Allen Allen & Hemsley

ALLENS
ARTHUR ROBINSON
GROUP

LAWYERS

D01/4561

RAC00078YT

The Chifley Tower
2 Chifley Square
Sydney NSW 2000
Australia
Tel 61 2 9230 4000
Fax 61 2 9230 5333

Correspondence
GPO Box 50
Sydney NSW 2001
Australia
DX 105 Sydney

www.allens.com.au

6 February 2001

Mr Tim Grimwade
Acting General Manager
Adjudication Branch
Australian Competition and
Consumer Commission
470 Northbourne Avenue
Dickson ACT 2602

BY COURIER

Dear Mr Grimwade

APMA Code of Conduct

Further to your letter of 27 November 2000 to Mr Evans of the Australian Pharmaceutical Manufacturers Association Inc (***the APMA***) and to a subsequent telephone conversation between Joanne Palisi of the Commission and Janey Draper of our office we confirm that we act for the APMA. We enclose the following documents in support of the APMA's application for authorisation of its Code of Conduct (***the APMA Code***) under section 88(1) of the Trade Practices Act (Cth) 1974:

1. Completed forms A and B;
2. Submission accompanying authorisation application; and
3. The enclosures to the submission as follows:

   Enclosure 1 – 3rd edition of the APMA Code

   Enclosure 2 – AMPA Code of Conduct Annual Report for 2000

   Enclosure 3 – Therapeutic Goods Administrations marketing approval letter.

We understand that at a meeting between Ian Searles and Jaime Norton of the Commission and Fiona Woodard of the APMA on 27 June 2000 the Commission suggested that the APMA ask the Commission to revoke the current authorisation for the APMA Code and seek a new application which would attract no fee. On this basis we do not enclose an authorisation fee.

Our Ref RGBS NKNS 203293921

If you have any questions or require any further information please let us know.

Yours sincerely

Gaire Blunt
Partner
Gaire.Blunt@allens.com.au
Tel (02) 9230 4902

Nicola Nygh
Senior Associate
Nicola.Nygh@allens.com.au
Tel (02) 9230 4616

Copy To Fiona Woodard, APMA

Form A

Commonwealth of Australia
Trade Practices Act 1974 ---- Sub-section 88(1)
EXCLUSIONARY PROVISIONS:
APPLICATION FOR AUTHORISATION

To the Australian Competition and Consumer Commission:

Application is hereby made under sub-section 88(1) of the *Trade Practices Act* 1974 for an authorisation under that sub-section

- to make a contract or arrangement, or arrive at an understanding, where a provision of the proposed contract, arrangement or understanding would be, or might be, an exclusionary provision within the meaning of section 45 of that Act.
- to give effect to a provision of a contract, arrangement or understanding where the provision is, or may be, an exclusionary provision within the meaning of section 45 of that Act.

- (Strike out whichever is not applicable).

(PLEASE READ DIRECTIONS AND NOTICES ON BACK OF FORM)

1. (a) Name of Applicant AUSTRALIAN PHARMACEUTICAL MANUFACTURERS' ASSOCIATION INC (APMA)

(*See* Direction 2 on the back of this Form)

(b) Short description of business carried on by applicant INDUSTRY BODY REPRESENTING PHARMACEUTICAL MANUFACTURERS IN AUSTRALIA

(c) Address in Australia for service of documents on the applicant
ALLEN ALLEN & HEMSLEY, GPO BOX 50, SYDNEY NSW 2001

2. (a) Brief description of contract, arrangement or understanding and, where already made, its date
APMA CODE OF CONDUCT - 13th edn, 5 SEPTEMBER 2000

(b) Brief description of those provisions of the contract, arrangement or understanding that are, or would or might be, exclusionary provisions
SEE SUBMISSION ACCOMPANYING APPLICATION

(*See* Direction 4 on the back of this Form)

(c) Names and addresses of other parties or proposed parties to contract, arrangement or understanding

3. Names and addresses (where known) of parties and other persons on whose behalf application is made

4. (a) Grounds for grant of authorisation
SEE SUBMISSION ACCOMPANYING APPLICATION

(b) Facts and contentions relied upon in support of those grounds
SEE SUBMISSION ACCOMPANYING APPLICATION

(*See* Notice 1 on the back of this Form)

5. This application for authorisation may be expressed to be made also in relation to other contracts, arrangements or understandings or proposed contracts, arrangements or understandings, that are or will be in similar terms to the above-mentioned contract, arrangement or understanding.

(a) Is this application to be so expressed .....NO.....

(b) If so, the following information is to be furnished: –

(i) the names of the parties to each other contract, arrangement or understanding .....

.....

.....

.....

(ii) the names of the parties to each other proposed contract, arrangement or understanding which names are known at the date of this application .....

.....

.....

.....

(*See* Direction 5 *and* Notice 2 on the back of this Form)

6. (a) Does this application deal with a matter relating to a joint venture (See section 4J of the *Trade Practices Act* 1974) ...NO.....

(b) If so, are any other applications being made simultaneously with this application in relation to that joint venture?

.....

.....

(c) If so, by whom or on whose behalf are those other applications being made?

.....

.....

7. Name and address of person authorised by the applicant to provide additional information in relation to this application ...GAIRE BLUNT - ALLEN ALLEN & HEMSLEY, GPO BOX 50, SYDNEY NSW 2001.....

.....

.....

Dated 9. 2, 19 01

Signed by/on behalf of the applicant

Gaire Blunt

.....

(Signature)

APPLICANTS SOLICITOR

.....

(Full Name)

ALLEN ALLEN : HEMSLEY

.....

(Description)

(ROGER GAIRE BLUNT)

DIRECTIONS

1. Where there is insufficient space on this form to furnish the required information, the information is to be shown on separate sheets, numbered consecutively and signed by or on behalf of the applicant.

2. Where the application is made by or on behalf of a corporation, the name of the corporation is to be inserted in item 1(a), not the name of the person signing the application and the application is to be signed by a person authorised by the corporation to do so.

3. In item 1(b), describe that part of the applicant's business relating to the subject matter of the contract, arrangement or understanding in respect of which the application is made.

4. Furnish with the application particulars of the contract, arrangement or understanding in respect of which the authorisation is sought. Those particulars shall be furnished ---
(a) in so far as the particulars of any of them have been reduced to writing --- by lodging a true copy of the writing; and
(b) in so far as the particulars or any of them have not been reduced to writing --- by lodging a memorandum containing a full and correct statement of the particulars that have not been reduced to writing.

5. Where the application is made also in respect of other contracts, arrangements or understandings, which are or will be in similar terms to the contract, arrangement or understanding referred to in item 2, furnish with the application details of the manner in which those contracts, arrangements or understandings vary in their terms from the contract, arrangements or understanding referred to in item 2.

NOTICES

1. In relation to item 4, your attention is drawn to sub-section 90(8) of the *Trade Practices Act* 1974 which provides as follows: ---

"(8) The Commission shall not ---

(a) make a determination granting:
   (i) an authorisation under sub-section 88(1) in respect of a provision of a proposed contract, arrangement or understanding that is or may be an exclusionary provision; or
   (ii) an authorisation under sub-section 88(7) or (7A) in respect of proposed conduct; or
   (iii) an authorisation under sub-section 88(8) in respect of proposed conduct to which sub-section 47(6) or (7) applies; or
   (iv) an authorisation under sub-section 88(8A) for proposed conduct to which section 48 applies;

unless it is satisfied in all the circumstances that the proposed provision or the proposed conduct would result, or be likely to result, in such a benefit to the public that the proposed contract or arrangement should be allowed to be made, the proposed understanding should be allowed to be arrived at, or the proposed conduct should be allowed to take place, as the case may be; or

(b) make a determination granting an authorisation under subsection 88(1) in respect of a provision of a contract, arrangement or understanding that is or may be an exclusionary provision unless it is satisfied in all the circumstances that the provision has resulted, or is likely to result, in such a benefit to the public that the contract, arrangement or understanding should be allowed to be given effect to.".

2. If an authorisation is granted in respect of a proposed contract, arrangement or understanding the names of the parties to which are not known at the date of the application, the authorisation shall, by sub-section 88(14) of the *Trade Practices Act* 1974, be deemed to be expressed to be subject to a condition that any party to the contract, arrangement or understanding will, when so required by the Commission, furnish to the Commission the names of all the parties to the contract, arrangement or understanding.

Form B

Commonwealth of Australia
Trade Practices Act 1974 ---- Sub-section 88(1)
AGREEMENTS AFFECTING COMPETITION:
APPLICATION FOR AUTHORISATION

To the Australian Competition and Consumer Commission:

Application is hereby made under sub-section 88(1) of the *Trade Practices Act* 1974 for an authorisation under that sub-section

- to make a contact or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of that Act.
- to give effect to a provision of a contract, arrangement or understanding which provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45 of that Act.
- (Strike out whichever is not applicable)

(PLEASE READ DIRECTIONS AND NOTICES ON BACK OF FORM)

1. (a) Name of Applicant AUSTRALIAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION INC (APMA)

(*See* Direction 2 on the back of this Form)

(b) Short description of business carried on by applicant INDUSTRY BODY REPRESENTING PHARMACEUTICAL MANUFACTURERS IN AUSTRALIA

(c) Address in Australia for service of documents on the applicant ALLEN ALLEN & HEMSLEY, GPO BOX 50 SYDNEY NSW 2001

2. (a) Brief description of contract, arrangement or understanding and, where already made, its date
APMA CODE OF CONDUCT, 13th edn, 5 SEPTEMBER 2000

(b) Names and addresses of other parties or proposed parties to contract, arrangement or understanding
A SEE SUBMISSION ACCOMPANYING APPLICATION

(*See* Direction 4 on the back of this Form)

3. Names and addresses (where known) of parties and other persons on whose behalf application is made

4. (a) Grounds for grant of authorisation
SEE SUBMISSION ACCOMPANYING APPLICATION

(b) Facts and contentions relied upon in support of those grounds
SEE SUBMISSION ACCOMPANYING APPLICATION

(*See* Notice 1 on the back of this Form)

5. This application for authorisation may be expressed to be made also in relation to other contracts, arrangements or understandings or proposed contracts, arrangements or understandings, that are or will be in similar terms to the above mentioned contract, arrangement or understanding.

(a) Is this application to be so expressed?.....NO.....

(b) If so, the following information is to be furnished:

(i) the names of the parties to each other contract, arrangement or understanding.....

.....

.....

(ii) the names of the parties to each other proposed contract, arrangement or understanding which names are known at the date of this application .....

.....

(*See* Direction 5 *and* Notice 2 on the back of this Form)

6. (a) Does this application deal with a matter relating to a joint venture (See section 4J of the *Trade Practices Act* 1974)

.....NO.....

(b) If so, are any other applications being made simultaneously with this application in relation to that joint venture

.....

.....

(c) If so, by whom or on whose behalf are those other applications being made

.....

.....

7. Name and address of person authorised by the applicant to provide additional information in relation to this application.....

GAIRE BLUNT, ALLEN ALLEN & HEMSLEY (Address Above)

.....

.....

Dated 9. 2, 1901

Signed by/on behalf of the applicant

Gaire Blunt

.....

(Signature)

ROGER GAIRE BLUNT

.....

(Full Name)

SOLICITOR FOR APPLICANT

.....

(Description)

DIRECTIONS

1. Where there is insufficient space on this form to furnish the required information, the information is to be shown on separate sheets, numbered consecutively and signed by or on behalf of the applicant.

2. Where the application is made by or on behalf of a corporation, the name of the corporation is to be inserted in item 1(a), not the name of the person signing the application and the application is to be signed by a person authorised by the corporation to do so.

3. In item 1(b), describe that part of the applicant's business relating to the subject matter of the contract, arrangement or understanding in respect of which the application is made.

4. Furnish with the application particulars of the contract, arrangement or understanding in respect of which the authorisation is sought. Those particulars shall be furnished ---
   (a) in so far as the particulars or any of them have been reduced to writing --- by lodging a true copy of the writing; and
   (b) in so far as the particulars or any of them not been reduced to writing --- by lodging a memorandum containing a full and correct statement of the particulars that have not been reduced to writing.

5. Where the application is made also in respect of other contracts, arrangements or understandings, which are or will be in similar terms to the contract, arrangement or understanding referred to in item 2, furnish with the application details of the matter in which those contracts, arrangements or understandings vary in their terms from the contract, arrangements or understanding referred to in item 2.

NOTICES

1. In relation to item 4, your attention is drawn to sub-sections 90(6) and (7) of the *Trade Practices Act* 1974 which provide as follows: -

"(6) The commission shall not make a determination granting an authorisation under sub-sections 88(1), (5) or (8) in respect of a provision (not being a provision that is or may be an exclusionary provision) of a proposed contract, arrangement or understanding, in respect of a proposed covenant, or in respect of proposed conduct, unless it is satisfied in all the circumstances that the provision of the proposed contract, arrangement or understanding, the proposed covenant, or the proposed conduct, as the case may be, would result, or be likely to result, in a benefit to the public and that that benefit would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if

(a) the proposed contract or arrangement were made, or the proposed understanding were arrived at, and the provision concerned were given effect to;
(b) the proposed covenant were given, and were complied with; or
(c) the proposed conduct were engaged in, as the case may be.

"(7) The Commission shall not make a determination granting an authorisation under sub-section 88(1) or (5) in respect of a provision (not being a provision that is or may be an exclusionary provision) of a contract, arrangement or understanding, or, in respect of a covenant, unless it is satisfied in all the circumstances that the provision of the contract, arrangement or understanding, or the covenant, as the case may be, has resulted, or is likely to result, in a benefit to the public and that that benefit outweighs or would outweigh the detriment to the public constituted by any lessening of competition that has resulted, or is likely to result, from giving effect to the provision or complying with the covenant."

2. If an authorisation is granted in respect of a proposed contract, arrangement or understanding the names of the parties to which are not known at the date of this application, the authorisation shall, by sub-section 88(14) of the *Trade Practices Act* 1974, be deemed to be expressed to be subject to a condition that any party to the contract, arrangement or understanding will, when so required by the Commission, furnish to the Commission the names of all the parties to the contract, arrangement or understanding.

Australian Pharmaceutical Manufacturers Association Inc (*APMA*) Submission accompanying authorisation application February 2001

1. Introduction

This submission accompanies an application for authorisation of the Code of Conduct of the APMA (***the APMA Code***). The APMA asks that the deemed authorisation of the APMA Code in July 1977 be revoked on the grant of the fresh authorisation requested in this application.

A copy of the 13th edition of the APMA Code, which was adopted on 5 September 2000, is enclosed (**Enclosure 1**). The APMA Code was first published in 1960 and since then it has been revised on a regular basis. On 30 June 1977 the Trade Practices Commission granted clearance of the Code under s92(2) of the Trade Practices Act 1974.

The APMA Code sets out standards of conduct for marketing of prescription products to health professionals. The purpose of the APMA Code is to protect consumers and to maintain high ethical standards in the marketing of prescription products. As such the APMA Code complements and reinforces:

(a) the provisions in the Therapeutic Goods Act 1989 including in particular the prohibition on the direct advertising of prescription products to members of the public; and

(b) the prohibition on misleading and deceptive conduct in s52 of the Trade Practices Act.

To the extent that the provisions in the Code may have an anti-competitive or exclusionary effect, such detriments are insignificant in relation to the public benefits that accrue from the implementation of the APMA Code and indeed are necessary in order to achieve an appropriate level of consumer protection and high ethical standards within the industry.

The APMA Code has received international recognition. In 1992 Health Action International evaluated various Codes of Conduct against the World Health Organisation ethical criteria for medicinal drug promotion. The APMA Code scored the highest rating in an international comparison of a number of countries' Codes of Conduct.

2. Background to proposal

2.1 The APMA

The APMA is the peak industry body representing prescription medicine manufacturers in Australia. The 49 member companies of the APMA are responsible for the production of over 90% of the medicines available through the Pharmaceutical Benefits Scheme (***the PBS***). The APMA encourages its members to maintain the highest standards in the promotion of and education about prescription medicines through its Code and its continuing education program for medical representatives (***CEP***).

2.2 Purpose and scope of the Code

The APMA Code sets out standards of conduct for the marketing of prescription products to health professionals. While the direct promotion of prescription products to the general public is prohibited by the Therapeutic Goods Act (Cth) 1989, the APMA Code sets out standards of conduct for communications between members of the pharmaceutical industry and members of the public.

To support compliance with the APMA Code provisions are included for:

(a) a Code of Conduct Committee to hear complaints about the conduct of members and, with their consent, non-members;

(b) the sanctioning of non-compliance; and

(c) a Monitoring Committee to monitor the promotional material of member companies on a regular and ongoing basis.

The APMA also has a communications and education plan for members and external audiences.

2.3 Prior dealings with the Trade Practices Commission and ACCC (*the Commission*) in relation to the APMA Code

(a) Clearance of the APMA Code in 1977

On 30 June 1977 the Commission granted clearance under s92(2) of the Trade Practices Act in respect of the fourth edition of the Code. On 1 July 1977 s92 of the Trade Practices Act was repealed but clearances granted previously under s92(2) were deemed to be authorisations granted by the Commission under s88(1) or (5) of the Act.

(b) The Commission's Final Report on the Self Regulation of Promotion and Advertising of Therapeutic Products (July 1992)

The 9th edition of the Code was considered in some detail by the Commission in its Final Report on the Self Regulation of Promotion and Advertising of Therapeutic Goods published in July 1992 (***the Report***). In the Report the Commission considered that the scheme was being administered effectively overall but recommended certain changes to enhance the effectiveness of the Code. All of the changes recommended by the Commission were considered by the APMA and most, if not all, of them can still be seen in the current version of the APMA Code including:

(i) the Code of Conduct Committee which hears complaints is now formally established in the APMA Code and includes a consumer representative on the Committee and a representative of the Therapeutic Goods Administration as an observer;

(ii) the existence, membership and reporting responsibilities of the Monitoring Committee are now specified in the APMA Code;

(iii) section 11.3 of the APMA Code provides for the APMA to carry out a review of the provisions of the Code at least every 3 years after seeking input from interested parties;

(iv) the APMA publishes a Code of Conduct Annual Report which details the complaints considered by the Code of Conduct Committee and the activities of the Monitoring Committee. A copy of the Code of Conduct Annual Report for 2000 is enclosed (**Enclosure 2**).

(c) Subsequent Revision of the APMA Code and consultation with the Commission

Since 1977 the APMA Code has undergone regular review and revision. Indeed the Code is now in its 13th edition. With each amendment to the APMA Code since 1977 the APMA has sent a copy of the new edition to the Commission together with an outline of the amendments which have been made. Over the years the APMA has dealt with various officers of the Commission in relation to the APMA Code including Messrs Bill Dee and Alan Asher.

In 1996 the APMA consulted extensively with Deputy Chairman Alan Asher on the content of the Code prior to the release of edition 12 on 9 December 1996.

(d) Complaint by Health Care Marketing Group to the Commission

On 10 June 1999 the Commission wrote to the APMA in relation to a complaint from Mr Nicholas Edwards of Health Care Marketing Group Pty Limited (***HMG***). The complaint related to notification given by the APMA to its members that an appointment making service for medical practitioners and pharmaceutical company representatives offered by HMG and known as QuickPlan was in breach of section 4.9 of the APMA Code. Section 4.9 provides:

> *"Under no circumstances shall representatives pay a fee in order to gain access to a health care professional".*

The Commission expressed concern that the APMA may be involved in an exclusionary provision in breach of s45 of the Trade Practices Act. The matter was resolved after the APMA sent corrective notification to its members in February 2000 that:

> *"Members should in no way feel constrained by the provisions of the Code of Conduct from entering into arrangements with QuickPlan or indeed other third parties in relation to proposals for medical representatives or companies access to general practitioners".*

This is the only occasion on which the APMA has received a complaint from the ACCC about the APMA Code.

(e) Subsequent Communications about Authorisation of the APMA Code

On 20 December 1999, in the course of correspondence regarding HMG's complaint, the Commission informed the APMA that the deemed authorisation of the APMA Code granted in 1977 does not extend to edition 12 of the Code. While we do not accept it we understand that the Commission has taken this view as a result of the number of amendments to the APMA's Code since 1977. On 27 June 2000 Mr Ian Searles and Ms Jaime Norton of the Commission met with Fiona Woodard from the APMA to discuss possible authorisation of edition 13 of the Code. At this meeting the ACCC suggested that it could be possible to make a new application which would attract no fee and then revoke the current authorisation.

3. Market definition

The relevant market in which to assess the potential effects of the APMA Code is the:

> Market in Australia for prescription products used under medical supervision as permitted under Australian Law.

4. Legislative Framework

The supply and promotion of pharmaceutical products in Australia is highly regulated. Under the Therapeutic Goods Act and Regulations all prescription products must be approved for registration on the Australian Register of Therapeutic Goods prior to supply and/or promotion. Direct promotion of prescription products to the general public is prohibited by the Therapeutic Goods Act.

Within this framework the marketing of prescription products is largely self regulated by the industry through the APMA Code which complements and reinforces the general prohibition on misleading and deceptive conduct in the Trade Practices Act.

Restrictions on the sale and promotion of prescription products have been imposed by the legislature largely in order to protect consumers from the risk of misuse or

inappropriate use of these products. There is also concern about the cost of inappropriate use of products subsidised under the Pharmaceutical Benefits Scheme.

5. Application of the APMA Code

Members of the APMA are required to comply with the Code as a condition of membership. Recently the Therapeutic Goods Administration (***the TGA***) amended its marketing approval letter to require that promotional material for goods on the Australian Register of Therapeutic Goods must comply with the requirements of the APMA Code. A copy of the TGA's marketing approval letter is enclosed (**Enclosure 3**). The APMA Code includes provisions for the hearing of complaints about the conduct of non-members. If a non-member refuses to have the matter considered by the APMA Code of Conduct Committee, the APMA reserves the right to refer such matters to the TGA and the Commission.

6. Effect of the Code on competition and public benefits

It is submitted that the APMA Code has little adverse effect on the state of competition in the relevant market particularly given that the market is highly regulated. In fact the Code contributes substantial public benefit in a number of ways including:

(i) consumer protection through the setting out and enforcement of standards of conduct for the marketing of prescription products;

(ii) the APMA Code complements and encourages compliance with the prohibition of misleading and deceptive conduct in the Trade Practices Act by setting out in detail the types of claims relating to prescription products which will be considered to be in breach of the Code and also by setting out details of the level of supporting information which should accompany claims; and

(iii) the Code encourages rational prescribing practices through the regulation of promotional activity including advertisements, gifts and incentives to medical practitioners and the education of medical representatives.

The Commission has indicated that it regards Codes which incorporate the following aspects as an efficient means of encouraging competition and creating an efficient, economic and business environment[1]:

(i) the Code of Conduct should cover a substantial proportion of the members of the industry;

(ii) the Code of Conduct should include commercially significant incentives to encourage compliance;

(iii) the Code of Conduct should allow for an industry based forum for complete arbitration including appeal; and

(iv) the Code of Conduct should allow room for public input.

Each of these aspects are evident in the APMA Code. Indeed the Commission has cited the APMA Code as a model code.

7. Analysis of the sections of the APMA Code

7.1 Nature & availability of information & claims

Section 1 provides that it is the responsibility of members to ensure that all promotional and medical claims are balanced, accurate, correct and able to be substantiated. It emphasises the need for all claims to be consistent with the product information approved by the Therapeutic Goods Administration. Specific provisions deal with:

(a) the responsibility of members to provide substantiating data on request;

(b) the obligation of members not to make false or misleading claims;

(c) the limited circumstances in which unapproved products may be displayed;

(d) the requirement that promotional material be in good taste;

(e) prohibition on the use of unqualified superlatives;

[1] See *Re Quilted Products Manufacturers Association of Australia* (1988) ATPR (Com) 50070

(f) limitations on the use of the word "new" to describe a product;

(g) guidelines for comparative statements;

(h) prohibition on imitation of material used by other manufacturers in a way that is likely to mislead or confuse;

(i) prohibition on the use of doctors' names or photographs in a way that is contrary to medical ethics; and

(j) the requirement that promotional material must be clearly distinguishable as such.

The above provisions together with the explanatory notes which accompany them complement and encourage compliance with s52 of the Trade Practices Act. The provisions support responsible prescribing practices and protect consumers.

7.2 Product Information

Certain types of promotional material must be accompanied by either full or abridged Product Information approved by the TGA and/or by details of changes in the Product Information or boxed warnings.

These requirements in section 2 encourage rational prescribing practices and help to protect consumers.

7.3 Promotional material

Section 3 sets out mandatory information to be included in different types of promotional material. This provision helps to ensure that claims are not misleading or deceptive, encourages rational prescribing practices and helps to protect consumers.

7.4 Medical representatives

Section 4 sets out standards of conduct and knowledge for medical representatives and requires medical representatives to undertake the APMA MedRep Diploma course or CEP which includes a Code of Conduct module.

These provisions heighten awareness of the APMA Code among medical representatives. The education requirements help maintain a high standard

of delivery of information to medical practitioners and thereby encourage rational prescribing practices.

7.5 Products starter packs (samples)

Section 5 regulates the distribution of starter packs and the information to be included with starter packs so as to ensure the safe and appropriate use of the prescription products included in the starter packs. The limitations on the size of starter packs also discourage use of starter packs as incentives for inappropriate prescribing practices.

7.6 Trade displays

Section 6 sets out requirements for trade displays to ensure that trade displays are used to disseminate knowledge to health care professionals and do not include incentives which may encourage irrational prescribing practices.

7.7 Travel and sponsorship

Section 7 restricts sponsorship by members of delegates travelling from or within Australia to symposia and/or congresses. The purpose of the provisions is to prevent sponsorship of delegates attending symposia being used as an incentive to support irrational prescribing practices.

7.8 Research

Section 8 includes provisions regulating post-marketing surveillance studies and market research so that such studies are not used as promotional exercises. Limitations on the use of product familiarisation programs are also included. These provisions encourage rational prescribing practices.

7.9 Communications with the general public

The provisions in section 9 dealing with general enquiries, media statements, general media articles, promotion to the general public and patient education and patient aids are consistent with the prohibition on direct advertising of prescription products to the general public and help to protect consumers.

7.10 Relations with health care professionals

The provisions in section 10 relating to entertainment, medical education material and general remuneration prevent members from providing financial or other incentives for prescribing their products.

7.11 Administration of the Code

Section 11 establishes the Code of Conduct Committee and sets out procedures by which the Committee hears complaints about the conduct of members and non-members.

Section 11.3 provides that the APMA will carry out a review of the provisions of the Code of Conduct after seeking input from interested parties no later than every 3 years.

7.12 Sanctions

Section 12 contains a variety of sanctions for promotional activities found to be in breach of the APMA Code. These sanctions include the immediate withdrawal or cessation of the promotional activity, the publication of corrective advertising, the publication of corrective advertising, corrective letters to practitioners and pharmacists, fines of up to $30,000 and suspension or expulsion from APMA membership.

7.13 Appeals

Section 13 establishes the APMA Code of Conduct Appeals Committee and sets out the procedure for appeals to be made from decisions of the Code of Conduct Committee.

7.14 Monitoring

Section 14 establishes the Monitoring Committee which proactively monitors selected promotional material of member companies on a regular and ongoing basis in order to:

(a) encourage compliance with the APMA Code;

(b) provide advice on compliance where necessary;

(c) obtain and publish statistical data on the rate of compliance; and

(d) provide an ongoing mechanism for the identification of potential future amendments to the Code.

7.15 Compliance procedures

Section 15 encourages compliance with the Code by requiring each APMA member to ensure that it has an internal compliance procedure.

7.16 Reporting

Section 16 sets out the information to be included in the annual report on the activities of the Code of Conduct Committee and also provides for external reporting of all Code breaches and sanctions imposed. The reporting requirements ensure that the activities of the Code of Conduct Committee are transparent and provide further encouragement to members to comply with the Code.

8. Conclusion

The APMA seeks authorisation of its Code under s88(1) of the Trade Practices Act and asks that the previous authorisation of the APMA be revoked on the grant of the fresh authorisation requested in this application. In view of the nature and scope of the APMA Code it is suggested that the authorisation be subject to review every 5 years or whenever the APMA Code is significantly amended whichever is the earliest.

We do not propose that the authorisation be reviewed every time the APMA Code is amended given that amendments occur on virtually an annual basis. Instead the APMA proposes to continue its practice of sending copies of all amendments to the Code to the Commission and asks that the Commission notify it if it considers the amendments warrant review of the authorisation.

Enclosure
1

edition

of the australian
pharmaceutical
manufacturers
association inc

APMA

Contents

TE: Explanatory notes have been provided throughout the Code to assist with its implementation at an operational level. The notes made are based on the experiences with review of Code complaints, general inquiries, comments from APMA Members and determinations made by the APMA Board.

Preface

The pharmaceutical industry* promotes the concept of good health, and a positive, health-oriented approach to daily living. Recognising that medicines play a vital role in the prevention, amelioration and treatment of disease states, the industry undertakes:

- to provide medicines that conform to the highest standards of safety, efficacy and quality;
- to ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience;
- to use professionalism in dealing with healthcare professionals*, public health officials and the general public.

The industry is committed to the quality use of medicines and rationale prescribing, and urges that its products be used only in accordance with the directions and advice of healthcare professionals. To ensure that the information* is available upon which to make informed prescribing decisions, it is necessary for the Member* to disseminate to healthcare professionals the specialised product information gained during the research and development process, and from experience gained in clinical use. In doing so, the Member draws attention to the existence and nature of a particular product* by appropriate educative and promotional measures.

With the full cooperation of the industry, there is now adequate legislation designed to safeguard the public by ensuring that all products marketed meet standards of quality, effectiveness and safety which are acceptable in the view of present knowledge and experience.

While it is possible to legislate satisfactorily for the testing, manufacture and control of medical products, appropriate standards of marketing conduct cannot be defined by the same means. For this reason, responsible manufacturers have concurred in the promulgation of the Code of Conduct and submitted to its constraints.

A Member* of the Australian Pharmaceutical Manufacturers Association Inc. undertakes to comply with the Objects, the Rules* and the Code of Conduct of the Association*.

Complaints against any activity of a Member company should be made to the Chief Executive Officer* or his or her delegate of the Association, as provided for in the Code (Section 11 and Appendix 1).

It should be noted that the Therapeutic Goods Administration requires that promotional material (other than Product Information) for registered goods must comply with the requirements of the Code of Conduct.

Note:

A glossary of terms is provided. The first inclusion in the Code of a term defined by the glossary is denoted thus * and the word(s) defined underlined.

Preamble

(a) This Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation. The Code owes its origin to the determination of the Australian Pharmaceutical Manufacturers Association Inc. to secure universal acceptance and adoption of high standards in the marketing of prescription products for human use.

(b) Acceptance and observance of the Code is a condition of membership of the Australian Pharmaceutical Manufacturers Association Inc., and a Member must comply with both the letter and the spirit of the Code. Members should ensure that all agents acting on their behalf are fully conversant with the provisions of this Code. Pharmaceutical companies outside the Association are invited to accept and observe this Code.

The Code shall be supervised and administered by the Board of the APMA. The Board may issue determinations from time to time for the purpose of interpretation of certain sections of the Code. Complaints concerning alleged breaches of the Code should be reported to the Chief Executive Officer of the APMA or his or her delegate.

The Marketing Committee of the APMA is responsible for proposing amendments to the content of the Code of Conduct for adoption by the APMA membership. This Committee normally meets every month and welcomes comments or suggestions that will improve the content and operation of the Code of Conduct. Although this Committee comprises APMA Member representatives, other interested parties are invited to make representations to the Committee regarding improvements to the Code.

(c) A major guiding principle of the Code is that, whene[redacted] a promotional claim* is made for a product, it shall be accompanied by appropriate information based on the approved Product Information* for that product.

(d) Failure to comply with the Code will result in sanctions being applied under the provisions of Section 12. Adherence to this Code in no way reduces Members' responsibilities to comply with the Trade Practices Act, Commonwealth and State Therapeutic Goods Acts and other requirements, legislation and Codes, including the IFPMA* Code. It should be recognised that the APMA Code is based upon the provisions of the IFPMA Code. Promotion* of prescription-only products to the general public is prohibited by law.

PROVISIONS OF THE CODE

1. Nature and Availability of Information and Claims

1.1 Responsibility

It is the responsibility of Members, their employees and their medical/technical advisers to ensure that the content of all promotional and medical claims is balanced, accurate, correct*, fully supported by the Product Information, literature* or "Data on File"* or appropriate industry source, where the latter do not conflict with the Product Information. Activities of company representatives* must comply with the Code at all times.

1.2 Provision of Substantiating Data

Further to the information supplied or generally available, the Member will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets, including company information.

Substantiating information must not rely solely on data on file.

Data cited in promotional material in support of a claim, including "data on file" or "in press" must be made available to healthcare professionals and industry companies upon reasonable request.

Where this material is not available through standard library services, it must be made available without delay.

EXPLANATORY NOTES

1.1 This responsibility relates not only to the product being promoted, but to any information given or claims made about other products.

Of importance is that any claim made must be consistent with the Australian Product Information document, irrespective of the source on which the claim is based.

1.2 (a) All data to substantiate claims must be easily retrievable so that they could be supplied on request within 10 working days.

(b) Evaluated data* contained in an application for marketing in accordance with the Australian Guidelines for the Registration of Drugs Vol. 1 or preceding Guidelines as the basis of the registration* of the product by the Department Health and Aged Care may be used to substantiate claims. Such data must be supplied in detail when requested to substantiate a claim. A statement that the data are "Confidential" will not be accepted.

(c) If the information on which a claim is based may not be released, eg an "in press" article which is subject to confidentiality provisions, then that information may not be used to substantiate a claim for the purposes of satisfying this section. Papers cited as "in press" must have been accepted for publication and be available as a final approved manuscript or in proof form. Papers submitted for publication and not yet accepted by a journal may be identified only as "unpublished data", "personal communication" or in similar terms.

(d) Data relating to the cost effectiveness of a product may be used to substantiate promotional claims, however these data must conform with Sections 1.1, 1.2, 1.3, 1.5 and 1.7 of this Code.

1.3 False or Misleading Claims

Information, medical claims* and graphical representations about products must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

Information, claims and graphics* must be capable of substantiation*, such substantiation being provided without delay at the request of health professionals.

1.3.1 Unapproved products and indications

Products that have not been approved for registration by the Department of Health and Aged Care must not be promoted. However, samples of unapproved products may be displayed and educational material* made available at International Congresses* and Australasian Congresses in accordance with Section 6. This restriction also applies to unapproved indications for registered products.

EXPLANATORY NOTES

3 The majority of breaches of the Code which have been found concern this section. The following are examples of situations where promotional material may breach the Code. This list is not all inclusive and is based on the experience of the Code of Conduct Committee.

(a) Literature references or quotations derived from a study or studies and citations of individual opinions which are significantly more favourable or unfavourable than has been demonstrated by the body of clinical evidence or experience. It is unreasonable to cite the results of an excessively favourable (or excessively unfavourable to a comparative product) study in a manner which suggests that those results are typical and may mislead.

(b) Information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions.

(c) Citation of data previously valid but made obsolete or false by the evaluation of new data.

(d) Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information not approved by the Commonwealth Department of Health and Aged Care.

(e) Shortening an approved indication (eg in a by-line) so as to remove a qualification or limitation to the indication.

(f) Use of animal or laboratory data to directly support a clinical claim.

(cont..)

1.4 Good Taste

Promotional material (including graphics and other visual representations) should conform to generally accepted standards of good taste and recognise the professional standing of the recipients.

1.5 Unqualified Superlatives

Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique* or has some special merit, quality or property unless this can be substantiated. The word "safe" must not be used without qualification.

1.6 New Products

The word "new" must not be used to describe any product, presentation, or therapeutic indication which has been available and generally promoted for more than 12 months in Australia.

3 (cont...)

(g) Presentation of information in such a manner eg type size* and layout, which, to the casual reader could produce an incorrect perspective. The type size used for qualifying statements must not be less than 2mm. The qualifying statement must not be included with other reference material but must be situated on the same page as the original statement. The original statement and the qualifying statement must be linked by use of an asterisk or a similar symbol.

(h) Statements made about a competitive product, particularly negative statements, not balanced with corresponding information about the product being promoted.

(i) Shortening the title of graphical representations reproduced from literature which alters the original author's meaning.

(j) Use of overseas Product Information to support a claim where that information is inconsistent with the Australian Approved Product Information.

(k) Literal or implied claims that a parameter, contraindication, cautionary statement, adverse reaction or limitation on a claim in the Product Information, is not cause for concern.

(l) Lack of substantiation of claims not of a medical or scientific nature. It includes information or claims relating to marketing factors such as pricing and market share. Care should be taken when extrapolating prescribing practices from sales data.

It should be noted that if animal or laboratory data are used a prominent statement identifying this type of data must be made on the same page and within reasonable proximity of the data in a manner that is not obscured by other material.

1.7 Comparative Statements

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis or in any other way. "Hanging" comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc must not be used.

"Data on file" when used to substantiate comparative statements must comply with the requirement of Section 1.2.

1.8 Imitation

Promotional information should not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse.

1.9 Medical Ethics

Doctors' names or photographs must not be used in any way that is contrary to medical ethics.

1.10 Distinction of Promotional Material

Promotional material must be clearly distinguishable as such.

1.7 Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of Product Information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Australian as well as overseas Product Information documents.

Claims of comparative efficacy or safety should be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.

The accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used, such data must comply with the following conditions:

- the lack of significance must be stated explicitly; it is insufficient to state the p value
- the data must not be used to generalise or to indicate superiority or inferiority

The statement that the claim is not statistically significant needs to be linked in some manner to the original claim, made on the same page and within a reasonable proximity of the original claim in a manner that is not obscured by other material using a type size of not less than 2mm.

1.9 Wherever a healthcare professional's name is specified in any kind of promotional material, other than by citation of a published reference, the Member should ensure that the individual specified is aware of and provides written approval for the use of his/her name in the context of the entire promotional material. For example, if a doctor agrees to introduce an educational video, he/she should be fully aware of the final content of that video, as such a situation would imply endorsement.

The Member should also obtain written approval from the individual if his/her name is used in subsequent promotional material.

1.10 Advertisements in a journal* should not be designed so as to resemble editorial matter unless clearly identified as an advertisement. See also sections 3.5 and 3.6.

PROVISIONS OF THE CODE

2. Product Information

Certain types of promotional material described in Section 3 must be accompanied by either full or abridged Product Information.

Wherever required, Product Information must appear in a type size of not less than 1 mm on a background sufficiently contrasting for legibility. Major headings should be easily identifiable.

Product Information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance*.

2.1 Full Disclosure Product Information

2.1.1. With the exception of full advertisements*, full disclosure Product Information must accompany all promotional material for a period of 24 months from the date of first advertising of a new chemical entity* in Australia or longer, at the discretion of the advertiser.

2.1.2 Where a Product Information document has been approved by the Department of Health and Aged Care, that document must be used in full without alteration unless such alteration is approved by the Department of Health and Aged Care. When used to accompany promotional material, it should appear under the heading "Approved Product Information".

2.1.3 Where a Product Information document has not been approved by the Department of Health and Aged Care, the document must comply with the format described in the Australian Guidelines for the Registration of Drugs Vol 1. When used to accompany promotional material, it should appear under the heading "Full Product Information".

The date on which Product Information was approved (full) and/or last updated (full or abridged disclosure) must be included.

2.1.3 The Product Information documents for some "grandfather" products have not been evaluated by the Department of Health and Aged Care. However, such documents can be subjected to review by the Department of Health and Aged Care if considered necessary, for example on safety grounds. Any complaints received about the content of such documents may be referred to the Department Health and Aged Care.

2.2 Abridged Disclosure Product Information

2.2.1 Abridged disclosure Product Information may be used after 24 months from first advertising of a new chemical entity in medical publications, except where Section 2.3.1 applies.

2.2.2 Abridged disclosure Product Information must accurately reflect the full disclosure Product Information but may be a paraphrase or precis of the full disclosure Product Information.

2.2.3 Under the heading "Abridged Product Information", the following shall appear:

(a) Approved indications for use

(b) Contraindications

(c) Clinically significant warnings

(d) Clinically significant precautions for use

(e) Clinically significant adverse effects and interactions

(f) Available dosage forms

(g) Dosage regimens and routes of administration

(h) Dependence potential of clinical significance

(i) Reference to special groups of patients (including Australian pregnancy categorisation if issued).

(j) boxed warnings*

Where the full disclosure Product Information does not include items under these headings, such headings are not required to be included in the document.

EXPLANATORY NOTES

2.3 Changes of Clinical Significance or the addition of a boxed warning

2.3.1 Where a change of clinical significance relating to product safety or the addition of a boxed warning is incorporated into the Product Information, it should be indicated in all representations of the Product Information for a period of 12 months from the date of change by an asterisk(s) to a footnote in type size of not less than 2mm:

Please note change(s) in Product Information

2.3.2 The full text of the changed section should be included in any abridged Product Information during this period.

2.3.3 Where a Member is not actively promoting the product, written advice of the change to Product Information should be forwarded to the appropriate healthcare professionals.