Brand Copy

Australian Competition & Consumer Commission

Determination

Application for Authorisation

Proprietary Medicines Association of Australia/Nutritional Foods Association of Australia

in relation to the Therapeutic Goods Advertising Code

Date: 2 July 1997

Authorisation Nos: A60830

File no: CA95/24

Commissioners: Fels, Asher, Smith, Bhojani, Lieberman, Shogren, Hilton

Summary

The Commission has considered an application for authorisation lodged jointly by the Proprietary Medicines Association of Australia (PMAA) and the Nutritional Foods Association of Australia (NFAA) regarding adoption and administration of the Therapeutic Goods Advertising Code (TGAC).

Application A90600 was made under sub-section 88(1) of the *Trade Practices Act 1974* (the Act) for an authorisation to make a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would or might have the effect, of substantially lessening competition within the meaning of section 45 of the Act. This application was concerned with proposed arrangements to:

- establish a new Therapeutic Goods Advertising Code Council (TGACC);
- adopt the TGAC; and
- establish a complaints resolution panel (CRP) and appeal mechanism to hear and determine complaints of breaches of the code and to impose sanctions.

According to the applicants, the arrangements are intended to ensure continuity of consumer protection following the abandonment of the industry self regulation scheme previously conducted by the Media Council of Australia (MCA).

On 18 December 1996 the Commission agreed to a request from the applicants for interim authorisation.

Following amendment to the proposed arrangements and consideration of further submissions by interested parties, the Commission issued a draft determination on 29 April 1997 noting that the proposed arrangements may substantially lessen competition. This effect on competition was attributed to:

- extension of advertising restrictions beyond the provisions of the Therapeutic Goods Act; and
- provisions for the imposition of sanctions where an advertisement is found to be in breach of the TGAC.

The Commission also noted in the draft determination its view that the arrangements have the potential for significant benefit to the public through:

- the continued application of a TGAC, together with effective mechanisms to ensure compliance;
- the implementation of a flexible system capable of responding quickly to complaints and changes in community needs and attitudes;

- broad coverage (albeit incomplete for the time being) of the TGAC across various media; and
- consistency in application of the TGAC between over-the-counter medicines and health and nutrition products.

Given the nature of therapeutic goods, as a means of relieving pain and suffering, it was considered particularly important that consumers be able to rely on claims made in any associated advertising. For this reason, the Commission considered there to be substantial public benefit associated with mechanisms that support the accuracy and validity of therapeutic claims. The proposed arrangements were identified as an example of such mechanisms.

As the Commission considered the importance of these public benefits to outweigh any anti-competitive detriment associated with the proposed arrangements, it was proposed in the draft determination that authorisation be granted to application A90600.

On 26 May 1997 the Commission held a pre-decision conference in response to a request pursuant to s.90(A) of the Act. Additional submissions were also received by the Commission following the draft determination.

The Commission now confirms the draft determination, granting authorisation to the proposed arrangements for four years.

Contents

Glossary

AANA	Australian Association of National Advertisers
ACA	Australian Consumers' Association
AFA	Advertising Federation of Australia
AHF	Australian Health Forum
ANTA	Australian Natural Therapists Association
APMA	Australian Pharmaceutical Manufacturers' Association
ASC	Advertising Standards Council
ATMS	Australian Traditional Medicines Society
the Act	the *Trade Practices Act 1974*
Commission	Australian Competition and Consumer Commission
CHF	Consumers' Health Forum
CRP	Complaints Resolution Panel
CTFAA	Cosmetics, Toiletries and Fragrances Association of Australia
DFT	Department of Fair Trading
FNTA	Federation of Natural Therapists Association
MCA	Media Council of Australia
MIAA	Medical Industry Association of Australia
NFAA	Nutritional Foods Association of Australia
PGA	Pharmacy Guild of Australia
PMAA	Proprietary Medicines Association of Australia
PSA	Pharmaceutical Society of Australia
RACGP	Royal Australian College of General Practitioners
TGA	Therapeutic Goods Authority
TGAC	Therapeutic Goods Advertising Code
TGACC	Therapeutic Goods Advertising Code Council

1. Introduction

On 11 December 1996 an application for authorisation (No. A90600) was lodged with the Australian Competition and Consumer Commission on behalf the Proprietary Medicines Association of Australia and the Nutritional Foods Association of Australia. This application was made under sub-section 88(1) of the *Trade Practices Act 1974* for an authorisation to make a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would or might have the effect, of substantially lessening competition within the meaning of section 45 of the Act.

The purpose of the arrangements, which were the subject of the application, was to gain authorisation for:

- the establishment of a new Therapeutic Goods Advertising Code Council;
- the adoption of the Therapeutic Goods Advertising Code by the applicants (refer Attachment A); and
- the establishment of a complaints resolution panel and appeal mechanism that would hear, and determine complaints regarding breaches of the code and that would impose sanctions.

2. Background

Historically, the TGAC has been administered in accordance with authorisations granted to the Media Council of Australia. These authorisations covered a system of advertising standards which provided for:

- a general code of ethics and other codes dealing specifically with therapeutic goods, slimming preparations and alcoholic beverages;
- the pre-clearance of advertisements by industry approval bodies;
- the operation of an Advertising Standards Council (ASC) to adjudicate on complaints regarding possible breaches of the codes; and
- the operation of code councils to monitor the adequacy of the codes in response to changing community needs and attitudes.

During 1996, however, the MCA announced that it would be disbanded, together with the ASC, on 31 December 1996.

In response to this announcement, the PMAA and NFAA lodged a joint application for authorisation to take over the administration of the TGAC.

Included with the PMAA/NFAA application was a request for interim authorisation from 1 January 1997. This request was submitted to ensure continuity of consumer protection following abandonment of the MCA system.

Following limited market inquiries the Commission announced on 18 December 1996 that the applicants request for interim authorisation had been accepted. Interested parties were advised of this decision in writing and invited to lodge submissions with the Commission regarding further consideration of the authorisation.

Included in the letter to interested parties was a list of issues that had been raised during the market inquiries. These issues concerned:

- the need to ensure adequate consumer representation on the TGACC and the CRP;
- cross membership between the TGACC and the CRP;
- the power of the TGACC to coopt experts not represented on the committee;
- the need for the code arrangements to comply with guidelines for codes of conduct agreed by Federal and State Ministers; and
- the possibility that the arrangements will become part of a broader system of advertising standards to replace the MCA system.

3. Statutory test

The application was made under sub-section 88(1) of the Act. The Act provides that the Commission shall grant authorisation only if the applicant satisfies the relevant test in sub-section 90(6) of the Act.

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

- the provisions of the subject arrangements or conduct would result, or be likely to result, in a benefit to the public; and
- that benefit would outweigh the detriment to the public constituted by any lessening of competition that would be likely to result from the arrangements or conduct.

In deciding whether it should grant authorisation the Commission must examine the anti-competitive aspects of the arrangements or conduct and the public benefits arising from the arrangements or conduct, and weigh the two to determine which is greater. Should the public benefit or expected public benefits outweigh the anti-competitive aspects the Commission may grant authorisation or grant authorisation subject to conditions.

If this is not the case the Commission may refuse authorisation or alternatively, in refusing authorisation, indicate to the applicant how the applications could be constructed to change the balance of detriment and public benefit so that authorisation may be granted.

4. Submissions

The applicants provided the Commission with a submission in support of the application for authorisation. This submission was placed on the public register for inspection by interested parties.

Seven other interested parties then provided submissions to the inquiry, in response to an invitation from the Commission. Each of these submissions welcomed the PMAA/NFAA initiative in adopting the TGAC with several submissions suggesting enhancements to the proposed arrangements.

Following consideration of the enhancements, and discussion with other interested parties, the applicants adopted many of the enhancements in a supplementary submission to the Commission.

Issues raised in each of the submissions by interested parties are considered below.

Membership

Membership of the TGACC was the most contentious issue raised by interested parties. Difficulties revolved around balancing the concerns of industry participants with those of the consumer movement.

Industry participants were concerned to ensure that adequate representation be provided to those organisations with an interest in the TGAC.

The consumer movement was not opposed to particular industry groups being represented on the TGACC, but considered the proposed membership to be too large to be workable. Several alternatives for membership of the TGACC were raised as possible solutions to the concerns of the consumer movement.

Following consideration of alternative proposals the application for authorisation was amended to provide for TGACC membership comprising:

- four industry members nominated by the NFAA, PMAA, Australian Direct Marketing Association and the Direct Sellers Association of Australia;
- two advertising industry members nominated by the Australian Association of National Advertisers (AANA) and the Advertising Federation of Australia (AFA);
- two consumer members nominated by the ACA and Consumers' Health Forum (CHF);

- three health care professional members nominated by the Australian Traditional Medicines Society (ATMS), Pharmacy Guild of Australia/Pharmaceutical Society of Australia (PGA/PSA) and the Royal Australian College of General Practitioners (RACGP); and
- one government member (nominated by the Therapeutic Goods Authority (TGA)).

These 12 members of the TGACC will have full voting rights, with observer status being granted to the Australian Pharmaceutical Manufacturers Association, the Cosmetics, Toiletry and Fragrance Association of Australia and the Medical Industry Association of Australia. Alternates will also be nominated for each member to ensure adequate representation.

The quorum for the amended TGACC membership will comprise the TGACC Chair plus the following six members:

- one member nominated by both the NFAA and PMAA;
- at least one each of the advertising industry, consumer and health care professional members; and
- one government member.

Membership of the CRP was also raised by the consumer movement as an area of concern. In particular, the proposed composition of ten members and two observers was considered too large to be effective.

Following consideration of an alternative proposed by the ACA, the application was amended to reduce membership of the CRP to eight full members. These members will comprise:

- a lawyer with trade practices experience (Chair);
- two industry members (nominated by the NFAA and PMAA);
- three health care profession members (nominated by each of the ATMS, PSA/PGA and the RACGP);
- two consumer members (nominated by the ACA and the Australian Health Forum (AHF)).

In addition to these members, the TGA will be granted full observer status and the Australian and New Zealand Food Authority will be granted observer status where appropriate, given the nature of the complaint.

The quorum for the new CRP membership will comprise:

- the Chair;
- two industry members;
- one health care profession member;
- one consumer member; and
- the observer from the TGA.

Decisions of the CRP will be subject to appeal. Such appeals will be heard by an independent arbiter appointed by the TGACC along the lines of the authorised PMAA appeals procedures.

These appeal provisions were accepted by all interested parties as reasonable.

Cross membership

Various interested parties raised concern regarding the possibility of cross-membership between complaints bodies. The TGA, for example, suggested there should be no cross-membership between the CRP and the appeals mechanism. This suggestion was supported by the applicants.

The ACA noted its opposition to any cross membership between the CRP and the individual NFAA, PMAA or other organisation's advertising pre-vetting bodies. In addition, the ACA recommended the separation of roles and members between the CRP and the TGACC, but noted that there may be limitations on human resources, particularly those with considerable experience in the area.

With the exception of cross membership between the TGACC and CRP, the applicants accepted each of the concerns raised by interested parties. The applicants argue, however, that cross membership between the TGACC and CRP:

> ... helps maximise understanding of the processes of each forum and ensures that any proposed changes to the TGAC resulting from a problem identified at CRP are fully understood at TGACC, and conversely that the policy developed by TGACC is understood and applied correctly by the CRP.
>
> PMAA/NFAA amended application, 24 March 1997

Terms of appointment

Both the ACA and the AFA proposed restricting the term of appointment for members of the TGACC. The AFA proposed three years as a suitable maximum term, while the ACA proposed an initial appointment of two years with re-appointment possible for a maximum of two additional years.

Other interested parties, including the applicants, accepted the concept of maximum terms of appointment as a sound proposal.

Accordingly, the applicants agreed to restrict initial appointments to the TGACC to two years. Re-appointment to the TGACC will be possible for a maximum of two additional terms, each lasting not more than two years.

Co-opting experts

The original application for authorisation provided the TGACC with the power to coopt experts, not otherwise represented, to assist decision making.

While recognising the potential benefit of input from experts on particular matters, several interested parties expressed concern that the power to coopt experts may be used to alter the balance of representation on the TGACC.

To address these concerns it was suggested that:

- experts coopted to the TGACC should have no voting rights; and
- TGACC members should be advised prior to any meeting where the power to coopt experts is to be exercised.

The applicants accepted these suggestions and proposed extending the power to coopt experts to meetings of the CRP. Where experts are to be coopted to the CRP, members will be advised at least one week prior to the meeting.

Independence of the Chair

With regard to independence of the TGACC Chair, there was a divergence of opinion among interested parties. The ACA argued that the Chair should be a non-industry, independent nominee to ensure independence and transparency.

Other interested parties, such as the AFA, argued that an industry member with trade practices experience would be preferable, providing the process remains transparent.

According to the applicants the Chair should be a member of the TGACC nominated in alternate years by the NFAA and the PMAA. This nomination could be from the nominating organisation or another member of the TGACC.

Interested parties agreed the CRP Chair should be an independent lawyer with trade practices experience.

Coverage of the system

Interested parties also agreed on the desirability of coverage of the TGAC including all forms of advertising as defined both in the TGAC and the *Therapeutic Goods Act 1989*. Such coverage includes the direct selling and marketing of therapeutic goods.

It was also agreed, however, that pre-clearance of therapeutic advertisements distributed through direct selling and marketing is currently beyond the resources of the clearance function. Pre-clearance in this area remains a goal for the future with post marketing control being achieved through the self-regulatory environment (i.e. the complaint handling provisions of the NFAA and PMAA Codes of Practice).

Sanctions

The applicants are currently developing uniform sanctions which will be applied, in addition to applicable regulatory sanctions, for breaches of the TGAC. Finalisation of these sanctions is expected to occur once members of the NFAA and PMAA have had an opportunity to debate them at a special meeting of members held by both associations, in accordance with the association rules. These meetings are planned to be held no later than August 1997.

The uniform sanctions which are expected to be debated at each special meeting of members are as follows:

1. the requirement, notified in writing, that the offender gives an undertaking to discontinue any practice that has been determined to constitute a breach of the TGAC;

2. the requirement, notified in writing, that the offender issue retraction statements and/or corrective statements or advertisements. The format, size, wording, mode of publication and method of distribution of such statements/advertisements shall be subject to the approval of the CRP prior to release and will generally conform to the original statement/advertisement; and

3. the issuing of a fine by the CRP to the offender in accordance with a published schedule of fines;

4. failure to comply with sanctions 1–3 shall entitle the CRP to direct the PMAA/NFAA to publish details of the breach in their newsletters and the CRP's requirements for remedial action;

5. continued refusal to comply shall entitle the CRP to direct the PMAA/NFAA to publish details of the breach in the trade press, the CRP's requirements for remedial action and the prospect of suspension or expulsion from the PMAA/NFAA; and to notify the Commission if deemed necessary; and

6. if in the course of hearing a complaint the CRP considers that it has been lodged for vexatious reasons, the CRP may request the complainant to show cause why the CRP should not impose a charge of $2000 for vexatious use of the TGAC.

Prior to adoption of any uniform sanctions the applicants have proposed applying the existing sanctions detailed in each association code of practice. In the case of the PMAA, these sanctions are already the subject of an authorisation, (No. A90549).

The ACA noted these arrangements and encouraged the applicants to move towards a system of uniform sanctions, providing this does not involve a weakening of the existing sanctions.

5. Commission consideration and draft determination

The Commission's evaluation of the application is in accordance with the statutory test as set out in Chapter 4 of this determination.

Membership

At 12 members the TGACC is considered by the Commission to be larger than desirable. Nevertheless, it is recognised that:

- the therapeutic goods industry is diverse and many organisations may have a legitimate interest in representation on the TGACC;
- there is benefit in providing membership of the TGACC to other organisations, such as the Australian Direct Marketing Association;
- the applicants have already taken action to reduce the TGACC membership through mechanisms such as observer status and the power to coopt experts; and
- the proposed membership includes adequate consumer representation.

Given these points the Commission is prepared to accept the proposed TGACC membership providing the proposed quorum (refer Chapter 4) is also adopted.

For the same reasons the Commission accepts the amended membership of the CRP proposed by the applicants.

Cross membership

The Commission agrees with interested parties that cross membership between the CRP and pre-vetting bodies, complaint bodies or the appeal mechanism is unacceptable. Accordingly, it welcomes the applicants action to clarify that such cross membership will not take place.

Cross membership between the CRP and TGACC is still possible under the proposed arrangements and may benefit the system by facilitating understanding between the two bodies.

Nevertheless, the different functions of the CRP and TGACC necessitate a degree of independence in membership and operation of the two bodies. To achieve this independence the Commission recommends that the number of individuals serving on both bodies should be restricted to not more than half of the CRP members.

Terms of appointment

Confidence in the integrity of bodies, such as the TGACC, is also maintained through restrictions on the term of appointment for individual members. Accordingly, the Commission welcomes the applicants' decision to limit TGACC members to a maximum of three two-year terms.

Co-opting experts

The Commission views the power to coopt experts as an important mechanism to facilitate decision making on technical matters. It notes, however, that the same power may be used to unduly influence decision making.

Given the reasonable measures introduced by the applicants to prevent abuse of the power to coopt experts, the Commission supports the granting of this power to both the TGACC and CRP.

Independence of the Chair

The Commission agrees with all interested parties that the Chair of the CRP should be an independent party.

An independent Chair of the TGACC is also considered by the Commission to be desirable. Nevertheless, it is recognised that the system is an initiative of the applicants and has the general support of all interested parties, suggesting a degree of confidence in the ability of the applicants to remain objective. Furthermore, it is noted that the previous system for administration of the TGACC permitted the appointment of a Chair drawn from the industry.

Accordingly, the Commission is prepared to accept the appointment of an industry based TGACC Chair. The Commission recommends, however, that elections for the position of TGACC Chair should be held at least once every 12 months.

Coverage of the system

The Commission agrees with interested parties that it is desirable to include advertising associated with direct selling and marketing of therapeutic goods within coverage of the TGAC. Accordingly, it supports the applicants' attempts to achieve this end.

Sanctions

The Commission also supports the adoption of uniform sanctions by the applicants for breaches of the TGAC. Action being taken by the applicants to achieve this end before August 1997 is noted and accepted on the understanding that the Commission will be advised of the sanctions prior to adoption.

The uniform sanctions that have been proposed (refer Chapter 4) appear reasonable, although some concern is held regarding the use of the final sanction listed (refer Chapter 4). This sanction provides for the imposition of a $2000 charge for vexatious use of the TGAC.

While the Commission supports measures to prevent vexatious use of the TGAC, the sanction could be used to exclude certain legitimate complaints from being heard. To guard against this scenario the Commission recommends that the applicants publish guidelines indicating what is likely to constitute a vexatious complaint.

Interim arrangements for the imposition of sanctions, prior to the finalisation of uniform sanctions, are considered by the Commission to be reasonable.

Anti-competitive detriment

The proposed arrangements for the TGAC have the potential for anti-competitive detriment by:

- extending advertising restrictions beyond the provisions of the Therapeutic Goods Act; and
- providing for the imposition of sanctions where an advertisement is found to be in breach of the TGAC.

While potentially significant, the Commission is of the view that detriment associated with these two aspects of the arrangements is likely to be limited.

With regard to extension of advertising restrictions beyond provisions of the Therapeutic Goods Act, the Commission notes that the restrictions are typically directed at protecting consumers from false, misleading or unsafe claims, rather than the prevention of competition between advertisers.

Furthermore, the proposed sanctions represent an important mechanism for ensuring compliance with the TGAC and, in this context, the sanctions are considered by the Commission to be reasonable.

Public benefit

The Commission is also of the view that the arrangements have the potential for significant benefit to the public through:

- the continued application of a TGAC, together with effective mechanisms to ensure compliance;
- the implementation of a flexible system, capable of responding quickly to complaints and changes in community needs and attitudes;
- broad coverage (albeit incomplete for the time being) of the TGAC across various media; and
- consistency in application of the TGAC between over-the-counter medicines and health and nutrition products.

Given the nature of therapeutic goods as a means of relieving pain and suffering, it is particularly important that consumers be able to rely on claims made in any associated advertising. For this reason the Commission considers there to be substantial public benefit associated with mechanisms that support the accuracy and validity of therapeutic claims. The proposed arrangements are an example of such mechanisms.

Conclusion

After examining the proposed TGAC arrangements, the Commission concluded in its draft determination that, in all the circumstances, the proposed arrangements for which the applicants have sought authorisation would be likely to result in a benefit to the public that would outweigh the detriment to the public constituted by any lessening of competition that was likely to result from the arrangements.

The Commission therefore proposed, subject to a pre-decision conference pursuant to section 90A of the Act that might be requested, to grant authorisation to the PMAA and NFAA for application A90600.

In the draft determination it was noted by the Commission that application A90600 included a request for interim authorisation from 1 January 1997. This request was submitted to ensure continuity of consumer protection following abandonment of the MCA system on 31 December 1996.

At its meeting of 18 December 1996 the Commission accepted the request for interim authorisation. When the Commission issued the draft determination on 29 April 1997 it noted that the rationale for an interim authorisation remained valid and the interim authorisation was allowed to stand until a final determination was reached on application A90600.

Subject to consideration of issues raised during a possible pre-decision conference the Commission proposed, in the draft determination to limit authorisation A90600 to four years from the date of the final determination.

6. Submissions and section 90(A) conference

At the request of Bionic Products, the Commission advised interested parties on 8 May 1997 of its intention to conduct a pre-decision conference, in accordance with s.90(a) of the Act.

Submissions

Prior to the conference the Commission received submissions from the CHF, ACA, MIAA, ANTA and Bionic Products relating to application A90600.

The CHF and ACA provided short submissions indicating support for application A90600, with the CHF expressing concern that further delay in the establishment of the TGACC and CRP may disadvantage consumers.

Submissions from MIAA and ANTA focussed on membership of the TGACC and CRP. In particular:

- MIAA requested that a mechanism be established to ensure that it receives voting rights, rather that basic observer status, on issues relating to devices or diagnostics; and
- ANTA suggested that the proposed membership of the TGACC and CRP may not adequately represent natural and traditional therapy professionals.

ANTA noted in its submission that the ATMS, PGA/PSA and RACGP have been accepted on the TGACC and CRP to represent health care professionals, but suggested that natural and traditional therapy professionals would be better represented by a nominee from the Federation of Natural Therapists Association.

Bionic Products used its submission to draw attention to the definition of a therapeutic good used in the TGAC. More specifically, Bionic Products argued that the ionisers which it manufactures should not be classed as a therapeutic good or bound by the TGAC.

Section 90(A) conference

Definition of a therapeutic good

The definition of a therapeutic good, as used in the TGAC and *Therapeutic Goods Act 1989*, was considered in further detail during the conference on 26 May 1997. At the hearing Bionic Products reiterated the view that its ionisers should not be covered by advertising restrictions associated with the TGAC. Bionic Products then extended this argument by suggesting that, should therapeutic devices be included in the definition of therapeutic goods used in the TGAC, membership of the TGACC and CRP is inadequate.

With regard to the definition of therapeutic goods, Bionic Products claimed that an appropriate definition should be restricted to goods or devices which cause a chemical reaction within the body.

The TGA responded that the definition of a therapeutic good contained in the *Therapeutic Goods Act* includes drugs and devices which are used to prevent, treat or have an effect on illness. According to the TGA, the ioniser manufactured by Bionic Products is a therapeutic device listed in the register of therapeutic goods. This argument was supported by the applicants who commented that advertisers should be able to substantiate claims made under the TGAC.

Membership of the TGACC and CRP

With regard to membership, Bionic Products argued that the medical profession was too heavily represented on the TGACC and questioned whether that the CRP was qualified to assess devices such as ionisers.

In response to these arguments, the applicants claimed that the CRP is responsible for examining the reliability of therapeutic claims, rather than assessing the merits of particular therapeutic goods.

In addition, the applicants noted that the several parties have been granted observer status for the TGACC. These parties were identified as the Australian Pharmaceutical Manufacturers' Association (APMA), the Cosmetics, Toiletries and Fragrances Association of Australia (CTFAA) and the MIAA.

During the conference, the applications clarified the meaning of observer status in response to a question from the APMA and a submission from MIAA. According to this advice, organisations granted observer status will receive agenda papers and minutes as if they were members and may, upon giving notice, attend any meetings of the TGACC. Full voting rights will be extended to these observers while particular issues of relevance are being considered,.

Submissions provided subsequent to the conference

Advice regarding the nature of observer status was subsequently confirmed by the applicants through a supplementary written submission.

Included in the applicants' supplementary submission was a request that the proposed four year restriction on the term of the authorisation be removed.

According to the applicants, public benefit associated with this particular application for authorisation overwhelmingly outweighs the associated anti-competitive detriment and there is no reason to suggest the position will change in the future.

Rather than imposing a time limit on the authorisation, the applicants proposed that it would be less onerous and costly if the parties were to be required to report periodically to the Commission, or if Commission staff attended meetings periodically to monitor the operation of the authorisation. Should circumstances surrounding the authorisation change, the Commission could use its powers to revoke the authorisation.

7. Commission consideration of the issues raised in the pre-decision conference and subsequent submissions

As previously noted, the Commission must apply the statutory test detailed in chapter 3. That test requires the Commission to consider issues raised at the pre-decision conference in reaching a final determination. Consideration of these issues, together with other issues raised in related submissions is provided below:

Definition of therapeutic goods

The Commission rejects the argument of Bionic Products that devices, such as ionisers, are not therapeutic goods.

According to the TGAC, therapeutic goods are:

> *'... those goods, as defined by the Commonwealth Therapeutic Goods Act 1989 (including pharmaceuticals, biological products, appliances and devices) which, under applicable Federal, State and Territory law, may be advertised to and purchased without prescription by the public and for which therapeutic claims are made.'*

This definition implies that advertising for a device may be covered by the TGAC if the advertising suggests that therapeutic benefit may be gained from use of the device.

Furthermore, the *Commonwealth Therapeutic Goods Act 1989* includes therapeutic devices in the meaning of therapeutic goods and defines such devices to mean:

> *'... therapeutic goods consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical immunological or metabolic means though it may be assisted in its function by such means ...'*

Membership of the TGACC and CRP

Having rejected the argument that therapeutic devices are not covered by the TGAC, the Commission then examined membership arrangements for the TGACC and CRP to ensure that adequate expertise was available to these bodies when examining issues concerning therapeutic devices.

In considering membership of these bodies, the Commission noted that:

- the TGAC covers a diverse range of goods and interests; and
- attempts to provide permanent representation for each of these interests are likely to result in an unworkable model for decision making.

Recognising these difficulties, the Commission is satisfied that the proposed membership arrangements for the TGACC and CRP strike a reasonable balance between the need to ensure efficiency in decision making and the need for adequate representation when considering issues of a specific nature.

With regard to the suggestion by Bionic Products, that representation for manufacturers of medical devices in inadequate, the Commission notes that:

- MIAA has now been granted observer status for the TGACC, providing the Council with additional expertise when considering issues concerning the advertising of medical devices; and
- the TGACC and CRP have the power to co-opt experts where specific knowledge or experience is required.

These arrangements are considered by the Commission to be adequate for the existing needs of the TGACC and CRP when issues concerning therapeutic devices arise.

With regard to the submission by ANTA that a natural therapy representative has not been nominated from the profession for the TGACC or CRP, the Commission acknowledges that natural and traditional therapy professionals may be better represented by a nominee from the Federation of Natural Therapists Association, (FNTA).

Nevertheless, it is also noted by the Commission that health care professionals are already represented on the TGACC and CRP by ATMS, PGA/PSA and RACGP. Widening the membership of the TGACC and CRP, to include representation from FNTA or other organisations, may occur at the expense of decision making efficiency.

Should issues concerning natural therapists arise more frequently than expected, it may be appropriate for changes to be made to the membership of either the TGACC or CRP through the inclusion of a representative from FNTA. Other membership changes may also be required periodically to reflect changes in community needs and attitudes. Such changes should not, however, be used to alter the balance of membership or to restrict consumer representation.

Conclusion

Having considered the views of interested parties raised subsequent to the draft determination, the Commission remains satisfied that authorisation application A90600 is likely to result in a benefit to the public that outweighs any detriment to the public constituted by any lessening of competition arising from the application.

In considering an appropriate period for the authorisation, the Commission notes that changes may occur which alter the balance between public benefit and anti-competitive detriment. For example, a shift in community attitudes to the advertising of particular therapeutic goods may necessitate changes in the membership arrangements for the TGACC and CRP. Should these changes not be made, or should inappropriate changes be made, then the balance between public benefit and anti-competitive detriment may cease to fall in favour of authorisation.

Accordingly, the Commission remains of the view that authorisation should only be granted for the four years proposed in the draft determination.

If, at any time before the four year term has expired, it appears to the Commission that the authorisation was granted on the basis of false or misleading evidence/information; or that circumstances surrounding the authorisation have changed materially, the Commission may set in train procedures to review the authorisation.

8. Determination

The Commission confirms its finding in the draft determination, that authorisation should be granted to application A90600 for four years from the date on which this determination is issued.

This determination is made on 2 July 1997. If no application is made for review to the Australian Competition Tribunal, it will come into force on 24 July 1997.

If an application for a 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.