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16 July 1993

J P O'Neill Esq
Senior Assistant Commissioner
Mergers & Adjudication Branch
Trade Practices Commission
P O Box 19
BELCONNEN ACT 2616

FAXED

Dear Sir

The Proprietary Medicines Association of Australia Inc - Application for Authorisation A90549

This letter constitutes the PMAA's response to submissions enclosed with your letter of 16 June 1993. If the Commission has received any further submissions, we would appreciate it if you would send us copies and allow PMAA an opportunity to respond to them.

Composition of the complaints panel

Before commenting upon the various submissions separately, we address the most significant issue, raised by several respondents to the Commissions request for comment, namely the composition of the complaints panel.

Having considered all the comments made, the PMAA Executive is prepared to amend the code so as to make provision for a consumer representative from a broad-based, representative consumer/community organisation to be a member of the complaints panel and for a representative of the Department of Health, Housing, Local Government and Community Affairs to be appointed to the panel as an observer, as

recommended by the TPC in its final report on self-regulation at p.75. If the Commission is prepared to authorise the code on this basis, the PMAA will make the necessary amendment to clause 7.4 of the code.

We now turn to other issues raised by the submissions.

A Submission from the Department of Clinical Pharmacology and Toxicology - Hunter Area Health Service on behalf of the ASCEPT Council Clinical Working Party.

A1 As to the way in which complaints get to the Complaints Panel (the 'main problem' of the working party) there seems to be an impression that the decision of the Executive Director can prevent complaints coming before the Panel. The Commission's attention is drawn to paragraphs 8.2.9 and 10.4 of the Code.

B Submission from the Pharmaceutical and Rational Use of Medicines Committee ('PHARM')

Introduction (Section 2)

B1 PMAA is not disposed to amend the Code as suggested. The Commission needs no reminder that its function

> 'is not to require the design of an ideal system of code administration within the ...industry, but to determine whether the proposed code...fulfil[s] the statutory tests prescribed by Sec. 90 of the Trade Practices Act.
>
> In performing its task, the [Commission] should look to matters of real substance and materiality.'
>
> (Re Media Council of Australia (No. 3) (1989) ATPR 40-933 at p.50,123)

Administration of the Code (Section 7)

B2 In addition to the change we have foreshadowed to the composition of the complaints panel, it is now intended that the Marketing and Ethics Committee will participate in the annual review of the code (see our initial submission para 42 and code para 7.5).

Complaints procedure

B3 The Executive Director will circulate to the Complaints Panel and to the Marketing and Ethics Committee monthly summaries of all complaints received and their disposition.

Right of appeal

B4 Agreed.

C **Submission by Public Interest Advocacy Centre**

Objectives of the Code

C1 PMAA's requirements are stated in clause 5.3 of the Code. PMAA is involved in developing guidelines for consumer information regarding OTC products. See attachment 1. The issue is much wider than and quite separate from the Code.

Advertising

C2 As to 5.1.4, members will determine whether requests to them for substantiation of claims are bona fide. If a person is dissatisfied with a refusal or failure to provide substantiation without delay, a complaint of breach of 5.1.4 may be made to PMAA, to be handled in accordance with the Code.

C3 As to 5.1.5, conduct of this kind is regulated under codes administered by the Media Council of Australia.

Administration of the Code

C4 As to 8.1, we refer to paragraph B1 above. The PMAA's record in handling complaints is a good one and is ground for concluding that, if authorised, the proposed procedure will likewise be fair, timely and accessible.

D **Submission by the Australian Consumers' Association**

Background

D1 There seems to be some confusion between the pre-clearance function of PMAA and enforcement of the PMAA Code. PMAA pre-clears radio and TV advertising in accordance with the Media Council of Australia's Therapeutic Goods Advertising Code under delegation pursuant to the Broadcasting Act. This activity is not the subject of this authorisation application. For members, PMAA also pre-clears print, cinema, outdoor, narrowcast (closed circuit video or audio network) advertising to the same standard. Attachment 2 comprises minutes of a meeting in May this year to review PMAA's broadcast pre-clearance performance since 1991.

D2 The suggestion that the PMAA self-regulatory scheme should cover the full range of promotional activity (in other words, every promotional piece emanating from every member (and non-member?) by way of pro-active monitoring (taken to mean pre-clearance) is beyond the resources of PMAA. The primary responsibility for compliance with the law and the Code rests with the individual company concerned.

D3 ACA refers to the possibility of 'capture' of the pre-clearance procedure, without spelling out what it means. In this respect it repeats a similar comment in the Trade Practices Commission's final report on the self-regulation of promotion and advertising of therapeutic goods (July 1992) at p77.

D4 The possibility that members of the industry might be able to skew the pre-clearance process in their favour as a result of PMAA being given 'full responsibility for print media advertising' in addition to its delegated functions in relation to broadcast media pre-clearance is highly unlikely for the following reasons.

D5 First, members and non-members of PMAA are vigorous competitors who do not remain idle if a rival's advertisement is published in breach of the code or in breach of the law.

D6 Second, pre-clearance does not guarantee publication, since neither FARB nor FACTS nor the print media proprietors are bound to publish advertisements pre-cleared by PMAA.

D7 Third, denial of pre-clearance does not guarantee denial of publication, since advertisers refused pre-clearance by PMAA may appeal to the Therapeutic Goods Advertising Code Council and thereafter to the Minister. (There is strong consumer representation on the Therapeutic Goods Advertising Code Council.)

D8 Fourth, consumer (or any other) dissatisfaction with the standard of advertisements pre-cleared by PMAA and subsequently published may be manifested in innumerable ways. Consumer organisations do not have difficulty in obtaining publicity for their views or in gaining access to politicians and enforcement agencies. Those who believe in the possibility of 'capture' will no doubt be both vigilant and vocal.

D9 Fifth, there is no reason to believe PMAA is not and will not be sensitive to changing community standards.

D10 As to community concern about increasing use of over the counter drugs such as analgesics, the regulation of such drugs and their availability are within the province of the Therapeutic Goods Administration.

Transparency

D11 Once the code can be fully implemented (upon authorisation being granted) PMAA intends to make the code publicly known and provide information to the public as to how complaints may be made.

Monitoring

D12 It is beyond the resources of PMAA to monitor compliance through, for example, random checking. Its scheme of pre-clearance and complaints handling, regular code review and transparency should be considered in light of the matters mentioned in D5 to D9.

Industry medical representatives

D13 The code covers the activities of medical representatives through the definition of 'advertisement', which includes 'every form of communication, whether .... in the spoken word, or in any other way' (clause 1).

Advertising and children

D14 FACTS is responsible for allocating appropriate time slots to individual advertisements. No amendment to the code is necessary.

Code Administration Committee

D15 The Marketing and Ethics Committee, which, for this purpose, will include the external members of the complaints panel, will perform this function.

Independent Appeals Mechanism

D16 PMAA is not satisfied the present appeals mechanism will not work satisfactorily. Some regard must be had for PMAA's independence in administering its code, as the Commission has recognised in its report on self-regulation. Should experience show that the system is not operating satisfactorily, the Commission will, no doubt, wish to make suggestions (which would be welcomed) as to how it may be improved. Should it become necessary, the Commission has power to review its authorisation under section 91(4).

E Submission from Australian Pharmaceutical Advisory Council ('APAC')

E1 See paragraph A1.

F Submission from the Australian Drug Evaluation Committee ('ADEC')

F1 As to 6.1.6, the rationale for the exemption in relation to unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use lies in the vigorous competition between members of PMAA and non-members. Non-members enjoy the dominant market shares in these fields. Members of PMAA would therefore be at a severe commercial disadvantage if prevented by this rule from engaging in this particular form of competition with non-members, so long as non-members, who are not subject to the PMAA code, are free to do so. An example of unscheduled therapeutic goods for external use is sunscreens which, having no systemic effect, compete in the wider market for toiletries.

F2 The Trade Practices Commission has recommended that the Nutritional Foods Association of Australia devise a code on this issue. Any such code would be of general application. The PMAA is participating in the consultative process in relation to this proposal.

F3 If a 'start should be made' in trying to establish a national basis for inappropriate [sic] promotion of such products, the removal of this exception to 6.1.6 would be an inappropriate start. It would not be of general application in the industry. It would tilt the present level playing field against those PMAA members who chose to continue their membership. PMAA is therefore not disposed to make such an amendment since it believes any changes should apply to all market participants.

G **Submission from the Department of Health, Housing, Local Government and Community Services**

Introduction (section 2)

G1 See B1.

Objectives (section 3)

G2 See B1.

Advertising of Schedule Three Items (5.3)

G3 At the next review of the code the Marketing and Ethics Committee will consider bringing 5.3.2.2 and 5.3.2.3 into line with the APMA code to ensure consistency of approach and to accommodate Dr Harvey's concerns. Meantime, the Commission is asked to authorise the code in its present form.

General principles etc (6.1.6, 6.1.7)

G4 See F1 to F3.

Complaint procedures (8.2.8)

G5 See B3.

Sanctions (section 9)

G6 The issue of pecuniary penalties will be considered at the next code review. Existing sanctions are considered to have 'teeth' since overseas parent companies are concerned if a subsidiary is expelled or otherwise seen to be 'in trouble' with a local industry organisation. Embarrassment and injury to reputation amongst the peer group are powerful influences which should not be overlooked. The Commission is asked to authorise the code as it stands and on the basis that consideration will be given to the possible added sanction of pecuniary penalties.

H **Submission from the Pharmaceutical Society of Australia ('PSA')**

Definitions

H1 '...we do not feel that there is any value in referring to a particular clause in a

Code merely because it appears to us the clause might be more finely tuned or better expressed than it presently reads. In performing its task, the [Commission] should look to matters of real substance or materiality.'

Re Media Council of Australia (No. 3) (1989) ATPR 40-933 at 50, 123

Promotion

H2 See H1.

Children

H3 The problems envisaged could well arise but to attempt a definition may not alleviate them. Experience alone will see whether this is an area of contention requiring amendment.

Sanctions and coverage

H4 The code applies to non-members by consent. PMAA cannot apply the code to non-consenting non-members.

I **Submission from Consumers' Health Forum ('CHF')**

I1 This supports the application.

Yours faithfully
MINTER ELLISON MORRIS FLETCHER

Alan L. Limbury

Alan L Limbury

CONSUMER INFORMATION

The need for improved levels of information to consumers on the use of medicines is a fundamental part of the philosophy and policy document entitled 'Quality Use of Medicines' produced by the PHARM Committee. The concerns are with increasing both access to information and the quality/useability of the information.

The concerns were given specific reference in the recommendations of the Baume Report which set timeframes for the implementation of consumer information provision for prescription products. The Jenkins Report later set time frames for the implementation of consumer information for Schedule 3 products, the 'pharmacist only' category of OTC medicines.

The work of the PHARM Committee and the reports referred to above mirrors overseas trends and seeks to pursue similar objectives in the Australian context.

With the concentration in the European Community on harmonised approaches to consumer information, local authorities have seen fit to accept the need to refer to international developments. The APMA succeeded in having a slightly modified version of the European Guidelines incorporated into Australian regulation governing consumer information for prescription pharmaceutical products.

In the case of non-prescription products, no regulations currently exist nor are they envisaged. Industry has voluntarily accepted the need to and the responsibility for developing guidelines for consumer information in the context of OTC products. A PMAA working party has been developing and testing such guidelines over the last eight months, establishing a clear need for specific guidelines for OTC products. It is industry's view that promulgation of the guidelines, once finalised, and supporting educational activities will lay a strong foundation for consumer information for OTC products to be self-regulated by industry.

In carrying out its research, the working party has consulted widely and has also taken account of the activities of other groups involved in the area, e.g. the PHARM Consumer Information Working Party (on which PMAA is represented).

PMAA is also about to undertake a major research project involving the production of a directory of OTC consumer information. The first stage will involve collection of material and the creation of a databank. This will be followed by evaluation of the materials, publication and distribution of a directory.

The project will not only identify the extent of materials available, but will, in later stages, facilitate the development of improved consumer information.

MINUTES OF A MEETING TO REVIEW PMAA 'S EXPERIENCE IN PRECLEARING ADVERTISEMENTS FOR MEDICINES FOR BROADCAST ON RADIO AND TELEVISION AS DELEGATE OF THE HEALTH SECRETARY UNDER SECTION 100 OF THE BROADCASTING ACT, MAY 1991 - MAY 1993.

Date: 28 May 1993
Venue: 12th Floor Conference Room, 65 Berry Street, North Sydney
Present were: Juliet Seifert - PMAA
Clare Martin - PMAA
Trudi Bean - FACTS
Barbara Duffy - FARB
Jeff Dutton - TGA

1. Preliminary - The delegation to the PMAA of the Health Secretary's preclearance function in relation to radio/tv advertisements for medicines under the Broadcasting Act was made on the basis that arrangements would be reviewed following two years experience with the delegation. The intention of the the current meeting is to attempt an objective assessment of the PMAA preclearance function.

2. Interaction with relevant organisations:
(a) TGA - Initial training was provided by TGA during the handover period, in May 1991. As PMAA expertise has increased, consultation with TGA has decreased. Currently, TGA & PMAA communicate once or twice weekly concerning advertising matters.
(b) FACTS - PMAA has good cooperation with FACTS and communicates with them on a daily basis.
(c) FARB - A very satisfactory relationship exists with FARB which tends to interpret the Code in the same way. Daily interaction.
(d) CTFAA - Does not have much interaction with CTFAA since there have been very few problems with radio/tv cosmetic advertising bordering into the therapeutic claims area.
(e) APB - satisfactory interaction, which is increasing particularly since PMAA has instituted an initial checking procdure of PMAA members' advertisements (in addition to where mandatory APB clearance applies.)
(f) Sponsors including non-PMAA sponsors - PMAA endeavours to treat all sponsors uniformly; relationship with NFAA is satisfactory.

A Clearance Officers Meeting (concerning all advertising codes - Ethics, Slimming, T.G.s, Alcohol) meets quarterly under the chairmanship of Trudi Bean (FACTS) as a result of a TPC suggestion that areas of mutual concern should be discussed. Clearance officers attend from Facts, Farb, PMAA (t.g.s only) outdoor advertising, & cinema. The mtg reports to the MCA. Garvin Rutherford (MCA) has details.

3. Role of the PMAA Monitoring Committee - The Monitoring C'tee has not been needed as the intended functions of the c'tee are provided for by other mechanisms. The Code Council provides a preliminary review if needed. PMAA's Marketing & Ethics C'tee monitors how the Code is affecting members. The Advertising Stds Council provides a formal mechanism for determination of issues/complaints. The Broadcasting Act also provides an appeals mechanism.

4. In-house compliance mechanisms of product sponsors - Large companies (nearly all PMAA members) have in-house compliance mechanisms, and PMAA has conducted seminars for companies on the Code and assisted some to upgrade their internal arrangements. Of course, PMAA examines all adverts submitted to it for compliance with the Code, whether the submitting company has an in-house vetting system or not.

5. Objectivity of the preclearance process [i.e. the need to ensure that there is not a bias towards industry both in the perception and the reality; in other words is the public interest being adequately addressed] - Levels of formal complaint are low, as evidenced by complaints to the Code review process, the Advertising Stds Council, and to the Minister (see below.) However, it is noted that advertisements concerning the Advertising Stds Council complaints mechanism are not broadcast on television.

6. Radio/tv advertisements referred via PMAA to the TGACC "review process" and outcome - 1 advert referred, a Strepsils TV advert. The TGACC review upheld the PMAA position. PMAA always indicates to advertisers that there is a review process and a complaints process.

7. Complaints to the Advertising Standards Council concerning radio/tv advertisements for medicines:
(a) May 1989 - May 1991: 2 (no adjudication on 1; 1 withdrawn)
(b) May 1991 - May 1993: 14 (1 upheld; 13 not upheld)

8. Appeals to the Minister under the Broadcasting Act - Nil

9. Trends in radio/tv advertising of medicines - Seasonal trends in relation to winter/summer products. More recent reapprovals of current adverts rather than new adverts, possibly related to the economic situation. Increase in number of advertorials (or infomercials.) Activities of the Doctors Television Network (which operates outside the Broadcasting Act) were noted. DTN is not required to accede to those aspects of the Code which are not adopted by law. Thus, DTN offers non-PMAA sponsors the opportunity to have professional endorsement of their products. PMAA members submit DTN adverts to PMAA for checking and amendment for compliance with the Code. Other sponsors do not, and therefore are not constrained by all Code requirements.

10. Radio/tv advertising of therapeutic devices - Not obliged to refer to PMAA in terms of legislation, nevertheless PMAA clears TV adverts by arrangement with FACTS. Does not clear radio adverts because cannot justify the preclearance fee.

11. Statistical information, May 1991 - May 1993 -

(i) number of radio advertisements submitted = 154
not approved = 7
withdrawn = 4
on hold = 8
original = 138
revisions = 16

(ii) number of television advertisements submitted = 336
(inclusive advertorials = 32, informercials = 2)
not approved = 7
withdrawn = 4
on hold = 12
original = 262
revisions = 74

A submission consists of one advert & 6 variables for radio, and one advert and 4 variables for television.
(iii) average approval time - 5 working days for new adverts; same or next day for re-approvals.
(iv) current pre-clearance fees - TV $400 (for initial concept plus 1 cutdown/variation); radio $150 (for initial concept plus 6 cutdowns); revisions - 50% of fee; advertorials $300 for first 60 secs plus 25% for each additional 60 secs e.g. 3min $450; narrowcast media - no charge.

12. Conclusion - The delegation to the PMAA of the Health Secretary's preclearance function under the Broadcasting Act appears to be operating satisfactorily and it is therefore appropriate to continue the delegation indefinitely. A further meeting to monitor the function, in two years time, would be useful.

Jeff Dutton
Compliance Branch
Therapeutic Goods Administration