns and changes in the applicable laws and the other relevant Codes. Section 7.5 provides for at least annual review by the Executive Sub-Committee in consultation with the external Complaints Panel members. In fact, the Code's predecessors were regularly amended and the new Code has already been amended twice. The Marketing and Ethics Subcommittee will have an ongoing role in the annual review process.

GROUNDS FOR GRANT OF THE AUTHORISATION

47. The Code establishes basic parameters to guide members in advertising and promoting OTC products. These summarise the legal requirements (including the legislated requirements of the TGAC and the relevant requirements of other self-regulatory bodies (eg, the MCA's Advertising Code of Ethics) and extend them in a manner consistent with government and community concerns about the advertising and promotion of OTC products to the general public, and particularly to children, and to health care professionals.

48. To the extent the Code's parameters are simply a statement of what the law requires and permits, they cannot restrict competition at all. The PMAA submits they apply more broadly than the law only to the extent required to address government and community concerns. Hence they improve the quality of advertising and promotion, without restricting unduly members freedom to advertise.

49. To be effective, the Code's requirements need an effective and speedy enforcement mechanism, and this will be provided through the Complaints Panel.

50. Accordingly, the public benefit arising from full implementation of the Code will outweigh any anti-competitive detriment that might arise.

The Proprietary Medicines Association of Australia

CODE OF PRACTICE

Adopted : 8 October 1991

Revised : (1) 28 May 1992
(2) 15 October 1992

Note : Authorisation by the Trade Practices Commission pending

11TH FLOOR, 65 BERRY ST., NORTH SYDNEY, NSW 2060
POSTAL ADDRESS: PRIVATE BAG 938, NORTH SYDNEY 2059
TELEPHONE: (02) 922 5111 FAX:(02) 959 3693

CONTENTS

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 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 broad classes of advertisements defined below and appearing in professional/trade journals:

  Abbreviated Advertisements – the effect of which is to remind the reader of the name of the product, its major application and some elementary commercial information;

  Commercial Advertisements – the effect of which is to communicate commercial information such as details of packaging, pricing, trading terms or marketing incentives;

  Technical Advertisements – the effect of which is to communicate technical information about the product.

- **"Associate Member"** means any Company including associated or related Company, wholesaler, distributor or Advertising Agency admitted to membership, which conducts in Australia the packaging, or promotion of Proprietary Medicines or the manufacture or fabrication of packaging for Proprietary Medicines, or the manufacture or operation of equipment or devices for the application of Proprietary Medicines.

- **"The Association"** means the Proprietary Medicines Association of Australia Incorporated.

- **"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.

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

- **"Executive Sub-Committee"** means the Committee comprising 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 pastiles, throat sprays or throat tablets.

- 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.

- "**Ordinary Member**" means any Company admitted to membership which conducts in Australia the basic manufacture and/or formulation and/or importation and/or basic applied research into and/or the registration and/or marketing of Proprietary Medicines.

- "**Proprietary Medicines**" means products for health and 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.

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 health-care 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 products which are both safe and effective when used as directed.

2.3 In this commitment, the Association's members recognise that, whilst their products 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 Member companies 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 member companies in the conduct of their business and particularly in matters of advertising and promotion of proprietary medicines.

Specifically, the Code seeks to assist member companies:

- responsibly to inform consumers about Proprietary Medicines which are available
- to uphold a high standard in the communication of information about Proprietary Medicines
- to ensure that all claims made for Proprietary Medicines are accurate, balanced and based on sound and objective scientific considerations
- to 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 of 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 PRODUCTS

5.1.1 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 Proprietary Medicines.

5.1.2 Application

"Advertisement" has the meaning specified in Section 1 of this Code.

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 Health, Housing and Community Services.

5.1.6 No member shall advertise an offer to return money to dissatisfied users of Proprietary Medicines.

5.1.7 Section 5 of this Code applies to member companies whose products are promoted to both the medical and paramedical professions.

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 products, shall comply with the terms of this section.

- No Advertisement will unfairly denigrate or attack any other product, goods or services.

- Comparative Advertisements should be so designed that there is no likelihood of the consumer being misled as a result of the comparison, either about the product 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 product 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 products 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 advertisers product also has been subjected and the results of such tests are stated.

5.3 ADVERTISING OF SCHEDULE THREE ITEMS

5.3.1 Background

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

Schedule 3 products 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".
>
> (Substances so listed in the current issue of the Standard are covered by this section of the Code)

Consequently their sale to the general public requires the involvement of the pharmacist personally to ensure the product is suitable for the customer and that the customer is informed on the correct method of use. Schedule 3 products must be stored in pharmacy in areas to which the public does not generally have access and promotional or advertising material relating to S3 products must not be visible to the public.

With this background, it is clear that the advertising of such products should be informative where possible, should be directed to the pharmacist or medical practitioner only and must not be directed to pharmacy assistants or other non-qualified personnel. Since only Professional Advertisements are permitted, Schedule 3 products 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 4.3, this Code picks up and extends the provisions of the Therapeutic Goods Advertising Code.

Apart from restrictions placed on the advertising of Proprietary Medicines covered in other sections of this Code additional requirements applying to the advertising of Scheduling 3 products fall into three broad categories namely:

(i) technical
(ii) abbreviated; and
(iii) commercial

The minimum standards for such classes of Advertisements are contained in the following paragraphs of this Code (5.4.2.1 – 5.4.2.3), and, together with previous paragraphs 5.1.3 to 5.3 inclusive, formalise a set of minimum standards for such classes of Advertisements.

5.3.2 Requirements :

5.3.2.1. Technical Advertisements

Members' Technical Advertisements for "S3" therapeutic substances shall contain the following information as a minimum requirement;-

- the Brand Name of the product;
- the Australian Approved Names of the active ingredients;
- the level of presence of such active ingredients expressed as their mass present in each recommended adult dose;
- the indications for the use of the substance as approved by Australian Health Authorities, or as adopted, or endorsed, by internationally recognised pharmacopoeia or monograph systems;

- clear unequivocal statements of significant contraindications, potential adverse interactions and precautions where such have been recognised;
- dosage regimens and directions for use;
- reference to sources of published detailed product information such as Mims, Bi-Monthly, Mims Annual, the Prescription Products Guide; and
- the name and full address of the Australian registered office of the manufacturer, importer or distributor of the product.

5.3.2.2 Abbreviated Advertisements :

Members' abbreviated Advertisements for S3 therapeutic substances shall contain the following information as a minimum requirement:-

- the Brand Name of the product;
- the Australian approved names of the active ingredients;
- the recognised indications for use;
- advice that full product information should be consulted where significant contraindications or adverse interactions have been recognised; and
- the name and full address of the Australian registered office of the manufacturer, importer or distributor of the product.

5.3.2.3 Commercial Advertisements:

Members' Commercial Advertisements for S3 therapeutic substances shall not contain information of a technical nature, unless such information conforms to the minimum requirements of either Abbreviated or Technical Advertisements as previously specified.

5.4 ADVERTISING IN NON-BROADCAST ELECTRONIC MEDIA

All member companies shall submit electronic media advertising to PMAA for preclearance. In addition to broadcast electronic media preclearance, member companies shall obtain preclearance of advertising through closed circuit video or audio networks in locations such as pharmacies, retail stores or doctors' surgeries.

5.5 ADVERTISING IN CONSUMER PRINT OUTDOOR AND CINEMA MEDIA

All member companies 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.

6. PROMOTION

6.1 GENERAL PRINCIPLES – ALL PRODUCTS

6.1.1 Methods of promotion must never be such as to bring discredit upon, or reduce confidence in, the industry.

6.1.2 All methods of communicating promotional information must be carried out in accordance with the requirements of this Code.

6.1.3 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.

6.1.4 Requests from individual members of the public for advice of a diagnostic nature must always be refused and the enquirer recommended to consult his or her own doctor.

6.1.5 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.

6.1.6 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.

6.1.7 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.