



# AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

The General Manager  
ACCC  
PO Box 1199  
Dickson ACT 2602

14 January 2003

Dear Mr. Cassidy

**Proposed amendments to ASMI Code of Practice  
Authorisation A90549, 27 January 1994.**



The Commission will recall that it is a condition of this authorisation that the ASMI Code of Practice be regularly reviewed.

The ASMI membership requested that the Code be formatted in a fashion which would make it easier to locate specific provisions for advertising/promotion of non-prescription healthcare products.

The ASMI Marketing and Ethic Subcommittee, which is responsible for the maintenance of the Code, considered and recommended amendments to address this issue. The proposed amendments were subsequently endorsed by the Committee of Management and adopted by members at the Annual General Meeting on 12 September 2002, subject to the Commission's approval in accordance with the terms of the authorisation granted in 1994.

Attached are a rationale document and the proposed amended code, in which the amendments are highlighted in red for your convenience. I also include a copy of the current Code – last revised in April 2001, which indicates the sections (blue or pink) that have been moved to different parts of the proposed code. The boxes in the margin show where these are now located. The sections are indicated by their relevant number and the expression "E.N." refers to explanatory notes.

Because the proposed amendments are predominantly a rearrangement of existing provisions, are in accordance with the Therapeutic Goods Act and Regulations and the Therapeutic Goods Advertising Code and are otherwise unexceptionable in the trade practices context, it is submitted that the Commission should be satisfied that *"the proposed amendments are not significant and will not materially alter the circumstances of the authorisation"*, as contemplated by the 1994 authorisation.

As the Commission knows from the discussions following the April 2001 amendments, ASMI values highly the open-ended authorisation it obtained in 1994 and, so long as the existing authorisation remains in effect, ASMI does not wish to avail itself of the procedure for minor variations that was subsequently introduced into the Act. Accordingly, if the Commission has any concerns that the proposals may not satisfy the condition of the 1994 authorisation regarding future amendments, we would welcome the opportunity to discuss the Commission's concerns with a view to ensuring that the existing authorisation continues to apply.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Arblaster', written in a cursive style.

Chris Arblaster

**Marketing and Development Director**

# ASMI CODE OF PRACTICE

## NEW FORMAT

### RATIONALE DOCUMENT

#### Preface

In the (current) April 2001 version, as in previous versions, operative provisions and explanatory notes are scattered throughout the Code. The ASMI membership requested that the Code be reformatted so as to make it easy to locate the specific operative provisions.

The Marketing and Ethics Subcommittee addressed the concerns of the membership and made it a priority to reformat the Code in order to make it easy to use and understand. The majority of the wording in this reformatted version has not been changed. New definitions have been included, provisions have been separated from the explanatory notes and all requirements for advertising /promoting to consumers has been grouped together as have all the requirements for advertising /promoting to healthcare professionals.

This document clarifies the changes.

#### CONTENTS

Indexing has changed reflecting the changes to the formatting.

#### PART B MANAGEMENT OF THE CODE

Unchanged.

#### PREFACE

The 10 working day time limit for the ACCC to respond to proposed changes to the Code has been removed as ACCC cannot meet this timetable.

#### Section 1 DEFINITIONS

New definitions have been added to this section, these include;

- Branded advertising
- Broadcast media
- Consumer Advertisement (in line with the definition in the TGAC)
- Direct-to-consumer advertising
- Generic information – (similar to the definition in the TG Regulations)
- Indirect-to-consumer advertising
- Mainstream print media – (in line with s.42B of the TG Act)
- Specified media – (in line with the definition in TG Regulation 2)

Unbranded advertising

**Rationale:** Provides definitions, consistent with the TG Act and Regs and the TGAC, of the more commonly used terms for types of advertisements and clarification of a subtype of media.

• The word *advertising* is replaced with the word *advertisement* in the body of the text for purposes of clarity and consistency throughout the Code.

• “**Advertisement**” has been changed to “**Advertisement/promotion**” to ensure consistency given the amalgamation of the two sections.

•“**Consumer advertisement**” has been expanded as per the TGAC definition.

## **Section 2 INTRODUCTION**

Unchanged.

## **Section 3 OBJECTIVES OF THE CODE**

New number introduced but content has remained unchanged.

## **Section 4 PRINCIPLES OF PRACTICE**

New numbering. All points relating to the Code and its application have been included in this section. Most of the text copy is the same as the April 2001 version except for 4.9, 4.10 and 4.11, which are additions to this section. These points were previously located in sections dealing with the general principles of advertising and promotions (previously sections 5 and 6 of the ASMI Code).

**Rationale:** It is more logical that points 4.9, 4.10 and 4.11 are located here rather than sections 5 and 6.

## **Section 5 ADVERTISING AND PROMOTION**

The provisions governing the advertising and promotion of non-prescription consumer healthcare products have been combined under this section. Previously these had been treated separately in sections 5 and 6.

### **Section 5.1**

The general principles governing advertising and promotion to both consumers and healthcare professionals are covered in sections 5.1.

Minor changes have been made to the wording to improve consistency.

### **Section 5.2**

Numbering has been introduced and one part now incorporated in 5.1.3 and explanatory notes.

### **Section 5.3**

Now refers to Scheduled substances and internal analgesics from Section 6. Minor changes have been made to the wording to improve grammar and the examples have been moved to the Explanatory Notes

The specific requirements for consumers and healthcare professionals are then dealt with separately in sections 5.4 and 5.5 respectively.

### **Section 5.4**

Explanatory notes now include the procedure for the approval of advertisements required by the TG Act and Regs.

Minor changes have been made to the wording to improve consistency.

#### **Section 5.4.4.2**

**Rationale:** Clarification : Some companies distribute products on behalf of sponsors.

#### **Section 5.4.4.5**

**Rationale:** Deletion because an unbranded advertisement cannot mention even the product name.

#### **Section 5.4.4.6**

**Rationale:** Deletion because appropriate programs are suitable for healthcare professionals such as pharmacists.

## **Section 5.5**

The April 2001 version separated the requirements for advertising of schedule 2 and schedule 3 products. This was repetitive since most of the requirements were the same, with only a few additional requirements for schedule 3. In this new version the requirements for schedule 2 and schedule 3 have been combined and a short paragraph added to address the additional requirements for schedule 3 products.

Minor changes to the wording have been undertaken to remove ambiguity and to improve clarity.

### **Sections 5.5.1 and 5.5.2.1 (in relation to the statements proposed to be deleted)**

**Rationale:** Deletions because these requirements are stricter than for advertisements to consumers.

## **Section 6 CONSUMER MEDICINES INFORMATION**

The number has changed but the content is the same as in the April 2001 version.

## **Section 7 ADMINISTRATION OF THE CODE**

New numbering. Text has not changed.

## **Section 8 COMPLAINTS**

New numbering. Flow charts of the complaints process have been introduced and the text has not changed.

## **Section 9 SANCTIONS**

New numbering. Text has not changed.

## **Section 10 RIGHT OF APPEAL**

New numbering. Text has not changed.

## **Section 11 MONITORING OF ADVERTISING**

New numbering. Text has been expanded to accord with the procedures adopted since this Panel was established.

## **Index**

An index has been included to assist with seeking specific topics.