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Trade Practices Commission

Determination

Application for authorisation

under sub-section 88(1) of the Trade Practices Act, 1974 by

The Proprietary Medicines Association of Australia Inc

In relation to its code of practice

Application No: A90549

Commissioners: Broome, Hilton

File No: CA93/4

Date: 27 January 1994

PO Box 19, BELCONNEN ACT 2616

Trade Practices Commission

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Summary

The Proprietary Medicines Association of Australia Inc (PMAA) lodged an application under section 88(1) of the Trade Practices Act 1974(the Act), for authorisation of its code of practice (the code). Application No A90549 seeks authorisation of the code, insofar as provisions of it are, or may be, exclusionary provisions, or have or may have the effect of substantially lessening competition within the meaning of section 45 of the Act.

PMAA has maintained a code of practice for its members' advertising and promotion of over-the-counter medicines (known as proprietary medicines) since 1977. The code was reviewed from time to time, and in October 1991 a new code was adopted by PMAA members, subject to authorisation by the Commission.

The code is intended to establish the basic parameters that guide member companies in the conduct of their business and particularly in matters of advertising and promotion of proprietary medicines. It is directed at every form of communication by the industry to consumers and health professionals.

The therapeutic goods industry is heavily regulated at State and Commonwealth levels in a wide range of activities, including advertising and promotion. The code adopts the statutory requirements and goes beyond them in two ways.

- 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).
- Some provisions on advertising and promotion are more restrictive than the law.

The Commission agrees that the regulation of the advertising and promotion of therapeutic goods is necessary and protects the public, This is achieved by legislation. This code extends the effect of the legislation and provides for industry self-enforcement of the legislation as well.

The Commission examined the ability of the code to deliver public benefit against a number of criteria, consistent with its approach to self regulation as set out in its report, *Self-regulation in Australian industry and the professions.* It also took into account a number of actions which PMAA advised it would be prepared to undertake with respect to the code if the code were authorised, and found that the conduct would result, or would be likely to result, in public benefits.

Two of the extra-statutory provisions of the code, however, were found to be unspecific and therefore capable of being applied in a manner either inconsistent with the objectives of the code, or anti-competitively, or both. They are clauses 5.2 and 6.1.1 which provide, respectively, that 'no advertisement will unfairly denigrate or attack any other product, goods or services', and 'methods of promotion must never be such as to bring discredit upon, or reduce confidence in, the industry.' This, coupled with a procedure for appeal against sanctions levied by either the complaints panel or the committee of management which lacks the appearance of independence, contributed, the Commission's view, to the anti-competitive detriment, or likely anti-competitive detriment, of the conduct.

The Commission considered that the anti-competitive detriment would be outweighed by public benefit if the code were amended in a manner which redressed these deficiencies, in addition to those amendments PMAA had advised that it would be prepared to make to the S3 products advertising provisions and the composition of the complaints panel.

The Commission issued a draft determination on 29 November 1993 proposing to grant authorisation to the code subject to the following conditions :

That PMAA revise or amend the code

- to provide 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;
- to make clauses 5.3.2.2. and 5.3.2.3 (advertising of S3 products) consistent with the APMA code and WHO ethical criteria;
- to remove or clarify clauses 5.2 and 6.1.1; and
- provide that appeals from decisions of the complaints panel and the committee of management be heard by an agent independent from the industry.

The Commission required further that PMAA undertake those actions it had offered to carry out if authorisation were granted, as a condition of authorisation. Namely, that PMAA would

- consider the issue of pecuniary penalties on the next occasion on which the code is reviewed;
- have the executive director circulate to the complaints panel and to the marketing and ethics committee monthly summaries of all complaints received and their disposition;
- make the code publicly known and provide information to the public as to how complaints may be made; and
- have the marketing and ethics committee participate in the annual review of the code.

In response, PMAA agreed to all the Commission's conditions except for those relating to clauses 5.2 and 6.1.1, and to appeals. PMAA requested a pre-decision conference, where these and other issues were discussed. PMAA requested that authorisation be granted in a form that enabled the code to be amended following annual review, and that a time limit not be imposed on the authorisation.

Following the pre-decision conference, the Commission remained of the view that the conditions it had initially proposed should stand, It was disposed to grant PMAA's requests concerning the form of the authorisation provided it could do so within the terms of the Act and provided PMAA agreed to conduct the reviews of the code in a manner acceptable to the Commission.

PMAA accepted the Commission's conditions.

The Commission therefore grants the authorisation sought by PMAA.

1. The application

1.1. The Pharmaceutical Manufacturers Association of Australia (PMAA) lodged an application for authorisation (A90549) with the Trade Practices Commission (the Commission) on 1 February, 1993, pursuant to sub-section 88(1) of the *Trade Practices Act 1974* (the Act).

1.2. It seeks authorisation of its code of practice insofar as provisions of it are, or may be, exclusionary provisions, or have the purpose, or have or may have the effect, of substantially lessening competition within the meaning of section 45 of the Act. A copy of the code and PMAA's submission in support of it are on the Commission's Public Register.

1.3. The code establishes basic parameters to guide members in advertising and promoting over-the-counter products (that is, medicines that can be sold legally to the general public without a prescription from a medical practitioner; known in the industry as 'proprietary medicines') to health professionals and consumers. Administrative matters affecting the operation of the Code, such as membership, committee of management, general meetings, etc are provided for in the rules of PMAA, which do not form part of the application.

The applicant

1.4. PMAA is the corporate representative and advocate for organisations involved in the production, advertising and promotion of proprietary medicines in Australia. Proprietary medicines are products produced for health and personal care, and include, but are not limited to, products which are available to the public without medical prescription, and which are commonly referred to as 'over -the-counter' (OTC) products.

1.5. The categories of membership of PMAA are:

(a) ordinary — companies conducting manufacture, formulation, importation, registration and/or marketing functions of proprietary medicines ('OTCs'); and

(b) associate — other organisations such as wholesalers, fine chemical suppliers, packaging equipment suppliers, contract manufacturers, regulatory affairs consultants, and advertising agencies.

1.6. Membership of PMAA is voluntary and is obtained by application to the committee of management and payment of subscription, with fees (payable by 1 July annually and based on annual turnover) ranging from $2 500 for turnover of less than $800 000 to $45 000 for turnover exceeding $50 million for ordinary members. A flat fee of $2 000 for associate members applies.

1.7. PMAA has 44 ordinary members who represent approximately 95 per cent of the turnover in the PM product industry, and 23 associate members. Sales of OTCs in Australia in 1990-91 approximated $420 million. Australian manufacturers' share of this was approximately 75 per cent.

1.8. As a condition of membership, members are required to abide by the rules, adhere to the code (which is the subject of this application) and comply with the *Guidelines for Tamper Resistant Packaging of Proprietary Medicines*.

1.9. PMAA stated that benefits are provided to members through its broad role, which is to:

- build a positive climate for OTCs with government, opinion leaders and the community;
- act as an effective lobby and be the acknowledged point of consultation with Commonwealth and State governments on PM affairs;
- provide a review mechanism and early warning system on technical, regulatory, legal and social developments affecting OTCs, both in Australia and overseas;
- ensure members' compliance with industry codes to maintain the PM industry's high level of performance in relation to self-regulatory matters; and
- commission research to assist in promoting understanding of the role of self-medication in Australia's health care system.

In addition, PMAA stated that it can provide the following benefits to members:

- provide members with information and advice on specialised PM issues involving marketing, advertising, promotion, distribution, individual regulatory or technical problems;
- act, where appropriate, as an advocate or conciliator or lobbyist — at arms length --- on a particular issue; and
- provide regular confidential mailings on issues of current interest and concern, newsletters on PM subjects, and updates on regulatory matters affecting PM products.

1.10. PMAA is governed by a committee of management consisting of representatives elected by active member companies, and its activities are conducted under the direction of sub-committees which attend to the scientific and technical matters, public affairs, inter-industry relations and other functions. The committee has twelve members — twelve representatives of ordinary members of whom three are office bearers.

History of the code

1.11 PMAA has maintained a code for its members' advertising and promotion of PM products since 1977. The code has been reviewed from time to time, with a major review undertaken in 1989. A new code was adopted by members in October 1991, subject to the Commission's authorisation. It was last revised in October 1992.

1.12. In July 1992 the Commission issued a report entitled *Promotion and advertising of Therapeutic goods,* following a request from the Minister for Consumer Affairs to undertake a review of the existing self-regulation arrangements dealing with the advertising and promotion of therapeutic goods. The Commission separately assessed the self-regulatory mechanisms pertaining to each of 4 discrete categories of therapeutic goods (prescription drugs, non-prescription drugs, medical devices and natural therapies). The Commission noted that the PMAA's code had been expanded to apply to all promotional and advertising activities of members in all media to all audiences.

1.13. The Commission made the following recommendations with respect to the code:

(a) that the code be re-assessed two years from the date of the Commonwealth Government response to the report;

(b) that the constitution of the PMAA complaints panel be expanded to include a consumer representative from a broad-based, representative consumer/community organisation, and that a representative from the Department of Health Housing & Community Services (DHHCS) be appointed to the panel as an observer;

(c) that appeals be heard by an agent independent from the industry;

(d) that there should be allowance for the complaints handling mechanism to be applied to non-member companies with their consent;

(e) that provision should be made for the referral of complaints against non-PMAA members to DHHCS or the Commission;

(f) that a monitoring program be developed, with regular publication of results;

(g) that the PMAA publicise the existence of all codes relevant to all PM medicines and the relevant complaint handling mechanisms;

(h) that once the PMAA arrangements under its code have achieved the necessary coverage, assembled sufficient independent expertise, and put effective monitoring and review mechanisms in place, consideration be given to giving PMAA the responsibility for pre-clearance of print media advertising;

(i) that the complaints panel monitor the PMAA pre-clearance process annually and advise/adjudicate on disputes;

(j) that the code incorporate a specific code administration committee (membership of which would include representation from a broad-based consumer/public interest group and DHHCS) and its terms of reference; and

(k) that the codes of the Australian Pharmaceutical Manufacturers Association, PMAA, Nutritional Foods Association, and the Media Council of Australia contain a requirement that the administrators of the schemes meet at least once a calendar year with representatives of the Commission and DHHCS to discuss issues of mutual concern.

1.14. The Government has not responded to this report to date.

Regulatory framework

1.15. The therapeutic goods industry is heavily regulated at Commonwealth and State levels. Specific government regulation occurs through the Pharmaceutical Benefits Scheme and through a range of controls covering the import, manufacture, marketing and advertising of pharmaceutical products. The *Therapeutic Goods Act* and Regulations 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.

1.16 There are four discrete categories of therapeutic goods:

- prescription drugs;
- non-prescription, or over-the-counter medicines;
- medical devices; and
- natural therapies.

1.17 Where the use of therapeutic products has potential health risks as well as benefits, their production and role is subjected to various forms of government regulation. The selling of pharmaceuticals is restricted to protect consumers from possible health risks and deception. For example, drugs are subjected to testing and approval by the health authorities and the product information which must be provided is also subject to approval by them. Government regulations require that certain classes of drugs can only be supplied by registered pharmacists on the basis of a medical practitioner's prescription whereas other classes may be purchased over the counter.

1.18. In addition, there are industry self-regulation arrangements in place to ensure that appropriate information on therapeutic goods is available to doctors, pharmacists and consumers. The Commonwealth Government took the view that a more cost effective approach to addressing the cost of unregulated promotion of therapeutic goods was likely to be through industry self-regulation, and in 1987 ceased direct regulation in this area in favour of self-regulation on a trial basis.

1.19. Each of the categories of therapeutic goods has its own trade association, of which APMA and PMAA regulate advertising and promotion.

1.20. With respect to the PM category the controls are as follows.

- *PMAA code of practice* — controls all advertising and promotional activity by members in all media and to all audiences.
- *Therapeutic Goods Advertising Code (TGAC) of the Media Council of Australia (MCA)* — controls advertising to consumers through print and broadcast media and by display by MCA members.
- PMAA on delegated authority of DHHCS (using the MCA Therapeutic Goods Advertising Code) pre-clears advertising to consumers through the electronic media. PMAA's exercise of this delegation was reviewed in May 1993 and renewed indefinitely.

1.21. PMAA pre-clears radio and television advertising and, for members, print advertising. Non-members must have print advertising pre-cleared by the Australian Publishers' Bureau.

Summary of provisions of the code of practice

1.22. The code addresses standards of commercial conduct generally, and advertising and promotional practices in particular, of members of PMAA. The code is in 2 parts, A and B. Part A deals with the code and its application: principles of practice, advertising and promotion. Part B deals with the management of the code: administration, complaint procedure, sanctions, and appeal.

1.23. The principal provisions are summarised below.

Objectives

- To assist members to inform consumers about available proprietary medicines (OTCs) responsibly.
- To uphold a high standard in the communication of information about OTCs.
- To ensure that all claims for OTCs are accurate, balanced, and based on sound and objective scientific considerations.
- To ensure that information is communicated in a way which promotes the responsible use of OTCs.

Principles of practice for members

These require that members:

- do not engage in any unfair or unconscionable conduct or commercial practices;
- ensure that they are familiar with, and comply with, the relevant Commonwealth or State legislation, regulations, or other legal instruments relevant to the industry;
- comply with the provisions of the Advertising Codes of the Media Council of Australia, the Code of Good Manufacturing Practice, and other relevant codes; and

- cooperate in the investigation of problems, in education programs, and with government authorities in regulation reviews and voluntary schemes.

Advertising principles

General principles — all products

- Information and medical claims about OTCs must be current, accurate, balanced, and must not mislead either directly, by implication, or by omission, and must be capable of substantiation.
- No advertisement shall offer to return money to dissatisfied users of OTCs.

Comparative advertising

- No advertisement will unfairly denigrate or attack any other product or service.
- Consumers should not be misled by comparative advertising, which should be based on previously substantiated facts and reflect the body of scientific evidence.

Advertising of Schedule 3 items

The Therapeutic Goods Regulations prohibit the advertising of these products directly to the public. They must be stored in pharmacies in areas to which the public does not have access and promotional or advertising material must not be visible to the public. Hence, advertising of Schedule 3 items should be directed only to pharmacists or medical practitioners, and must not be directed to pharmacy assistants, other non-qualified personnel, or the general public. Advertising of these products does not fall within the ambit of the TGAC of the MCA. However the PMAA code picks up and extends the provisions of the TGAC. Advertising of Schedule 3 products must, in addition to complying with the requirements of the rest of the code, conform to the requirements laid down in three broad categories: technical advertisements, abbreviated advertisements and commercial advertisements.

Advertising in non-broadcast electronic media

- Pre-clearance is required for electronic media advertising (including those through closed circuit video or audio networks in locations such as pharmacies, retail stores or doctors' surgeries).

Advertising in consumer print outdoor and cinema media

- Pre-clearance is required for consumer print/outdoor/cinema advertising, as well as clearance by the Australian Publishers' Bureau, Outdoor Advertising Association of Australia, or Australian Cinema Advertising Council, as appropriate.

Promotion

General principles — all products

- Promotion is not to bring discredit on or reduce confidence in the industry.
- Promotional material should not imitate the devices, copy, slogans, or general layout adopted by other manufacturers in a misleading , deceptive, or confusing manner.
- Promotion to the general public of prize competitions which are conditional on the purchase of OTCs are not permitted (except for promotional activity relating to unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use).

Scheduled substances and internal analgesics

- Promotion of Schedule 2 or 3 substances and internal analgesics should not be able to be construed as persuading consumers to purchase unnecessary or excess quantities of OTCs.

Children

- Promotion of OTCs to children is prohibited.

Administration

- PMAA is governed by a committee of management consisting of representatives elected by active member companies, and its activities are coordinated by the executive director and supervised by an executive sub-committee.
- The executive sub-committee is to nominate a code of practice complaints panel which is to comprise a trade practices lawyer, a nominee from the RACGP, a community pharmacist nominated by the Pharmaceutical Society of Australia (PSA), three members of the committee of management, and the executive director.
- The executive sub-committee shall at least annually review the code.

Complaint procedure

Complaint handling

- The executive director is to consider whether the advertising codes of the MCA may have been breached, and if this is likely, is to ensure that the Advertising Standards Council is aware of the complaint.
- If the executive director forms the opinion that a breach of the code may have occurred, the complaint is to be referred to the complaints panel.
- A complainant has a right of appeal where the executive director determines that no breach has occurred.
- Where it determines that a breach of the code has occurred, the complaints panel shall determine appropriate sanctions as provided by the code.

Guidelines for complainants

- In the case of externally generated complaints, complainants are encouraged to contact the member concerned before lodging a complaint.
- In the case of industry generated complaints, in the absence of an adequate reason for not undertaking dialogue with the member concerned, the complaint may not be accepted.

Annual report

- The executive director is to publish annually a report of all complaints, sanctions and appeals.

Sanctions

Sanctions to be applied by complaints panel

- An undertaking in writing to discontinue the practice.
- The issue of retraction statements and/or corrective statements or advertisements.
- PMAA to publish in its next newsletter details of the breach and PMAA's consequent requirement for remedial action.

- PMAA to publish details in the trade press of the member's breach, PMAA's consequent requirement for remedial action, and the prospect of suspension or expulsion from membership in the event of the member's continued non-compliance.

Sanctions to be applied by committee of management

In addition, the complaints panel can recommend to the committee of management that further sanctions be applied. These can include:

- suspension for a determined period;
- expulsion;
- notification to the overseas parent company of the offending member of its expulsion; and
- notification of the offending member's suspension and/or expulsion from PMAA to the editors of all trade journals.

Appeal provisions

- A member cannot reactivate any promotional activity which has been required to cease or to be withdrawn while appeal procedures are in progress.
- A disciplined member may appeal to the committee of management against sanctions proposed by the complaints panel and to members in general meeting against those imposed by the committee of management.
- A complainant, on being informed by the executive director that no breach of the code has been considered to have occurred, may appeal to the complaints panel.

Applicant's submission in relation to public benefit and anti-competitive detriment

1.24. The *Commonwealth Therapeutic Goods Act 1989* and regulations under it regulate advertising of therapeutic goods, including PM 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 MCA's TGAC.

1.25. PMAA submitted that to the extent that it simply adopts legislative requirements, it cannot lessen competition. It is, therefore, only to the extent that the code goes beyond the statutory requirements that the Code could have a potentially anti-competitive effect.

1.26. The code goes beyond the statutory requirements in two ways:

- 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
- some provisions on advertising and promotion are more restrictive than the law.

1.27. The extent to which the code creates additional restrictions on advertising and promotion are as follows:

Advertising

- Members are to provide claim substantiation promptly after request (clause 5.1.4).
- There is to be no advertising offering refund of money if dissatisfied (clause 5.1.6).
- No advertising is to unfairly denigrate/attack other goods/services (clause 5.2).

- Information is to be included in trade advertisements for S3 products (clause 5.3).

Promotion

- Promotion is not to bring discredit on/reduce confidence in the industry (clause 6.1.1).
- Prize competitions are to be limited (clauses 6.1.6 and 6.1.7).
- Advertisements for S2 and S3 products are not to persuade consumers to buy unnecessary products or products in unnecessary quantities (clause 6.2).
- No promotion to children (clause 6.3).

1.28. PMAA submitted that the additional restrictions and wider application of the code improve the quality of PM advertising and promotion without unduly restricting members' freedom to advertise and promote.

1.29. PMAA submitted that adherence to the code's objectives ensures:

- a responsible approach to the advertising and promotion of PM products taken by members, who are responsive to community concerns; and
- continuity of consumer access to, and information about, quality PM products that are safe and effective when used as directed.

1.30. Further, that the code's principles are designed to:

- ensure the general public is properly informed about PM products, and is protected from inducements to buy PM products in excess of immediate requirements;
- reduce the likelihood of inappropriate or excessive consumption of scheduled substances or analgesics;
- reinforce responsible use and care of PM products; and
- protect children from direct advertising and promotion of PM products.

1.31. The code seeks to achieve these benefits in four ways:

- by its application being wider than required by law, thereby promoting consistency between all forms of advertising and promotional activity in all media to all audiences;
- by ensuring that to which the code's requirements go beyond the law, they are consistent with government and community concerns about advertising and not unduly restrictive;
- by offering an efficient and fair complaints handling procedure; and
- by including features to promote the code's acceptance by the public.

1.32. The code provides complaint procedures for use by members and non-members, and provisions to enforce compliance with the code. The PMAA provides training with respect to the code, and other relevant codes and the pre-clearance procedures.

1.33. PMAA stated that while it encourages members to comply with the objectives and principles of the code, it considers that it cannot enforce it through the mechanisms of the complaints panel and sanctions until authorisation is granted by the Commission. It considers that the ability to enforce the code will contribute to its effectiveness, and consequently to the public benefit of the code.

2. Submissions of interested parties

2.1. On 9 March 1993 a copy of PMAA's submission was sent to twenty-six organisations that were considered to have an interest in the application.

2.2. Submissions were received from the following organisations:

Advertising Federation of Australia Limited (**AFA**)

Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists-Council Clinical Working Party (**ASCEPT**)

Australian Consumers' Association (**ACA**)

Australian Drug Evaluation Committee (**ADEC**)

Australian Medical Association Limited (**AMA**)

Australian Pharmaceutical Advisory Council(**APAC**)

Commonwealth Dept of Health, Housing, Local Government and Community Services — Pharmaceutical Benefits Branch (**PBB**)

Commonwealth Dept. of Health, Housing, Local Government and Community Services — Therapeutic Goods Administration (**TGA**)

Consumer Health Forum of Australia Inc (**CHF**)

Media Council of Australia (**MCA**)

Medical Industry Association of Australia Inc (**MIAA**)

Motor Trades Association of Australia (**MTAA**)

Pharmaceutical Health and the Rational Use of Medicines Committee (**PHARM**)

Pharmaceutical Society of Australia (**PSA**)

Public Interest Advocacy Centre (**PIAC**)

The Pharmacy Guild of Australia (**PGA**)

The submissions made by these organisations are on the Public Register.

2.3. AFA, MCA and MIAA stated that they had clarified various issues directly with PMAA, and that following this they had no comments to make. AMA and PGA had no comment, other than that they did not oppose the application. MTAA submitted that it had no comment to make.

2.4. ACA and PIAC opposed authorisation of the application in its present form.

2.5. The remaining organisations listed in paragraph 2.2, while not opposing authorisation, provided various comments and criticism.

2.6. ACA submitted that the code should not be authorised for the following reasons.

- There is currently a mix of schemes regulating the advertising and promotion of PM medicines and the arrangements are too complex and confusing for the public and health professionals.
- The PMAA code:
  - lacks consumer and DHHLGCS representation on the complaints panel;
  - lacks any plan to publicise the code;

- lacks a scheme to monitor compliance;
- fails to regulate the activities of industry representatives;
- lacks explicit instructions regarding the placement of advertisements during children's viewing time;
- lacks a code administration committee; and
- lacks an independent appeals mechanism.

2.7. ACA considered that the offer of a pre-clearance service for print carries the risk of possible capture of the pre-clearance procedure. Further, ACA's assessment of some cough medicines found that many of those products contained irrational combinations, in contradiction of PMAA's stated aim '... to make available to the public products which are both safe and effective when used as directed.' (Article 2.2).

2.8. PIAC endorsed ACA's submission.

2.9. The consistent criticism of those organisations which did not oppose authorisation of the code was directed at the lack of consumer representation on the complaints panel, and the complaints and appeal provisions.

2.10. In response to the submissions made, PMAA advised the Commission by letter of 16 July 1993 that it would:

- 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 DHHLGCS to be appointed to the panel as an observer;
- consider the issue of pecuniary penalties on the next occasion on which the code is reviewed;
- have the executive director circulate to the complaints panel and to the marketing and ethics committee monthly summaries of all complaints received and their disposition;
- make the code publicly known and provide information to the public as to how complaints may be made, once authorisation has been granted;
- consider revising clauses 5.3.2.2 and 5.3.2.3 (abbreviated and commercial advertising of Schedule 3 items) to make them consistent with the APMA code on the next occasion on which the code is reviewed; and
- have the marketing and ethics committee participate in the annual review of the code.

2.11. The more significant of those issues raised by organisations, and not addressed by the above-listed proposals, are listed as follows under the code heading under which they arise, together with PMAA's response to them.

Introduction/objectives

Comment: contrary to PMAA's view that products covered by the industry are essentially safe, there is concern about the increasing use of certain PM drugs (eg analgesics), particularly among young people, and that some of the products marketed are not 'rational', in that they contain irrational ingredient combinations. The availability of such products for consumers seems contrary to PMAA's aim in Article 2.2. of the code.

Response: the regulation of drugs and their availability are within the province of the Therapeutic Goods Administration [in DOHHLGCS].

Comment: a number of comments as to the wording and extent of the objectives of the code.

Response: generally rejected on the grounds of substance and materiality.

Advertising

Comment: responsibility for pre-clearance of print media advertising carries a risk of possibility of 'capture' of the pre-clearance procedure.

Response: pre-clearance by PMAA does not guarantee publication, since neither FARB nor FACTS nor the print media proprietors are bound to publish advertisements pre-cleared by PMAA. Denial or pre-clearance does not guarantee denial of publication, since advertisers may appeal to the Therapeutic Goods Advertising Code Council. Consumer or any other dissatisfaction with the standard of advertisements may be manifested in innumerable ways.

Promotion

Comment: clause 6.3 (promotion to children) should include explicit instruction regarding the placement of advertisements during children's viewing time.

Response: FACTS is responsible for allocating appropriate time slots to individual advertisements.

Comment: there should be development of an article regulating the activities of medical representatives.

Response: the code covers the activities of medical representatives through the definition of 'advertisement', which extends to 'every form of advertisement, whether ... in the spoken word or any other way'.

Comment: the exemption of unscheduled vitamin and mineral preparations, and therapeutic goods for external use, from the prohibition of prize competitions which are conditional on the purchase of proprietary medicines, is unjustified.

Response: these goods are exempt because non-members have dominant market shares in them and members of PMAA would be at a severe commercial disadvantage if prevented from engaging in this form of competition. For example, sunscreens have no systemic effect and compete in the wider market for toiletries. PMAA is participating in the consultative process in relation to the Commission's recommendation that the Nutritional Foods Association of Australia devise a code for this purpose.

Administration

Comment: a code administration committee and an independent appeals procedure should be established.

Response: the marketing and ethics committee will perform the function of a code administration committee.

Comment: a monitoring committee, along the lines of the APMA monitoring sub-committee, to review advertisements by members, and if necessary, place advertisements before the complaints panel, should be established.

Response: PMAA does not have the resources for the function of pro-active monitoring of the full range of promotional activity emanating from every member. Responsibility

for compliance with the legislation and the code rests with the individual company concerned.

Comment: there is inadequate community consultation in the code review process — a consumer advisory panel should be established to assist the executive sub-committee review the code.

Response: the marketing and ethics committee will participate in the annual review of the code.

Complaints

Comment: details of complaints resolved by the executive director of PMAA should be relayed immediately to the independent complaints panel; the complaints panel and the marketing and ethics sub-committee should be advised of all complaints found to be in breach of the code, and the sanctions imposed should be commercially significant and include a retraction statement.

Response: the executive director will circulate monthly summaries of all complaints received and their disposition to the complaints panel and to the marketing and ethics committee .

Comment: the complaints handling mechanism should be applied to non-member companies with their consent.

Response: the code applies to non-members by consent. PMAA cannot apply the code to non-consenting non-members.

Comment: provision for the referral of complaints against non-PMAA members to DHHLGCS or the TPC.

Response: nil

Sanctions

Comment: the power to impose a fine on a member company should be added to the sanctions listed by PMAA.

Response: existing sanctions are considered to have 'teeth' as overseas parent companies already become concerned if a subsidiary is expelled or otherwise seen to be 'in trouble' with a local industry organisation. The issue of pecuniary penalties will be considered at the next code review.

Comment: it would be appropriate for PMAA to be given 'clear-cut' jurisdiction over non-member companies and to increase the range and weight of sanctions available to it in applying the code.

Response: in regard to sanctions and coverage, the code only applies to non-members by consent, and consequently PMAA does not have any authority over non-consenting non-members.

Appeals

Comment: there should be an appeals process independent of the industry.

Response: PMAA is satisfied that the present appeals mechanism will work satisfactorily, and that there will be no need for an independent appeals mechanism given PMAA's independence in administering the code.

Comment: members of the complaints panel and the marketing and ethics sub-committee should be precluded from hearing an appeal.

Response: agreed.

2.12. A number of positive comments were made about the code, and the public benefit that respondents considered flowed from it. Examples of support for the authorisation of the code are as follows.

- There is public benefit in the code governing advertising in all media to all audiences, requiring that all claims in advertising be capable of substantiation immediately if a bone fide question is asked.

  - A prime objective of TGA was to ensure that industry associations dealing with therapeutic goods have effective codes in place to encourage responsible and truthful advertising, and the PMAA code forms an integral part of this co-regulatory system. Laudably, the code's coverage now includes advertising through closed circuit video and audio networks in doctors' waiting rooms and retail stores.

- The revised code does not appear to limit competition '... more than is justified in the public interest insofar as that interest is served by truthful advertising and promotion which does not encourage inappropriate use of proprietary medicines'.

- The code represents an appropriate set of parameters for PMAA member companies to follow when advertising and promoting OTC products.

3. The statutory test

3.1. The application was made under section 88 of the Act for authorisation of a proposed contract, arrangement or understanding that would be, or might be, an exclusionary provision or would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of the Act.

3.2. The Act provides that the Commission may only grant authorisation if the application satisfies the relevant tests in sub-sections 90(6) and 90(8) of the Act. In the case of this application, the relevant test is that in sub-section 90(6).

3.3. Sub-section 90(6) provides that the Commission shall only grant authorisation if it is satisfied in all the circumstances that:

- the provisions of the subject arrangement have, or are likely to result in, a benefit to the public.
- any such public benefit outweighs any anti-competitive detriment flowing from the arrangements.

3.4. In deciding whether to grant authorisation the Commission must examine the anti-competitive aspects of the arrangements, the subject of the application, and the public benefits likely to arise from them, and must weigh the two to determine which is greater. Should the expected public benefits outweigh the anti-competitive aspects, the Commission may grant authorisation, or grant authorisation with conditions attached.

3.5. If that is not the case, the Commission may refuse authorisation. Alternatively, when refusing authorisation the Commission may indicate to the applicant how the arrangements could be restructured to change the balance of anti-competitive detriment and public benefit so that authorisation may be granted.

4. Commission evaluation of public benefit and anti-competitive detriment; draft determination

4.1. PMAA submitted that to the extent that the Code simply adopts legislative requirements, it cannot lessen competition. Therefore, it is only to the extent to which it goes beyond the statutory requirements that the code can have a potentially anti-competitive effect. (See paragraph 1.) PMAA submitted that the additional restrictions and wider application of the code improve the quality of PM advertising and promotion, resulting in responsible advertising and promotion of PM products by PMAA members, and a minimisation of the risk of abuse of those products. In addition, the code establishes a fair and efficient complaints procedure which is easily accessible.

4.2. The public, in respect to this application, is constituted by the consumers and potential consumers of PM products.

4.3. The Commission's approach to self-regulation is set out in its report, *Self-regulation in Australian industry and the professions,* published in 1988. The Commission evaluates self-regulatory arrangements such as this by reference to the following issues, which it considers relevant when assessing a scheme's ability to deliver public benefit:

- ability to contribute to the quality and standard of the service and to remind members of their obligations;
- existing regulation and the need for some form of regulation;
- ability of the industry to regulate its own affairs;
- coverage;
- complaints/disputes procedures;
- appeals;
- sanctions;
- external participation; and
- need for uniformity.

Existing regulation and the need for regulation

4.4. The pharmaceutical industry is heavily regulated in many aspects of its operation, including advertising and promotion. The *Commonwealth Therapeutic Goods Act 1989* and regulations under it regulate advertising of therapeutic goods, including PM medicines. 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 MCA's Therapeutic Goods Advertising Code (TGAC). The PMAA code and the TGAC are principally relevant to the advertising and promotion of PM products. (See also paragraph 1.5–1.21.)

4.5. ACA, referring to the regulatory regime for OTCs, commented that:

> ... such arrangements are too complex and confusing for either the public or the health professionals to know about such schemes, let alone utilise them, for example to make a complaint. An overhaul of the schemes to make it simple and accessible is an attractive one [sic].

4.6. ACA's comment contrasts with that of TGA, which submitted that

> It is a prime objective of the TGA that industry associations dealing with therapeutic goods have effective codes in place to encourage responsible and truthful advertising. The PMAA code of practice is an integral component of this co-regulatory system.

4.7. Streamlining of the regulatory mechanisms is not an issue the Commission can deal with in this context.

4.8. PMAA submitted that the extra-statutory restrictions imposed by its code with respect to advertising and promotion, and the wider application of the code (ie to all advertising in all media) improve the quality of PM advertising and promotion without unduly restricting members' freedom to advertise and promote.

4.9. The code requires members to abide by the Tamper Resistant Packaging Guidelines. Currently there is no legislation in Australia which regulates packaging from the tamper resistant point of view.

4.10. The extra-statutory requirements appear, by and large, to extend and reinforce the statutory requirements, and to reinforce the confidence of the public in the administration of drug testing and control.

4.11. The Commission agrees that the regulation of the advertising and promotion of therapeutic goods is necessary to protect the public. This is largely achieved by legislation. This code extends the requirements of the legislation and provides for the industry to self-enforce the legislation.

4.12. The Commission considered that public benefit flowed from this, and acknowledged the role of the code in the co-regulation of the advertising and promotion of OTCs.

Ability to contribute to the quality and standard of service and to remind members of their obligations.

4.13. As stated above, the Commission considered that regulation of the advertising and promotion of proprietary medicines, is, in the broader sense, necessary and good. Public benefit flows from this control, which contributes to the prevention of oversupply and overuse. This code, to the extent to which it supplements what is already in place to achieve these objectives, and in providing a mechanism for ensuring compliance, adds to the public benefit which flows from the legislation.

4.14. The issue for consideration here is whether the additional regulation (that is, the extra statutory provisions) affecting advertising and promotion by manufacturers of proprietary medicines is anti-competitive, and if so, if it is anti-competitive to an extent which overrides the public benefit.

4.15. The extra statutory provisions are listed at paragraph 1.27.

4.16. The requirements on members to:

- provide claim substantiation promptly on request;
- not to advertise that money will be refunded if the consumer is dissatisfied;
- to comply with specific information standards in trade advertisements for S3 products;
- not to promote prize competitions;
- not to persuade consumers to buy unnecessary products or products in unnecessary quantities; and

- not to promote to children

appeared to the Commission to be capable of achieving the code's principles and objectives (paragraphs 1.29 and 1.30). By controlling the advertising and promotion of proprietary medicines in a manner which restrains overuse and unwise use of them, and by extending that control to advertising and promotion in all media to all audiences (for example, children), the public benefit inherent in the legislation is extended and enhanced.

4.17. However, there are two requirements which, due to their lack of obvious nexus with the code's principles and objectives, and due to their unspecific character, could leave the complaints panel open to interpret them in anti-competitive way. That is, they could lead to a decision to discipline a member for competitive behaviour which is not in breach of the other provisions of the code, or the spirit of the code. These are the requirements that advertising is not to unfairly denigrate/attack other goods and services, and that promotion is not to bring discredit on, or reduce confidence in, the industry. The Commission has serious reservations about rules which prevent advertising which can be described as denigrating or which might bring discredit on, or reduce confidence in, an industry. While the Commission does not support offensive advertising, it is concerned that, in the absence of an objective standard, such rules may provide scope to prohibit advertising which others may judge to be informative, creative or appropriate. The presence of such rules may be sufficient to inhibit competitive and informative advertising and promotion.

4.18. The Commission considered that the terms of the code as they apply to the advertising and promotion of proprietary medicines (other than those discussed at paragraph 4.17) are largely clear and have a close nexus with the public benefits claimed. It considered however that the detriment that would result, or be likely to result, would not be outweighed by public benefit unless clauses 5.2 and 6.1.1 were either deleted or suitably amended.

Complaints/disputes procedures, sanctions, appeal

Complaints/disputes procedures

4.19. The code provides for a procedure to deal with both externally generated complaints (sub-section 8.3.1) and industry generated complaints (sub-section 8.3.2). This process is supported by sanction and appeal provisions (sections 9 and 10 of the code respectively).

4.20. The Commission believes that effective complaint handling mechanisms provide a service to the public, to members of the relevant organisation, and to individuals involved in the industry, and as such contribute significantly to a scheme's ability to deliver public benefit.

4.21. PMAA has, since making this application, agreed:

- to include a consumer representative from a broad-based consumer representative consumer/community organisation, and to have an observer from DHHLGCS, on the complaints panel;
- to have the executive director circulate to the complaints panel and the marketing and ethics committee monthly summaries of all complaints received and their disposition; and
- to make the code publicly known and provide information to the public as to how complaints may be made

once authorisation has been granted.

4.22. These changes lower the anti-competitive detriment of the complaints procedures, and significantly enhance their capacity to deliver public benefit.

4.23. PMAA has stated that the complaints procedures may apply to non-member companies with their consent. This further contributes to the capacity of the complaints procedures to deliver public benefit.

4.24. The Commission considered that the complaint procedures, taking account of the proposed changes, would be efficient, fair and accessible, and would therefore contribute to the capacity of the code to deliver public benefit.

Sanctions

4.25. The Commission is of the view that voluntarily adopted codes of practice enjoy greater public confidence if they are seen to incorporate commercially significant incentives to comply. Sanctions are an important factor in determining the effectiveness of a scheme in delivering public benefit. The anti-competitive effects of being excluded from an industry association, for example, may be outweighed by the public benefit that comes from certain and meaningful enforcement of the rules, observance of which is a condition of membership of the association in question. The lack of meaningful sanctions may result in the public being misled by a code of conduct — the public may reasonably presume that members are abiding by the terms of their membership. If they are not, but are able to continue to enjoy the commercial and other advantages of membership, a disadvantage to the public results. The code establishes sanctions for breaches of the code (see page 9).

4.26. In its report, *Promotion and advertising of Therapeutic goods*, the Commission accepted that the more punitive sanctions of suspension and expulsion from the association should be imposed only by the committee of management (on recommendation from the complaints panel).

4.27. The Commission considered that the sanctions imposed by the code are commercially significant (even without provision for pecuniary penalties), and should serve to ensure that persistent non-observers do not retain membership. In this way, the sanctions would serve to enable the code to deliver public benefit.

Appeals

4.28. The availability of an appeal mechanism contributes to the public benefit a self-regulation scheme may deliver. Public benefit is further enhanced if the appeal mechanism is independent of the industry.

4.29. The public benefit may not outweigh, in some circumstances, anti-competitive detriment if the appeal mechanism is not independent of the industry association which seeks to regulate the industry. The Commission considered the anti-competitive detriment of the appeal provision to be higher than it might otherwise be, having regard to the Commission's assessment of the ability of the code to contribute to the quality and standing of the service (see paragraphs 4.18 and 4.19).

4.30. Overall, the anti-competitive detriment that might come from the operation of the complaints, sanctions and appeal provisions of the code could be low, taking account of the fact that membership is not a pre-condition of operating in the industry. The availability to consumers of a complaints procedure and provisions to enforce compliance by members with the code can be a public benefit, and in respect to this code, it is.

4.31. However, the non-independent character of the appeal provisions adds significantly to the anti-competitive detriment, particularly where provisions of the code

which are to be enforced through these complaint and appeal mechanisms are of a character which leaves scope for them to be administered in an arbitrary, capricious or anti-competitive way. Members of an association should have the right of appeal or review of decisions, particularly where sanctions include suspension and expulsion and such action can affect their ability to compete or operate in an industry. This appeal should be to an appropriate independent individual or body, in the interests of transparency and objectivity. Appeal to an industry body may give the appearance that the industry is acting only in its members' interests.

Ability of the industry to regulate its own affairs

4.32. PMAA is the national advocate and representative for organisations involved in the production, advertising and promotion of PM products in Australia. Its membership includes the subsidiaries of large international companies. It has maintained a code for its members' advertising and promotion of PM products since 1977. It is funded by membership subscriptions levied in accordance with members' turnover.

4.33. The Commission concludes that PMAA is well able to administer the rules and code of the association, and that the industry has a high level of ability to regulate its own affairs.

Coverage

4.34. This criterion is discussed with reference to membership and barriers to entry, and the extent of the application of the code.

4.35. The Commission holds the view that the wider the industry coverage, the greater the public benefit, unless the wider coverage has been achieved at the expense of meaningful standards. It also holds the view that clear and objective membership criteria assist prospective members to assess their eligibility and guard against arbitrary barriers to entry.

4.36. Membership is open to any company, conducting in Australia:

- manufacture and/or formulation and/or importation and/or basic/applied research and/or registration and/or marketing of proprietary medicines (ordinary membership);
- any ancillary company wholesaler, distributor, or advertising agency in the proprietary medicines industry (associate membership); and
- natural persons who have rendered distinguished service to the Association (honorary life membership).

4.37. The Commission does not consider the fees to be unduly high having regard to the industry and the services provided by PMAA to its members.

4.38. The Commission concluded that the coverage of the industry is of a very high level, and that there are no unreasonable barriers to entry.

4.39. The code now applies to all advertising and promotional activities by members, in all media and to all audiences.

4.40. Commission concluded that the coverage of the code is high, given its high level of membership of manufacturers/importers, and its application to PM product advertising and promotional activity in all media to all audiences. Its capacity to contribute to public benefit is accordingly high.

External participation

4.41. The greater the scope for external participation in the development and administration of a scheme, the more effective it is likely to be in delivering public benefit. Clearly there is a balance to be struck in the extent to which an industry might invite industry input, and the industry's independence.

4.42. This criterion may be assessed with reference to PMAA's complaints and appeal mechanisms, and to its code review provisions.

4.43. The level of external participation on PMAA's complaints panel is very good. It is to include a trade practices lawyer, a nominee of the RACGP, a community pharmacist nominated by the PSA, a nominee of a representative consumer organisation, and an observer-representative of DHHLGCS.

4.44. The appeal committee does not have any external participation.

4.45. The code is to be reviewed at least annually by the executive sub-committee, the marketing and ethics committee, and the external members of the complaints panel (which is to be expanded to include a nominee of a representative consumer organisation).

4.46. This level of external participation in regular review of the code will contribute significantly to the public benefit.

4.47. The otherwise good level of external participation is detracted from by its absence in the appeal mechanism.

Need for uniformity

4.48. There is broad agreement about the desirability for Australia-wide uniformity in the legislative framework in which industry operates. As has been mentioned, this is a heavily regulated industry and notwithstanding the intention to have uniform therapeutic goods laws, this is very slow in happening. PMAA provides members with a legislation service, keeping member companies (which operate in a national market) up to date on the legislative developments in each State and the Commonwealth. PMAA also provides a comparison of poison scheduling across all States to members.

4.49. The code is a national code, and with respect to this criterion has a greater capacity to deliver public benefit than would otherwise be the case.

Conclusion and draft determination

4.50 The Commission, having examined the code against important determinants of the ability of self-regulation schemes to deliver public benefit, concluded that it was likely to result in benefit to the public. It satisfied many of the criteria to a high level, taking account of the changes and further actions PMAA had undertaken to carry out.

4.51. It found also, however, that the code contained restrictions on the conduct of competitors which were of an unspecific nature, and appeal provisions which were not independent in character. These provisions increase the anti-competitive detriment of the code. The Commission considered that the detriment that would result, or be likely to result, would not be outweighed by public benefit unless the code were amended

- to provide for a consumer representative from a broad-based, representative consumer 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;

- to make clauses 5.3.2.2. and 5.3.2.3 (advertising of S3 products) consistent with the APMA code and WHO ethical criteria;
- to remove or clarify clauses 5.2 and 6.1.1; and
- to provide that appeals from decisions of the complaints panel and the committee of management be heard by an agent independent from the industry.

4.52 On 29 October 1993 the Commission issued a draft determination by which it proposed to grant authorisation to the code subject to the above-listed conditions and on condition, further, that PMAA

- consider the issue of pecuniary penalties on the next occasion on which the code is reviewed;
- have the executive director circulate to the complaints panel and to the marketing and ethics committee monthly summaries of all complaints received and their disposition;
- make the code publicly known and provide information to the public as to how complaints may be made; and
- have the marketing and ethics committee participate in the annual review of the code.

4.53 PMAA had, prior to the issue of the draft determination, offered to undertake the four actions listed above on condition that the Commission grant authorisation (refer paragraph 2.10). By its draft determination the Commission required that PMAA undertake these actions as a condition of authorisation.

5. Pre-decision conference and submissions of interested parties

5.1 In response to the draft determination, PMAA agreed to all the Commission's conditions for authorisation except for those relating to clauses 5.2 and 6.1.1, and to appeals. PMAA requested a pre-decision conference.

5.2 A pre-decision conference was convened on 2 December 1993. It was attended by representatives of PMAA, MCA, AFA, ACA, APMA and PBB. The following issues were addressed.

Complaints procedures

5.3 MCA pointed out that as it does not handle complaints, section 8.2.3 of the code needed to be rectified so that references in it to MCA became references to the Advertising Standards Council. It followed from this point that there arose the issue of what it was that the Executive Director should do. MCA was of the opinion that the Executive Director of PMAA should only consider breaches of the PMAA code.

5.4 PMAA responded that it would replace 'MCA' in the penultimate sentence of section 8.2.3 with 'Advertising Standards Council' and consider adding the words 'PMAA code' to that clause.

Appeals mechanism

5.5 PMAA had submitted, prior to the pre-decision conference, that in imposing the condition that requires that appeals be heard by an agent independent of the industry, the Commission had failed to properly apply the statutory test. The Commission had referred to possible anti-competitive effect, rather than likely anti-competitive effect.

5.6 PMAA did not consider that the cost of establishing an independent agency to handle appeals could presently be justified. It had submitted that transparency and objectivity could be achieved by

- participation by an independent trade practices lawyer in appeals to the committee of management and through consideration by the members in general meeting of suspension and expulsion recommendations
- quarterly reports to the Commission
- annual code review
- Commission's power of revocation.

5.7 ACA had submitted that the existence of an independent appeals mechanism is essential to the credibility and efficacy of the code, and wished this issue to be discussed at the conference.

5.8 PMAA referred to the submission it had made on this issue, and suggested that the requirement seemed elaborate given that there was not a high level of complaint. There was also the issue of cost.

5.9 MCA stated that it has an independent appeal body which might consider acting for PMAA. ACA stated that it would like PMAA to consider adopting a structure similar to that of APMA.

Clauses 5.2 and 6.1.1

5.10 PMAA had submitted that the Commission's condition for authorisation that required removal or clarification of clauses 5.2 and 6.1.1 should not be imposed because the Commission had not applied the proper test. The Commission had failed to address the question of whether the public benefits would outweigh the anti-competitive detriments if the clauses remained. PMAA submitted that once potential anti-competitive detriment was properly excluded, public benefits would outweigh the likely anti-competitive detriments because the following factors will militate against the clauses being interpreted in an anti-competitive way:

- the proposed composition of the complaints panel
- circulation to complaints panel and marketing and ethics committee of monthly summaries of all complaints and their disposition (PMAA would be willing to provides copies to the Commission also)
- annual review of the code involving outside participation
- Commission's power to revoke
- the highly regulated nature of the industry.

Furthermore, similar clauses existed in the MCA's advertising code of ethics. PMAA members are required to comply with that code, which has been authorised. The condition therefore would be futile in any event.

5.11 At the conference PMAA referred to its submission above. While it appreciated that there was potential to use the language of these clauses anti-competitively in some circumstances, the question that needed to be answered was, was it likely to be used in that way. PMAA considered that several factors militate against this and that the Commission should be prepared to see how it worked and review it if necessary. The MCA code of ethics, which is authorised, contains comparable provisions.

5.12 The Commission responded that it would like to have heard argument about the need for such a clause, given the existence of similar provisions in the MCA code, and the increasing occurrence of comparative advertising.

5.13 ACA stated that it sounded as though clause 5.2 needed clarification and that perhaps PMAA could use explanatory clauses. ACA thought clause 6.1.1 on the other hand to be clear.

5.14 MCA pointed out that a clause relating to comparative advertising had recently been gazetted as part of the *Therapeutic Goods Regulations*.

Clauses 5.3.2.2 and 5.3.2.3

5.15 PMAA had agreed to make the above clauses consistent with the APMA code. It submitted that the condition whereby it was required to undertake to make these clauses also consistent with WHO ethical criteria was superfluous and it was concerned that the Commission should realise this.

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Regulation of the activities of medical representatives in their relationships with pharmacists and pharmacy assistants

5.16 ACA had submitted that the role and activities of medical representatives would be better addressed under a separate article in addition to coverage under the broad definition of 'advertisement'.

5.17 PMAA stated the code applies to the spoken word and that this includes representations to the staff of a pharmacy. There is not a problem at the present and if there should be, the code could be revised.

Review of the code and the form of authorisation

5.18 PMAA had submitted that authorisation should be granted in a form which accommodates the fact that the code will be reviewed annually and therefore subject to periodic amendment.

5.19 In response to a request for views as to whether or not the authorisation should be time limited, in view of PMAA's request that it be granted in a form that extended to the code as reviewed from time to time, PMAA submitted that it should not for the reason that the code will be reviewed annually.

6. Conclusion

6.1 Following the pre-decision conference, the Commission remained of the view that the conditions it had initially proposed should remain. It disagreed that it had failed to properly apply the statutory test when evaluating the appeals mechanism and clauses 5.2 and 6.1.1. In case the terms of its draft determination had contributed to a misunderstanding in this regard, it had re-examined the relevant paragraphs and ensured that they were now clear.

6.2 The Commission suggested that clauses 5.2 and 6.1.1 be replaced with a comparable clause in the *Therapeutic Goods Regulations*, as follows: 'Comparative advertisements should not be misleading, or likely to be misleading, either about the product advertised or that with which it is compared.'

6.3 The Commission suggested that an independent avenue of appeal against decisions of the committee of management could be constituted by a suitable person sitting alone, on an at-call basis.

6.4 The Commission proposed to retain the requirement that clauses 5.3.2.2 and 5.3.2.3 be amended consistent with WHO ethical criteria on the basis that this imposed no greater obligation on the Association than currently existed.

6.5 PMAA requested that authorisation be given in a form which enabled the code to be amended from time to time, and the Commission was disposed to grant this request provided that it could do so within the terms of the Act. PMAA requested further that no time limit be imposed on the authorisation. The Commission was disposed to grant this request also, if PMAA agreed to conduct the reviews of the code in a manner acceptable to the Commission.

6.6 PMAA accepted the Commission's conditions. It will delete the first point of clause 5.2 and amend the second point so that it reads 'Comparative advertisements should not be misleading, or likely to be misleading, either about the product advertised or that with which it is compared'. It will delete clause 6.1.1. It will provide an independent avenue of appeal in the form suggested by the Commission. It accepted the requirement that clauses 5.3.2.2 and 5.3.2.3 be amended to make them consistent with the APMA code *and* WHO ethical criteria.

6.7 As mentioned earlier in this determination, PMAA had agreed to the other conditions proposed for grant of authorisation, including the requirement to provide a consumer representative on the complaints panel.

6.8 With respect to the time limit issue, PMAA submitted that a sufficient degree of public access to code reviews was assured by the process whereby the code was to be made publicly known, information was to be provided to the public as to how complaints might be made, monthly summaries of complaints received and their disposition were to be provided to the marketing and ethics committee and to the complaints panel, all being steps likely to bring to the attention of the public representatives on the complaints panel (who would be included in the review and amendment processes) matters which should be addressed upon review of the code. PMAA submitted that this should meet the Commission's concern as to the manner in which the reviews of the code were conducted.

6.9 Agreement now having been reached on all matters, the Commission proposes to authorise the conduct the subject of the application.

7. Determination

7.1 The Commission grants authorisation to the conduct the subject of application number A90549.

7.2 This authorisation applies

- to PMAA and its members from time to time;
- to 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

and is conditional upon PMAA fulfilling all the conditions it has agreed to meet.

7.3 This determination is made on 27 January 1994. If no application for a review of this determination is made to the Trade Practices Tribunal in accordance with section 101 of the Trade Practices Act 1974, this determination will come into force on 18 February 1994. If an application for review is made to the Tribunal, the determination will come into force:

- where the application is not withdrawn - on the day on which the Tribunal makes a determination on the review; or
- where the application is withdrawn - on the day on which the application is withdrawn.