AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

Code of Practice

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Note:

Explanatory notes have been provided throughout the Code to assist with its implementation at an operational level. The notes made are based on the experiences with review of Code complaints, general enquiries, comments from ASMI members and determinations made by the ASMI complaints Panel

PREFACE

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

This authorisation applies to:

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

The Commission further required that:

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

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

- ASMI will notify the Commission of amendments it proposes to make to the Code;
- ~~Within 10 working days of the commission receiving these,~~The Commission will advise ASMI if it considers the proposed amendments are significant and would materially alter the circumstances of any authorisation granted by the Commission.
- both the proposed amendments and the Commission's advice to ASMI concerning those amendments will be placed on the public register of authorisation applications maintained by the Commission, subject to the Commission's power to, on request, exclude material from the public register.

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

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

1. DEFINITIONS

In this Code of Practice:

"Advertisement/Promotion" includes every form of communication whether in a publication, or by display or any notice, or by means of any catalogue, price list, leaflet, booklet, letter (whether circular or addressed to a particular person) or other document, or by means of any packaging materials (including all labels, cartons, direction folders, and other packaging components bearing printed matter), or by words inscribed on any article, or by exhibition of a photograph or film, or by way of sound recording, radio or television, the Internet, in the spoken word, or in any other way.

"Branded Advertising" This type of advertising is also referred to as direct to consumer advertising and is only permissible for unscheduled, schedule 2 and schedule 3 (listed on appendix H of SUSDP) products.

"Broadcast media" means any radio or television broadcast for consumers. It excludes only available to healthcare professionals and information available on the internet.

"Consumer Advertisement" means an advertisement ~~in consumer media~~ as defined and covered by the Therapeutic Goods Advertising Code:

> " *"Advertisement" in relation to therapeutic goods as defined in the Therapeutic Goods Act 1989 includes any statement, pictorial representation or design, however made, that is intended whether directly or indirectly to promote the use or supply of the goods"*

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

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

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

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

"Complaints Panel" means the ASMI Code of Practice Complaints Panel.

"Direct to consumer advertising" –This type of advertising is more commonly referred to as branded advertising and is only permissible for unscheduled, schedule 2 and schedule 3 (listed on appendix H of SUSDP) products. See definition of branded advertising above.

"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.

"Generic Information" means information as defined in the Therapeutic Goods Regulations 1990 Part 2B section 9.

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

"Indirect to consumer advertising"- more commonly referred to as unbranded advertising.

The **"industry"** means the basic manufacture and/or formulation and/or importation and/or basic or applied research into and/or the registration and/or marketing of non-prescription consumer healthcare products.

"Mainstream Print media" means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

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

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

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

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

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

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

"Rules" mean the Rules of the Association for the time being in force.

"Specified media" means:

(a) mainstream media within the meaning of section 42B of the Therapeutic Goods Act; or
(b) cinematography film; or
(c) displays about goods, including posters:
  (i) in shopping malls
  (ii) in or on public transport; and
  (iii) on billboards.

"Unbranded advertising" is also referred to as indirect to consumer advertising.

"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 non-prescription consumer healthcare products*.

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

2.3 In this commitment, the Association's Members recognise that, whilst non-prescription consumer healthcare products can bring substantial social and economic benefits to the community, the advertising and promotion of these products 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. Manufacturing companies of non-prescription consumer healthcare products outside the Association are invited to accept and observe this Code.

3. OBJECTIVES OF THE CODE

3.1 This Code is intended to establish the basic parameters which guide Members in the conduct of their business and particularly in matters of advertising and promotion of non-prescription consumer healthcare products.

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

3.2.1 Responsibly inform consumers about the products which are available;

3.2.2 Uphold a high standard in the communication of information about the products;

3.2.3 Ensure that all claims made for the products are accurate, balanced and based on sound and objective scientific considerations;

3.2.4 Ensure that such information is communicated in a way which promotes the responsible use of the products.

PROVISIONS OF THE CODE

PART A: THE CODE AND ITS APPLICATION

4. PRINCIPLES OF PRACTICE

4.1 Members shall not engage in any unfair* or unconscionable conduct or commercial practice.

4.2 Members shall at all times ensure that they are familiar with, and comply with, the relevant provisions of Commonwealth and/or State Acts, Regulations or other legal instruments which pertain to the functions and operations in the industry.

4.3. Members shall at all times comply with provisions of:

4.3.1 the Therapeutic Goods Advertising Code;

4.3.2 the Code of Good Manufacturing Practice;

4.3.3 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 non-prescription consumer healthcare products.

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 non-prescription consumer healthcare products.

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 non-prescription consumer healthcare products.

Previously 5.1.5

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

Previously 6.1.3

4.10 Requests from individual members of the public for advice of a diagnostic nature must always be refused and the inquirer recommended to consult an appropriate healthcare professional.

Previously 6.1.4

4.11 Requests for information on non-prescription consumer healthcare products 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.

EXPLANATORY NOTES

PROVISIONS OF THE CODE

5. ADVERTISING AND PROMOTION

5.1 General principles

5.1.1 ~~Section 5 of this~~ This section of the Code applies to Members whose non-prescription consumer healthcare products are promoted to healthcare professionals*, consumers, or both.

5.1.2 ~~**Scope:**~~Nothing in this Section of the Code of Practice shall be construed as replacing, diminishing or precluding requirements of The Therapeutic Goods Advertising Code in relation to consumer advertisements* of non-prescription consumer healthcare products. This section of the Code of Practice applies to all advertisements/promotions* for non-prescription consumer healthcare products.

Previously 5.2

5.1.3 ~~**Claims:**~~Information and medical claims about non-prescription consumer healthcare products must be current, accurate, balanced, and must not mislead either directly, by implication, or by omission. 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.

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

Previously 6.1.2

5.1.5 Advertisements/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.

Previously 6.1.5

5.1.6 No Member will promote to ~~the general public~~ consumers any prize competition which is conditional on their purchase of a non-prescription consumer healthcare product. Disinfectants (~~not including~~ other than those with antiseptic claims), unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use* are exempted from this clause.

Previously 6.1.6

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

5.2 Comparative Advertising

5.2.1 Advertisements containing comparison with other advertisers, or other non-prescription consumer healthcare products shall also comply with the terms of this section.

5.2.2 Advertisements and promotional material should not describe or show the non-prescription consumer healthcare 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 advertiser's product also has been subjected and the results of such tests are stated.

EXPLANATORY NOTES

5. ADVERTISING AND PROMOTION

5.1 General Principles

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

- literature references, or quotations or claims that are more favorable than has been demonstrated by the body of clinical evidence or experience;
- information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions;
- citing of data previously valid but made obsolete or false by subsequent findings;

Previously 5.1.3

- suggestions or representations of uses, dosages, or indications not approved by the Commonwealth Department of Health and Aged Care.

5.2 Comparative Advertising

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

- Where ~~it~~ it is unclear ~~should be clear~~ with what the advertised non-prescription consumer healthcare products is being compared ~~and~~ or upon what basis.

or

Previously 5.2

- Claims of superior or superlative status ~~should be~~ which are not expressed in terms which accurately reflect the extent or the nature of the evidence available to substantiate them.

PROVISIONS OF THE CODE

5.3 Scheduled Substances and Internal Analgesics

Previously 6.2

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

Previously 6.2

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

EXPLANATORY NOTES

5.3 Scheduled Substances and Internal Analgesics

Techniques which may be considered inappropriate and contrary to the provisions of the Code because they may be likely to persuade consumers to purchase a product which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser, include the following examples:

- Promotion to sales assistants, or to any healthcare professional, of prize competitions which are in any way related to sales to consumers of such non-prescription consumer healthcare products.~~, which may be likely to persuade consumers to purchase a product 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 product 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 product which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser~~

- Examples of ticketing which may constitute a breach of this Clause include: "special"; temporary "value"; "discount"; "get it while it lasts"; or similar forms of ticketing.

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

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

- Encouragement or support of promotional displays in off-site locations within reach of the public which may be likely to persuade consumers to purchase a non-prescription consumer healthcare product 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.

PROVISIONS OF THE CODE

5.4 Specific Requirements For Advertising And Promotion To Consumers

5.4.1 Approval of advertisements

Members and non-members shall submit copy for advertis~~ing~~ements to consumers in specified (which includes mainstream) and broadcast media to the appropriate bodies (eg. ASMI and CHCA) for approval in accordance with the delegations under the Therapeutic Goods Regulations and the Broadcasting Services Act. On approval Members shall submit advertising copy to the Federation of Commercial Television Stations (FACTS), the Federation of Australian Radio Broadcasters (FARB) or the Australian Cinema Advertising Council (ACAC) where applicable.

5.4.2 Compliance with the ASMI Code of Practice

In addition to the requirements in 5.4.1, Members shall submit all mainstream media advertis~~ing~~ements ~~material~~ directed to consumers to the ASMI for approval to ensure compliance with the ASMI Code of Practice.

EXPLANATORY NOTES

5.4 ADVERTISING/PROMOTIONS TO CONSUMERS

This section relates to all consumer advertising of non-prescription consumer healthcare products.

5.4.1 Approval of advertisements

All consumer advertising in specified and broadcast media must be approved by the appropriate industry association. Advertisements for Complementary Healthcare Products (other than devices) in mainstream print media are required under the Therapeutic Goods Act and Regulations to be submitted to:

Advertising Services
Complementary Healthcare Council
PO Box 104
DEAKIN WEST ACT 2600
Ph: (02) 6260 4022
Fax: (02) 6260 4122
Email: chc@chc.org.au

Advertisements for all other therapeutic goods (other than devices) in mainstream print media and all therapeutic goods (other than devices) in broadcast media are required under the Therapeutic Goods Act 1989 and Regulations, and the Broadcasting Services Act, to be submitted to:

Advertising Services
Australian Self Medication Industry
Level 4, 140 Arthur Street
NORTH SYDNEY NSW 2060
Ph: (02) 9955 7205
Fax: (02) 9957 6204
Email: sonia@asmi.com.au

Promotional material including internet content, which falls outside of the definition of specified and mainstream media such as shelf wobblers, in store posters and mobiles, do not require approval but must never the less comply with the provisions of this Code.

For a definition of mainstream and specified media please see "Definitions".

Minimum Requirements

Clause 6 of the TGAC contains minimum requirements for advertisements of therapeutic goods and these are:

This clause, other than paragraphs (b), does not apply to:

- Advertisements for unbranded therapeutic goods
- Labels

This clause does not apply to retail advertisements displaying only the name/picture of the goods and/or price and/or the point of sale, provided the advertisement does not contain a claim for therapeutic use.

An advertisement for therapeutic goods shall contain:

(a) the trade name of the goods
(b) A reference to the approved/permitted indication(s) for the use of the goods

(c) Where applicable, a list of ingredients or the following statement prominently displayed or communicated:

ALWAYS READ THE LABEL

except in the case of direct marketing and Internet marketing, where the catalogue or Internet communication must contain a full list of active ingredients

(d) Words to the following effect, prominently displayed or communicated:

USE ONLY AS DIRECTED

And, for claims relating to symptoms of diseases or conditions,

IF SYMPTOMS PERSIST SEE YOUR DOCTOR/HEALTHCARE PROFESSIONAL

(e) or, in the case of schedule 3 therapeutic goods listed in Appendix H of the Standard for the Uniform Schedule of Drugs and Poisons, words to the effect of

YOUR PHARMACIST'S ADVICE IS REQUIRED

(f) In the case of therapeutic goods that are able to be lawfully advertised and are available only from, or on the recommendation of, a health professional (except in the case of S2 and S3), the following displayed or communicated:

YOUR [APPROPRIATE HEALTHCARE PROFESSIONAL] WILL ADVISE YOU WHETHER THIS PREPARATION [PRODUCT NAME] IS SUITABLE FOR YOU/YOUR CONDITION

PROVISIONS OF THE CODE

Advertising of Pharmacist Only Medicines (Schedule 3)

5.4.3 Direct to Consumer Advertising of Pharmacist Only Medicines (Schedule 3)

5.4.3.1 For those Pharmacist Only Medicines (Schedule 3) for which branded advertising is permitted, all advertisingements and promotional activity should comply with this Code and the Therapeutic Goods Advertising Code and advertising shall be submitted for approval as provided for in clause 5.4.1 of this Code.

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

EXPLANATORY NOTES

Advertising of Pharmacist Only Medicines (Schedule 3)

Background

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

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

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

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

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

5.4.3 Direct to Consumer Advertising of Pharmacist Only Medicines (Schedule 3)

Advertising and promotion of Pharmacist Only Medicines (Schedule 3) not listed in Appendix H of the SUSDP by way of empty packs does not constitute a breach of the requirements.

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

5.4.4 Indirect/Unbranded advertisingements and promotion of Pharmacist Only Medicines (Schedule 3)
(Not Permitted to be advertised to consumers)

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

5.4.4.2 No sponsor company or distributor identification is permissible.

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

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

5.4.4.5 The indirect advertisement will contain one cautionary statement from each of the following ~~categories:,~~ or words to the same effect.

~~**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~~

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

EXPLANATORY NOTES

5.4.4 Indirect/Unbranded Consumer Advertising

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

Objectives

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

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

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

The Role of the Pharmacist

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

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

Indirect advertising simply indicates availability of the Pharmacist Only Medicines (Schedule 3) for certain conditions and communicates basic information.

The role of the pharmacist as adviser at the point of purchase is crucial and will not be usurped by indirect advertising of Pharmacist Only Medicines (Schedule 3). Rather, it should be enhanced.

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

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

5.4.5 Advertising and promotion to children

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

EXPLANATORY NOTES

5.4.5 Advertising and promotion to children

For therapeutic goods not listed in Appendix 5, techniques which may be considered inappropriate and contrary to the provisions of the Code, include the following examples:

- Encouragement or support of the positioning of non-prescription consumer healthcare products where they are readily accessible to children.

- Direction of advertising of non-prescription consumer healthcare products to children, except for those listed in Appendix 5 of the TGAC.

- Advertising of non-prescription consumer healthcare products in a manner which is likely to lead to its use by children without parental supervision.

PROVISIONS OF THE CODE

5.5 Specific Requirements For Advertising And Promotion To Healthcare Professionals

5.5.1 Minimum requirements for advertisements

Unscheduled and Pharmacy Medicines (Schedule 2)

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

- the brand name of the products
- 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".

Pharmacist Only Medicines (Schedule 3)

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

Advertisements of Pharmacist Only Medicines (Schedule 3) must include ~~as a minimum~~ in addition to the above:

- ~~the brand name of the product~~
- ~~the Australian Approved Name(s) of the active ingredient(s)~~
- ~~the approved indications for use~~
- a succinct statement of the contra-indications, clinically significant precautions and side-effects (unless the product is included in Appendix H of the SUSDP i.e. can be advertised by brand to consumers)
- dosage and method of use
- the name of the supplier and the city, town or locality of the registered office
- a clear and unambiguous statement for healthcare professionals to review the full PI (if more extensive than the above) before recommending, and alerting them to the availability of the full PI from the manufacturer on request.

5.5.2 Brand name reminder advertisements

5.5.2.1 A b~~B~~rand name reminder advertisingement (one containing only a brand name or branding device) i.e. conveying no claims or promotional statements, ~~shall contain the following minimum information~~ is not required to include any further information.

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

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

5.5.2.2 Advertisements which convey only purchasing details/information for the pharmacist and which communicates no claims or benefits of the goods ~~shall be exempted from the above requirements~~ does not require any further information.

EXPLANATORY NOTES

5.5 SPECIFIC REQUIREMENTS FOR ADVERTISING AND PROMOTION TO HEALTHCARE PROFESSIONALS

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

Advertising material directed to healthcare professionals does not require prior approval by ASMI's approval service. Approval is only required for consumer advertising in broadcast media, and other consumer media as detailed in Clauses 5.4.1. Companies must therefore satisfy themselves that any material they produce aimed at healthcare professionals complies with the Code.

Complaints regarding advertising or promotion of any ~~OTC medicines~~ non-prescription consumer healthcare product directed to healthcare professionals will be adjudicated through ASMI's Complaints Handling Process outlined in clause 8.

Excluded from the scope of this Code are advertising and promotional activities relating to prescription (Schedules 4 and 8) products. These activities fall under the ~~APMA~~ Medicines Australia Code of Conduct.

Advertising for ~~OTC medicines~~ non-prescription consumer healthcare product, directed to healthcare professionals must comply with the body of the ASMI Code, as well as this Clause.

PROVISIONS OF THE CODE

6. CONSUMER MEDICINES INFORMATION

6.1 CMI content

6.1.1 Members shall ensure that all CMI's developed for their products comply with Schedule 13 of the Therapeutic Goods Regulations and the Australian Guidelines for the Registration of Drugs Vol.2. Non-Prescription Drug Products (AGRD2).

6.1.2 No member shall attempt to use CMI as a direct/indirect form of advertising for the product.

6.2 Complaint handling—CMI

If on initial review of the complaint, the Executive Director believes that Schedule 13 of the Therapeutic Goods Regulation and ARGD2 has been breached, the complaint will be referred to the Chemicals and Non-Prescription Medicines Branch, TGA, for resolution.

If however, the breach relates to Clause 6.1 above, and does not relate to Schedule 13 of the Therapeutic Goods Regulation and ARGD2, the Executive Director will refer it to the Complaints Panel. Where the Complaints Panel is to hear a complaint concerning a CMI, an ad hoc observer will be coopted onto the panel to provide expertise in the area ~~in the area~~ of writing CMI.

For details on the complaint procedure with regard to CMI, refer to Clause 9.

EXPLANATORY NOTES

6. CONSUMER MEDICINES INFORMATION

Background

Since 1 July 1995 all new Pharmacist Only Medicines (Schedule 3) are required to develop Consumer Medicines Information (CMI).

Existing Pharmacist Only Medicines (Schedule 3) as at 1 July 1995 will be required to have CMI available by 1 January 2004. Companies will be encouraged to progressively develop CMI during the interim period.

6.1 CMI content

~~Schedule 13 requires that CMI is:~~

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

~~CMI must include the following :~~

- ~~Identification~~
- ~~What the product is used for and how it works~~
- ~~Advice before using the product~~
- ~~How to use the product properly~~
- ~~Further information~~
- ~~Unwanted effects~~
- ~~In Storage conditions~~
- ~~Where case of over dosages~~
- ~~to go for further information~~

Details of the information required can be found in Schedule 13 and AGRD2. The Usability Guidelines and Glossary of Terms are to be referred to for additional guidance.

6.1.2 CMI is not an advertising or promotional tool and as such should be confined to factual information concerning the product and its use.

As a consequence, the following techniques are considered contrary to the provisions of the Code:

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