THE PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA INC.
BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

FAXED 29/9/99

29 September 1999

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The Acting General Manager
Adjudicating Branch
ACCC
PO Box 1199
Dickson ACT 2602

Dear Mr Hones

PMAA CODE OF PRACTICE AUTHORISATION A90549

Thank you for your feedback on the proposed amendments to the PMAA Code of Practice and also for forwarding copies of previous correspondence between yourselves and Mr Alan Limbury regarding a change in the arrangements. We wish to apologise for this oversight.

I attach copies of the relevant pages reflecting the corrections you have proposed.

I have discussed your comments in relation to the proposed amendments to clause 8.4 with our legal adviser, Mr Alan Limbury.

- The reference to "nominee" rather than "representative" reflects more accurately the independence of this member of the Complaints Panel from any organisational dictate and is more appropriate nomenclature in this instance.

- The representative from the Dept of Health and Aged care had always had observer (and hence non-voting) status under the self-regulatory arrangement. Furthermore the TGA is not to be taken to be bound by any decision of the Panel. The proposed amendment merely clarifies this.

- The Complaints Panel is an independent body and it would be inappropriate for the PMAA Secretariat (Executive Director and other representatives) to be afforded voting powers as this would materially affect the independence of the Complaints Panel. Again this had always been the case and the proposed amendment serves to clarify their status as advisers to the Panel.

ACCC
- 5 OCT 1999

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CMI is a specialised subject which would necessitate the presence of an expert in the field in the event of this matter becoming a subject of complaint before the Complaints Panel. The CMI expert is an adviser (with observer status) to the Panel and the insertion of "non-voting" is not removing any existing powers.

The rationale for the proposed amendment to clause 9.3.2 in relation to the lodgement fee is to avoid amendments to the Code every time the lodgement fee is revised. The lodgement fee serves a dual purpose, ie. as a deterrent against vexatious complaints and also to cover administrative costs. The intention is certainly not to generate profit or to deter legitimate complainants. The PMAA Executive Committee has not considered any changes to this lodgement fee.

I trust that this will clarify the points you raised. Please do not hesitate to call me if you require further information.

Your sincerely

Deon Schoombie
Advertising Services Manager

Corrected Copy

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~~ does 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, 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, 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.~~

- ***"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 counseling 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).***

- ~~**"Professional Advertisements"** means one of the three categories of advertisements defined below and directed at healthcare professionals:~~

  ~~**Full Disclosure Advertisements** - the effect of which is to communicate the full text of product information as required by any applicable conditions of registration;~~

  ~~**Abridged Disclosure Advertisements** - the effect of which is to remind the reader of the name of the proprietary medicine, its indication(s) for use, including safety related statements, and some elementary commercial information;~~

  ~~**Short Advertisements** - the effect of which is to communicate commercial information only, such as details of packaging, pricing, trading terms or marketing incentives.~~

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

- **"Code"** means the PMAA Code of Practice, ***and includes (unless the context requires otherwise) the Therapeutic Goods Advertising Code***

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

- **"Complaints Panel"** means the PMAA Code of Practice Complaints Panel.

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

Corrected copy

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) ~~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 ***Pharmacist Only Medicines*** (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 *Pharmacist Only Medicines* (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 ***Pharmacist Only Medicines*** (Schedule 3) ~~products~~ may detail the condition, conditions or class of condition where ***Pharmacist Only Medicines*** (Schedule 3) ~~treatments~~ have become available or where new indications for ***Pharmacist Only Medicines*** (Schedule 3) ~~treatments~~ are allowed.

- Claims must focus on building consumer awareness that certain treatments are available.

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

- The indirect advertisement will contain one cautionary statement from each of the following categories:

  Category 1

  "Consult your pharmacist and/or doctor"
  "Seek your pharmacist's and/or doctor's advice"
  "Ask your pharmacist and/or doctor for advice about suitable products for you"

  Category 2

  "Always read the label"
  "Read label instructions carefully"
  "Make sure you understand the labeled instructions"

Or words to the same effect.

Corrected copy

	Maximum: $50,00020000.00

~~[1] a breach of the Code that has no safety implications and will have no effect on how consumers or healthcare professionals view the product or its competitors~~

~~[2] a breach of the code with no safety implications but will impact on the perceptions of the consumer or healthcare professionals regarding the product or competitor product.~~

~~[3] a breach of the Code that has safety implications and/or will also have a major impact on how consumers or healthcare professionals view the product or competitor products~~

~~[4] when a similar breach is repeated in the promotion of either a particular product, or any product of a company, which had been found to be in breach of the Code within the preceding 24 months. (This clause does not apply to minor breaches).~~

10.2.4 Failure of the offending Member to comply with any of the above sanctions shall entitle the Complaints Panel to direct the Association to publish in the next edition of the Association's Newsletter details of the breach of the Code and the Association's consequent requirements for remedial action as described in 10.2.1, 10.2.2 and 10.2.3.~~10.1.1.1 , 10.1.1.2 and 10.1.1.3.~~

10.2.5 Continued refusal by the offending Member to undertake the required remedial action/s shall entitle the Complaints Panel to direct the Association to publish details in the trade press of the Member's breach of the Code, the Association's requirements for remedial action/s and the prospect of suspension or expulsion from the Association in the event of the continued failure by the Member to comply, and notify the ACCC if deemed necessary.

10.2.6 One or more of the following sanctions against a Member notified in writing may be applied by the Complaints Panel where breaches of Clause 7.3 of the Code have been established.

10.2.6.1 That the Member discontinue immediately distribution of the ***CMI*** ~~CPI~~.

10.2.6.2 That corrective measures be taken to redraft the ***CMI*** ~~CPI~~ in accordance with the findings of the Complaints Panel.

10.2.6.3 That the Member issue retraction and/or corrective statements, as appropriate, flagging the redrafted ***CMI*** ~~CPI~~.

10.2.6.4 That the matter be referred to TGA as a breach of Schedule 13

10.2.7 Abuse of the Code

If in the course of hearing a complaint lodged by an Industry member, the Complaints Panel considers that the complaint has been submitted as a