10. SANCTIONS

10.1 SANCTIONS ABLE TO BE APPLIED BY CODE OF PRACTICE COMPLAINTS PANEL

10.1.1 One or more of the following sanctions against a Member may be applied by the Complaints Panel where breaches of the Code have been established.

10.1.1.1 The requirement, notified in writing, that the Member give an undertaking in writing to discontinue any practice which has been determined to constitute a breach of the Code on or before a date determined by the Complaints Panel, such date being determined in line with the severity of the breach of this Code.

10.1.1.2 The requirement, notified in writing, that the Member issue retraction statements and/or corrective statements or advertisements, as appropriate. The format, size, wording, mode of publication and method of distribution of such statements/advertisements shall be subject to the approval of the Complaints Panel prior to release and will in general conform to the original statement/advertisement.

10.1.1.3 The issuing of a fine by the Panel to the subject company in accordance with the schedule of fines, detailed in 10.1.1.4. The fine to be paid within 30 days of being advised subject to any appeal that may be lodged under Clause 11.2 of the Code.

10.1.1.4 Proposed Schedule of Fines

BREACH	FINES
Minor Breach[1]	**NIL**
Less Severe Breach[2]	**Minimum: $2000.00** **Maximum: $5000.00**
Severe Breach[3]	**Minimum: $5000.00** **Maximum: $20000.00**
Repeat of Previous Breach[4]	**Minimum: $10000.00** **Maximum: $20000.00**

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

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

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

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

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

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

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

10.1.2.1 That the Member discontinue immediately distribution of the CPI.

10.1.2.2 That corrective measures be taken to redraft the CPI in accordance with the findings of the Panel.

10.1.2.3 That the Member issue retraction and/or corrective statements, as appropriate, flagging the redrafted CPI.

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

10.1.3 Abuse of the Code

If in the course of hearing a complaint lodged by an Industry member, the Complaints Panel considers that the complaint has been submitted as a competitive tool and for vexatious reasons, the Panel may request the complainant to show cause why the Panel should not impose a charge of $2,000 for vexatious use of the Code.

10.2. SANCTIONS ABLE TO BE APPLIED BY COMMITTEE OF MANAGEMENT

10.2.1 The Complaints Panel may recommend to the Committee of Management application of further sanctions. Such further sanctions may consist of one or more of the following or any other action deemed appropriate by the Committee of Management, under the procedures laid down in Section 9 of the Code.

10.2.1.1 Suspension of the Member from the Association for a period to be determined by the Committee of Management, under the provisions of the Rules of the Association (refer Appendix 3).

10.2.1.2 The expulsion of the Member from the Association, under the provisions of the Rules of the Association (refer Appendix 3).

10.2.1.3 Notification, wherever applicable, to the overseas parent company of the offending Member of its expulsion from the Association.

10.2.1.4 Notification of the offending Member's suspension and/or expulsion from the Association to the editors of all trade journals.

11. RIGHT OF APPEAL

(refer Appendix 2 for diagrammatic representation of Appeal mechanism)

For the purposes of the appeal procedure, "Member" includes non-member companies agreeing to be bound by the Code (refer definition of "Member").

11.1 COMPLIANCE WITH SANCTIONS

In the event of a Member being required by a determination of the Complaints Panel to cease or withdraw a promotional activity, the Member shall at once make every endeavour to comply with the ruling pending any appeal against the decision pursuant to this Code. A promotional activity thus suspended shall not be recommenced before the appeal process has been concluded, nor shall any similar promotional activity be commenced during the period in question.

11.2 APPEAL AGAINST DETERMINATIONS OF THE COMPLAINTS PANEL

11.2.1 A party dissatisfied with a determination of the Complaints Panel may, within 10 working days of being notified of the determination, lodge a written appeal to the Executive Director of the Association setting out the grounds for objection. If the party lodging the appeal is a member of industry a lodgement fee of $1,000 will be required to have the appeal heard. If the appeal is upheld the lodgement fee will be reimbursed.

11.2.2 The appeal shall be considered by an independent person appointed by the Marketing & Ethics Subcommittee (the "Arbiter") with appropriate legal and/or technical expertise and not involved in any previous hearing of the particular complaint, sitting alone on an at-call basis. The appeal shall be held not later than 28 days after receipt of the written appeal.

11.2.3 The parties shall be advised of the date, time and place of the appeal meeting and any adjournment thereof, and may, either in person and/or through legal representatives, do either or both of the following:

(i) attend and speak at that meeting;
(ii) submit to the Arbiter at or prior to the date of that meeting written representations relating to the appeal.

11.2.4 At the appeal meeting held as referred to in 11.2.3 above, the Arbiter shall:

- give the parties the opportunity to make oral representations; and
- give due consideration to any written representations submitted by the parties.

11.2.5 Within 10 working days following the conclusion of the appeal meeting, the Arbiter shall determine whether to confirm, modify or revoke any determination made or sanction applied or recommended by the Complaints Panel and shall notify the Executive Director in writing of the determination and of the reasons for it. The determination of the Arbiter shall be final,

except where the Arbiter recommends suspension or expulsion of a Member (refer Appendix 2).

11.2.6 The Executive Director shall, as soon as practicable, inform the parties in writing of the Arbiter's decision and reasons, and shall also so inform the Committee of Management where the Arbiter recommends suspension or expulsion of a Member.

EXTRACT FROM THE THERAPEUTIC GOODS REGULATIONS **APPENDIX 1**

PART 2—ADVERTISEMENTS

This Part not to apply to advertisements directed at health professionals, etc.

4. (1) This Part does not apply to advertisements directed exclusively to:

(a) medical practitioners, psychologists, dentists, veterinary surgeons, dietitians, pharmacists, physiotherapists, scientists working in medical laboratories or nurses; or

(b) persons who are:

(i) engaged in the business of wholesaling therapeutic goods; or

(ii) purchasing officers in hospitals; or

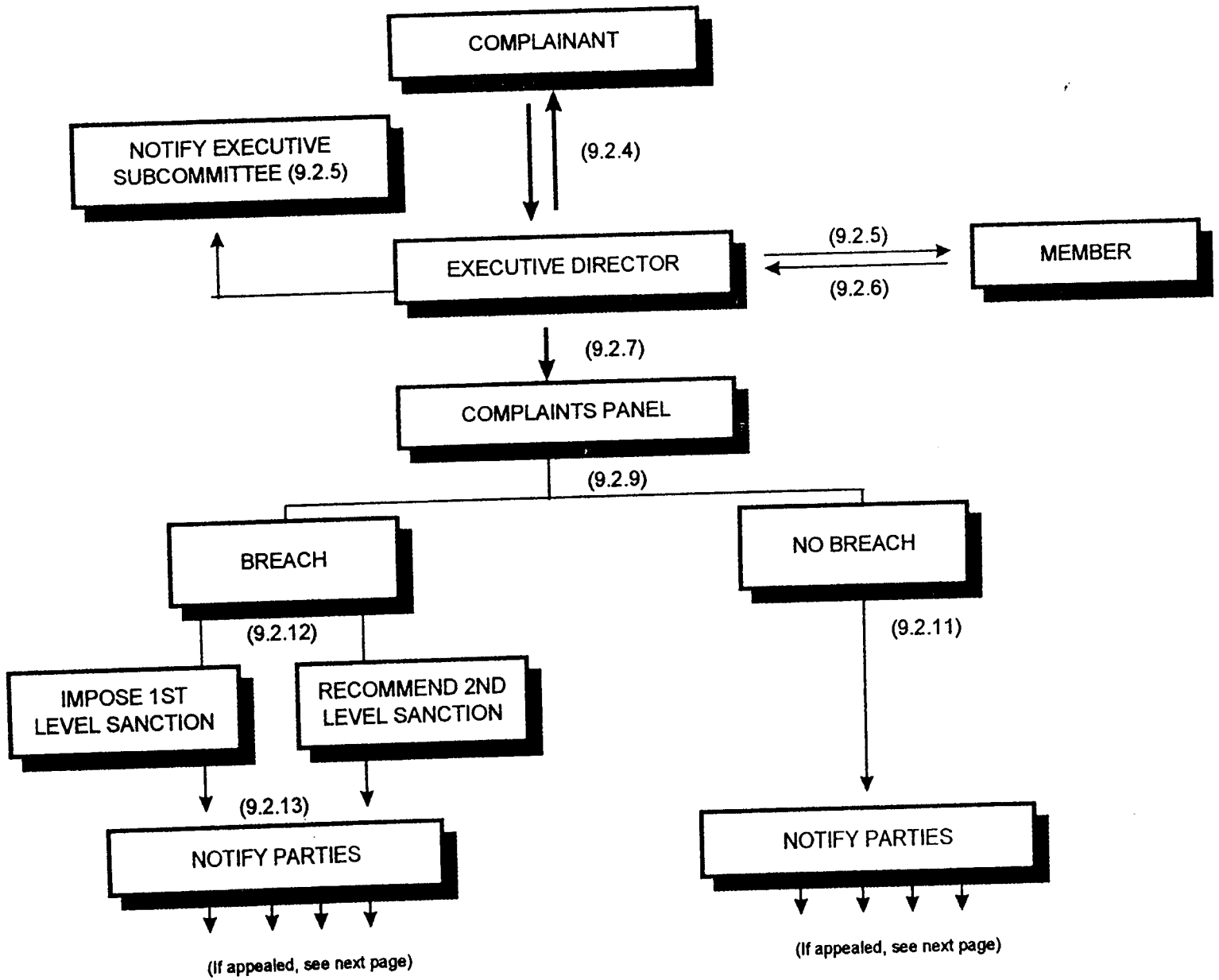
(c) herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine or osteopaths registered under a law of a State or Territory.

(2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies referred to in Schedule I.

(2A) For the purposes of subregulation (2), a person is taken to be a member of an Australian branch of one of those bodies if, and only if, the person has the qualifications and training that are necessary or appropriate for membership of the relevant body.

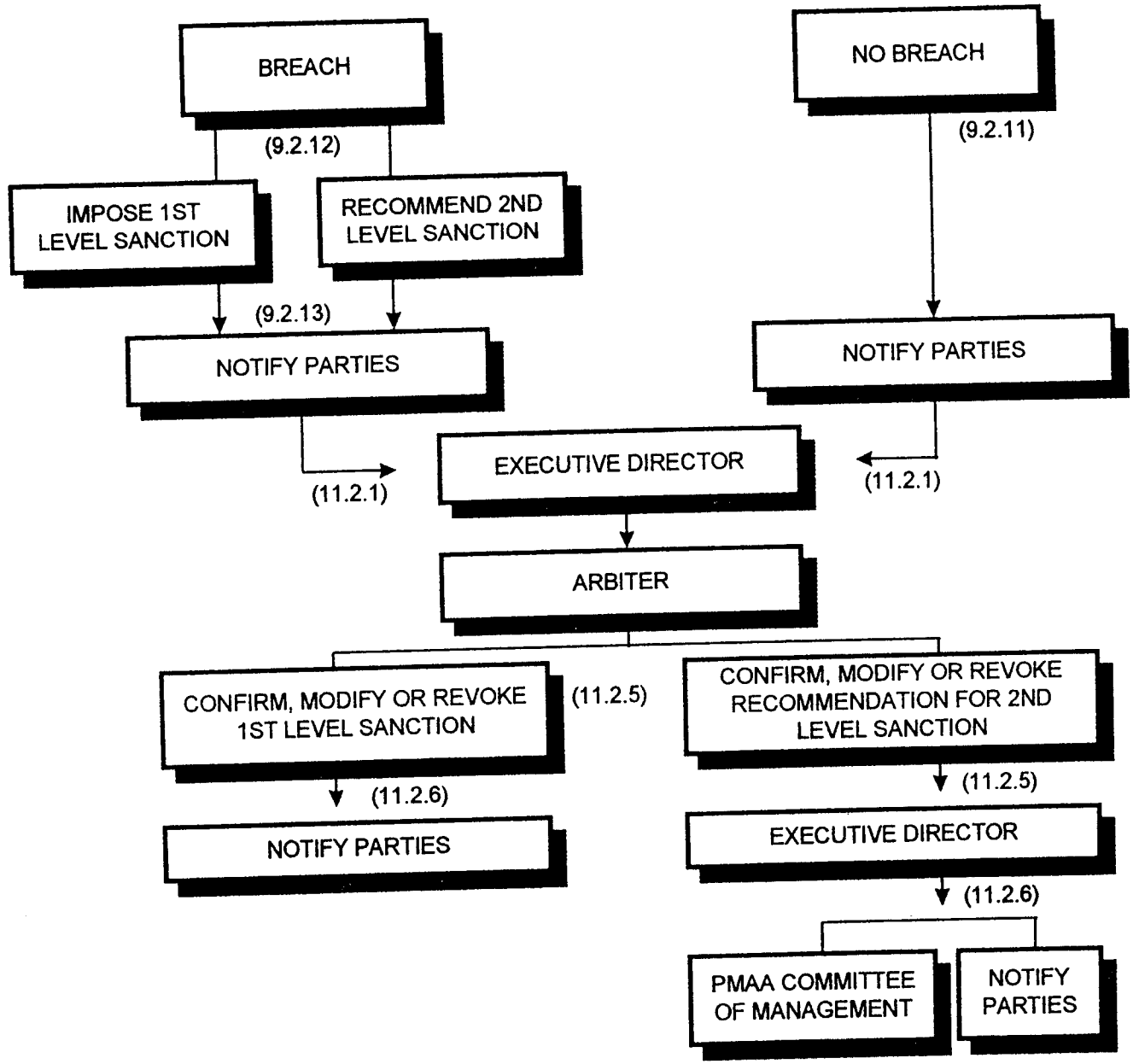
COMPLAINT PROCESS

APPENDIX 2

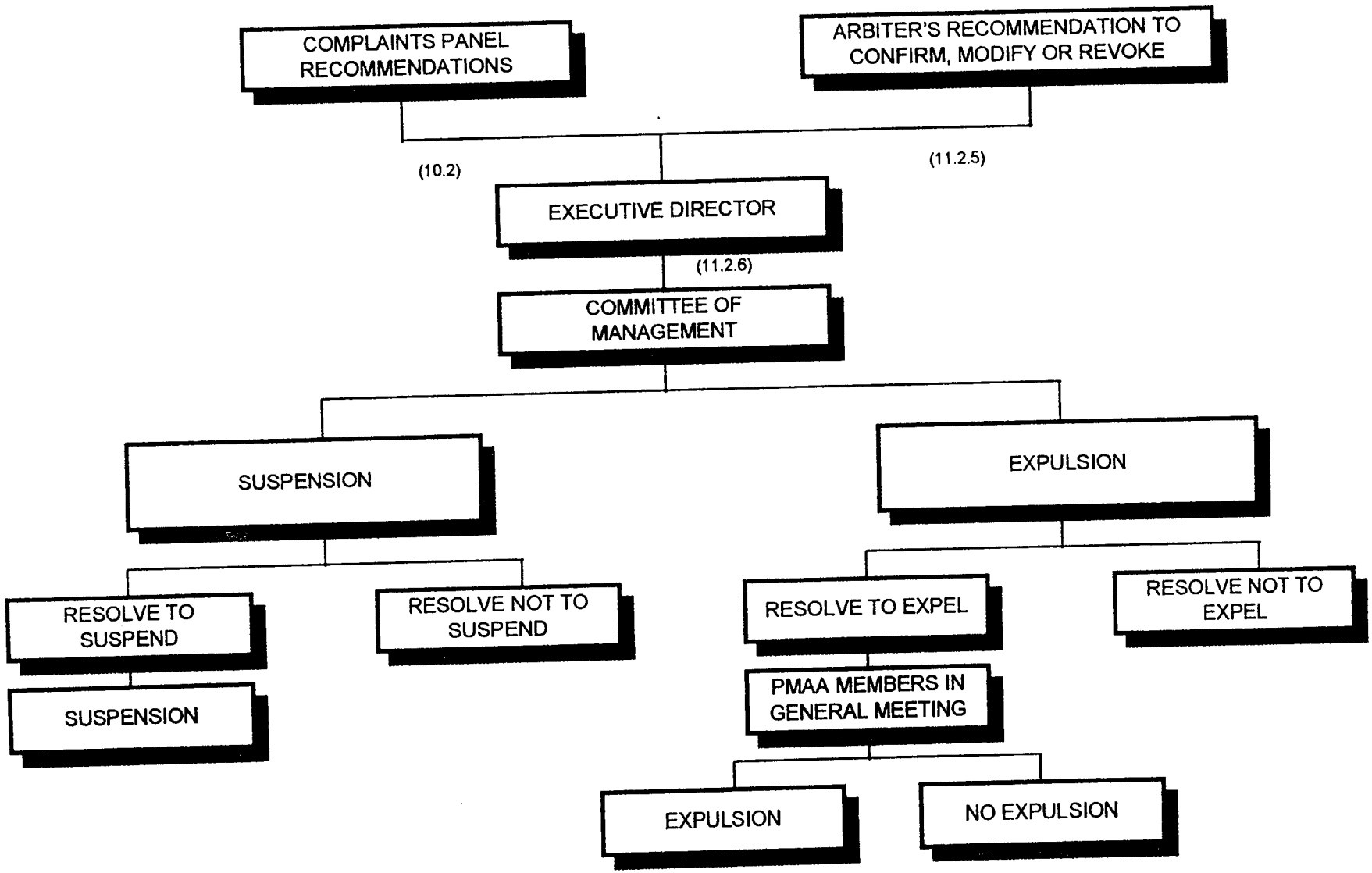


APPEAL PROCESS

APPENDIX 2 cont'd.



APPEAL PROCESS - SECOND LEVEL SANCTIONS APPENDIX 2 cont'd.



SCHEDULE 1 Subregulation 4 (2)

PART 2 DOES NOT APPLY TO MEMBERS OF AN AUSTRALIAN BRANCH OF ONE OF THESE BODIES

Column 1 Item No.	Column 2 Body
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
3	Association of Natural Health Practitioners
4	Australasian Federation of Natural Therapy Associations Inc.
5	Australian Acupuncture Association Inc.
6	Australian Association of Professional Homoeopaths
7	Australian Committee of Natural Therapies Inc. (SA)
8	Australian Council of Natural Therapies Inc.
9	Australian Federation of Homoeopaths
10	Australian Natural Therapists Association Ltd
11	Australian Naturopathic Practitioners and Chiropractors Association
12	Australian Traditional Chinese Herbalists Association (Qld)
13	Australian Traditional Chinese Medicine Association Inc.
14	Australian Traditional Medicine Society
15	Chinese Medicine Association Pty Ltd
16	Complementary Medicine Association
17	Homoeopathic Education and Research Association
18	National Herbalists Association of Australia
19	Queensland Naturopathic Association
20	Register of Acupuncture and Traditional Chinese Medicine
21	Society of Natural Therapists and Researchers Inc.
22	Society of Classical Homoeopathy Ltd
23	Traditional Medicine of China Society Australia
24	Society of Chinese Medicine and Acupuncture (Vic) Inc.
25	Naturopathic Practitioners Association Inc.
26	The Acupuncture Association of Australia, New Zealand and Asia
27	The New South Wales Research Association of Traditional Chinese Medicine

EXTRACT FROM RULES OF THE ASSOCIATION

APPENDIX 3

Rule 5 Membership Obligations

Code of Practice

The Association shall establish and maintain a Code of Practice which:

(a) shall be adopted and/or amended as from time to time recommended by the Committee of Management, by Ordinary members in general meetings;

(b) upon such adoption shall become binding upon all Ordinary and Associate Members as a condition of membership of the Association; and

(c) shall be administered by an Executive Subcommittee constituted in accordance with rule 23 [relating to Delegation by the Committee of Management to Subcommittees] of these Rules.

Rule 12 Disciplining of Members

12.1 The Committee of Management may, by resolution:

(a) expel; or

(b) suspend for a specified period

from membership of the Association an Ordinary Member or Associate Member

(i) upon recommendation by the Code of Practice Complaints Panel or the Arbiter in accordance with the Code of Practice, or

(ii) where the Committee of Management is of the opinion that the Member

(A) has persistently refused or neglected to comply with

(I) a provision or provisions of these Rules or of the Code of Practice;

(II) a sanction imposed by the Code of Practice Complaints Panel or the Arbiter in accordance with the Code of Practice; or

(B) has persistently and wilfully acted in a manner prejudicial to the interests of the Association.

Rule 12 - Disciplining of Members (Continued)

12.2 A resolution of the Committee of Management under rule 12.1(a) is of no effect unless the Committee at a meeting held not earlier than 14 days and not later than 28 days after service on the member company of a notice under rule 12.3, confirms the resolution in accordance with this rule.

12.3 Where the Committee of Management passes a resolution under rule 12.1(a) the Secretary shall, as soon as practicable, cause a notice in writing to be served on the member company:

(a) setting out the resolution of the Committee and the grounds on which it is based;

(b) stating that a delegate of the member company may address the Committee at a meeting to be held not earlier than 14 days and not later than 28 days after service of the notice;

(c) stating the date, place and time of that meeting; and

(d) informing the member company that the delegate of the member company may do either or both of the following:

(i) attend and speak at the meeting;

(ii) submit to the Committee at or prior to the date of that meeting written representations relating to the resolution.

12.4 At a meeting of the Committee of Management held as referred to in rule 12.3, the Committee shall:

(a) give a delegate of the member company an opportunity to make oral representations;

(b) give due consideration to any written representations submitted to the Committee by the member company at or prior to the meeting; and

(c) by resolution determine whether to confirm or to revoke the resolution.

12.5 Where the Committee of Management confirms a resolution under rule 12.4, the secretary shall, within 7 days after that confirmation, by notice in writing inform the member company of the fact and of the member's right of appeal under rule 13.

12.6 A resolution confirmed by the Committee of Management under rule 12.4 does not take effect:

(a) until the expiration of the period within which the member company is entitled to appeal against the resolution where the member company does not exercise the right of appeal within that period; or

(b) where within that period the member company exercises the right of appeal unless and until the Association confirms the resolution pursuant to rule 13.4.

Rule 13 Right of Appeal of Disciplined Member Company

13.1 An Ordinary Member or Associate Member may appeal to the Association in general meeting against a resolution of the Committee of Management which is confirmed under rule 12.4 within 7 days after notice of the resolution is served on the member company, by lodging with the Executive Director a notice to that effect.

13.2 Upon receipt of a notice from a member company under rule 13.1, the secretary shall notify the Committee of Management which shall convene a general meeting of the Association to be held within 21 days after the date on which the secretary received the notice.

13.3 At a general meeting of the Association convened under rule 13.2:

(a) no business other than the question of the appeal shall be transacted;

(b) the Committee of Management and the member company shall be given the opportunity to state their respective cases orally or in writing, or both; and

(c) the member companies present shall, in writing and on the form specified in Appendix IV to these rules, vote by secret ballot, but in accordance with rule 33 of these rules, on the question of whether the resolution should be confirmed or revoked.

13.4 If at the general meeting the Association passes a special resolution in favour of the confirmation of the resolution, the resolution is confirmed.

THERAPEUTIC GOODS ADVERTISING CODE

PREFACE

In this Code the term "advertisement" shall mean matter which is published for payment or other valuable consideration and which draws the attention of the public, or a segment thereof, to a product, service, person, organisation or line of conduct in a manner calculated to promote or oppose directly or indirectly that product, service, person, organisation or line of conduct.

The object of this Code is to ensure responsible advertising in promoting the sale of therapeutic goods which may be purchased by the public without prescription and for which therapeutic claims are made.

In adopting this Code, PMAA has taken into account the World Health Organisation's "Ethical Criteria for Medicinal Drug Promotion 1988" in particular -

Advertisements to the general public relating to goods for therapeutic use (including analgesics and vitamins) should:

(a) help people make rational decisions on the use of drugs legally available without prescription;
(b) take into account people's legitimate desire for information concerning their health;
(c) not take undue advantage of people's concern for their health nor misrepresent or mislead the consumer into unwisely relying on medicines to solve emotional or mood problems.

This Preface forms part of the Code.

THE CODE

1. The conformity of an advertisement with this Code will be assessed in terms of its probable impact, taking its content as a whole, upon a reasonable person within the class of those to whom the advertisement is directed and also taking into account its probable impact on persons within other classes to whom it is likely to be communicated.

2. DEFINITION

2.1 For the purposes of this Code:

"ADVERTISING" does not include advertising that is contained in any publication the circulation of which is intended to be limited to persons who are medical practitioners, pharmacists, dentists, veterinary surgeons, nurses, physiotherapists, biomedical engineers, medical scientists in accredited laboratories, purchasing officers in hospitals, persons designated under Regulation 4 of the Therapeutic Goods Regulations, or other health care professionals registered under State or Territory legislation or who are engaged in the business of purchasing by wholesale therapeutic goods or that is intended to be published exclusively to or among such persons.

"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.

"THERAPEUTIC USE" means use in, or in connection with:

(i) the preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons;
(ii) the influencing, inhibiting or modifying of a physiological process in persons;
(iii) the testing of the susceptibility of persons to a disease or ailment;

and, without limiting the generality of the foregoing, includes use in, or in connection with, testing for pregnancy, contraception, prosthetics or orthotics.

"THERAPEUTIC DOSE" means the dosage range in the following order of priority:

(a) the dosage range approved by the Commonwealth relating to goods for therapeutic use;
(b) the dosage range set down in the latest edition of the British Pharmacopoeia; and
(c) the dosage range for goods for therapeutic use generally accepted by the medical profession in contemporary prescribing and usage.

"APPROVED NAME" means the name of the active substance(s) as defined in the Therapeutic Goods Order No. 32 - General Requirements for Labels for Drug Products - under The Therapeutic Goods Act 1989.

2.2 All advertisements for therapeutic goods shall comply with all Acts, Regulations and Standards of the Commonwealth, States and Territories.

3. GENERAL PRINCIPLES

3.1 An advertisement for therapeutic goods shall not:

3.1.1 contain incorrect statements, or unverifiable claims;
3.1.2 be designed to arouse unwarranted expectations of product effectiveness through the use of text, illustrations, or sound effects;
3.1.3 mislead, directly, or by implication, or through emphasis, comparisons, contrasts or omissions with regard to safety, usage or immediacy of relief; or
3.1.4 be directed to children.

3.2 Advertisements for therapeutic goods shall contain:

3.2.1 the trade name and pharmaceutical form (if applicable) of the goods;
3.2.2 in the case of therapeutic goods (other than therapeutic devices) advertised in the print media, the advertisement shall contain the principal/primary active substance(s), or the first label ingredient and a statement

"For full ingredients see the label"

3.2.3 a statement of the indications for use of the goods.

3.3 Advertisements for therapeutic goods listed in Schedule 2 of relevant State and Territory legislation (other than analgesics) shall contain one of the following statements:

"Read label instructions carefully";
"Always read the label";
"Use only as directed";
"Read directions before use"

or words to the same effect.

3.4 Advertisements containing direct comparisons with other advertisers, or other products, shall comply with the following provision:

Comparative advertisements should not be misleading or likely to be misleading, either about the product advertised or that with which it is compared.

4. PROHIBITIONS

An advertisement relating to goods for therapeutic use shall not contain a claim which makes reference either directly or by implication, to the following (other than as excepted or permitted in writing by the Secretary of the Commonwealth Department of Human Services and Health):

abortifacient action
aids - see immune system diseases
alcoholism
anaemia
arthritis (all forms including rheumatoid arthritis) - other than the temporary relief of pain
asthma - other than for peak flow meters, and nebuliser pumps and masks; which include a statement to the effect of "As an aid in the management of asthma in conjunction with medical supervision"
baldness, including hair growth, hair loss or hair thinning
blindness
boils - other than treatment by topical application
breast development
bronchitis - other than relief of cough
carbuncles - other than treatment by topical application
cardiovascular system diseases, ailments or defects (including high or low blood pressure) other than:

(i) the advertising of blood pressure appliances where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the meanings of recorded blood pressure; or
(ii) the advertising of cholesterol measurement appliances where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the meanings of recorded cholesterol levels; or
(iii) the advertising of purpose specific bandages for the relief or treatment of circulation related ailments; or
(iv) a statement to the effect of "aids or assists in the maintenance of peripheral circulation".

cataract
catarrh, other than relief of symptoms
chilblains, other than relief of symptoms
colds, other than relief of symptoms
coughs, other than temporary relief or other than relief, provided the advertisement carries a warning to the effect of "If coughing persists consult your doctor (or a health care professional)".
croup
deafness, other than relief by an appliance
diabetes, other than the advertising of urine testing or blood glucose monitoring products or insulin syringes
diphtheria
eczema, other than relief of symptoms
endocrine system diseases, ailments or defects
erysipelas
fertility
fungus infections, including tinea (athlete's foot), other than for relief or treatment by topical application
gall bladder diseases, ailments or defects

gastric, peptic or duodenal ulcer
genito-urinary system diseases, ailments or defects, other than
(i) a statement to the effect of "aids or assists in the treatment of fluid retention" provided the advertisement carries a warning to the effect of "If fluid retention persists, seek medical advice";
or
(ii) for products offering relief of the pain and burning sensation associated with cystitis provided the advertisement carries a warning to the effect of "If pain or irritation persists for more than 48 hours, consult your doctor" and "The presence of blood in the urine warrants immediate medical attention"
or
(iii) for absorbent pads, protective mats and urinary collection devices, for use in incontinence, provided the advertisement carries a statement to the effect of "As an aid in the management of urinary incontinence (or enuresis)"
(iv) relief of vaginal dryness discomfort by local application and where the directions for use include the statement that sufferers should consult a medical practitioner (or, alternatively, "a health care professional") if the symptoms persist
glandular diseases, ailments or defects (including glandular enlargement)
glaucoma
goitre
gout
haemorrhoids, other than:
(i) relief of discomfort by local application and where the directions for use include the statement that sufferers should consult a medical practitioner (or, alternatively, "a health care professional") if the symptoms persist; or
(ii) reference to bulk producing laxatives being of indirect benefit to people suffering from haemorrhoids.
hair and scalp - see baldness
headaches, other than temporary relief
height increase
hernia or rupture, other than advertising hernia appliances
herpes virus infections, other than:
(i) the relief of symptoms of cold sores; or
(ii) reduction of risk of the transmission of genital herpes by the use of condoms
hormonal disease, ailments or defects
immune system diseases, ailments or defects, including HIV induced diseases or ailments, such as Acquired Immune Deficiency Syndrome (AIDS), other than the reduction in the risk of the transmission of disease by the use of condoms
impetigo, other than treatment by topical application
impotence
indigestion, other than relief or treatment of digestive disorders, provided the advertisement carries a warning to the effect of "If symptoms persist, seek medical advice"
infectious diseases, other than as accepted elsewhere in this Code
infertility
influenza, other than relief of symptoms
liver diseases, ailments, defects or injuries
lupus

menopause or menopausal ailments or defects, except
- (i) for a statement that women's calcium requirements are increased after the menopause and (optional) that calcium supplementation may be of assistance in the treatment of osteoporosis
- (ii) relief of vaginal dryness discomfort by local application and where the directions for use include the statement that sufferers should consult a medical practitioner (or, alternatively, "a health care professional") if the symptoms persist

menstrual cycle diseases, ailments or defects, other than:
- (i) the relief of menstrual pain; and
- (ii) pre-menstrual symptoms; where the advertisement includes a statement to the effect of "Use only as directed and consult your doctor (or, alternatively, "a health care professional") if pain or symptoms persist"

mental diseases, ailments or defects

mouth ulcers, other than relief

muscular aches and pains, other than relief

neoplastic diseases (including cancer and leukaemia), other than the use of:
sun screening preparations as an aid in the prevention of skin cancer (being SPF4 or greater) and premature skin ageing (being a broad spectrum sun screen as defined in the current Australian Standard) but without implying that long hours of exposure in the sun are desirable.

nervous system diseases, ailments, defects or injuries (including convulsions, epilepsy, fits or paralysis), except for products providing a total daily dosage of 400-500 micrograms of folic acid which may make a claim to the effect of "Contains folic acid (or folate) which, if taken daily for one month before conception and during pregnancy, may reduce the risk of women having a child with birth defects of the brain and/or spinal cord such as the neural tube defects known as spina bifida and anencephaly. Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect you should seek specific medical advice".

obesity including the reduction of subcutaneous fat also referred to as "cellulite"

overweight including weight maintenance, weight loss, and slimming, weight control, or measurement loss, where weight loss is stated or implied other than suppression of appetite in conjunction with or as part of a "kilojoule/calorie controlled eating plan", or words to that effect

phlebitis

pregnancy testing kits - see sexual intercourse

prostate gland disease, ailments or defects

psoriasis, other than for the relief or treatment of the effects of psoriasis on the skin provided the advertisement carries a warning to the effect of "Do not use for prolonged periods without consulting a medical practitioner" (or, alternatively, "a health care professional")
and provided an advertisement for products which contain coal tar carries an additional warning to the effect of "Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a medical practitioner".

psychiatric disease, ailments or defects

purpura

pyorrhoea

rheumatism, other than temporary relief of pain

scabies, other than relief by topical application

sexual intercourse, other than:

(i) reduction in the possibility of conception; or

(ii) pregnancy test kits where the advertisement includes a statement to the effect that a medical practitioner is the only person qualified to evaluate the test results

sexually transmissible diseases, other than the reduction of the risk of transmission of sexually transmissible disease by the use of condoms

sexual function potency or virility

short stature

sinus infection, other than relief of sinusitis

sleeplessness, other than relief

sun screening - see neoplastic diseases

thrombosis, other than for the relief or treatment of circulation related ailments by means of purpose specific bandages

tuberculosis

vaginal itching, external, other than treatment by topical application where the advertisement includes a statement to the effect of "If symptoms persist, seek medical advice"

varicose ulcers or varicose veins, other than the temporary relief by the use of elastic hosiery

whooping cough

5. RESTRICTED ADVERTISING - ANALGESICS

5.1 Analgesics are those preparations for internal use containing one or more of the following substances intended for the relief of minor aches and pains:

salicylic acid, its salts, its derivatives (including aspirin) and their salts;
codeine;
other nonsteroidal anti-inflammatory drugs;
paracetamol.

This excludes preparations for internal use, in self-limiting conditions, and which contain an analgesic in combination with one or more other active ingredients such as cough mixtures and cold tablets.

5.2 An advertisement for analgesics shall contain the following information:

5.2.1 The trade name and pharmaceutical form of the analgesic.
5.2.2 The approved name of each analgesic constituent.
5.2.3 A statement of indications for use.
5.2.4 A warning statement that reflects the spirit of the NH&MRC statement:
"This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful".

The minimum requirement in regards to the warning follows -

(a) <u>Warnings in Print Media:</u>

Size: half page and over - one of the following warnings:

(1) Use only as directed for minor and temporary ailments.
(2) Prolonged use may be harmful. Use only as directed.
(3) Use only as directed and consult your doctor if pain persists.

All other sizes - one of the following warnings:

(1) If pain persists, consult your doctor.
(2) Prolonged use may be harmful.
(3) Use only as directed.

In print media all warnings should be in bold caps equal in size at least to body copy or prominently displayed on the package illustration.

(b) Warnings in Radio Commercials:

Up to and including 20 seconds -

"Use only as directed"

Over 20 seconds and up to and including 45 seconds -

One of the following warnings (or words to that effect):

(1) Use only as directed for minor and temporary ailments.
(2) Prolonged use may be harmful. Use only as directed.
(3) Use only as directed and consult your doctor if pain persists.

Over 45 seconds -

Two of the following warnings (or words to that effect):

(1) Use only as directed for minor and temporary ailments.
(2) Prolonged use may be harmful. Use only as directed.
(3) Use only as directed and consult your doctor if pain persists.

In using the two warnings the words "Use only as directed" need only be used once.

(c) Warnings in Television Commercials:

10 and 15 seconds -

A warning video super clearly visible and readable to the viewer:

"Use only as directed".

20 seconds -

One of the following warnings in video super clearly visible and readable to the viewer:

(1) Use only as directed for minor and temporary ailments.
(2) Prolonged use may be harmful. Use only as directed.
(3) Use only as directed and consult your doctor if pain persists.

30 seconds -

A warning video super clearly visible and readable to the viewer:

"Use only as directed".

and one of the following warnings in audio (or words to that effect):

(1) Use only as directed for minor and temporary ailments.
(2) Prolonged use may be harmful. Use only as directed.
(3) Use only as directed and consult your doctor if pain persists.

Over 45 seconds -

One warning video super clearly visible and readable to the viewer:

"Use only as directed".

and two of the following warnings (or words to that effect) in audio:

(1) Use only as directed for minor and temporary ailments.
(2) Prolonged use may be harmful. Use only as directed.
(3) Use only as directed and consult your doctor if pain persists.

In using the two statements the words, "Use only as directed" need only be used once.

5.3 An advertisement for analgesics should not contain directly or indirectly:

5.3.1 any claim that analgesic consumption is safe;

5.3.2 any claim that a preparation will relax, relieve tension, sedate or stimulate;

5.3.3 unsubstantiated claims that one preparation is appreciably less irritant to the stomach, more rapidly absorbed, faster in action, or more effective or less harmful than another.

6. VITAMINS

6.1 An advertisement for vitamin supplements shall not:

6.1.1 suggest that the use of vitamin supplements can be justified by claims that soil depletion reduces nutritional values of food, that processed foods lack nutritional value;

6.1.2 infer that vitamins are a substitute for good nutrition;

6.1.3 contain claims of benefits for pre-menstrual symptoms (except as provided for in the clause of this Code relating to "prohibitions"), sexual activity, nervousness, stress or that vitamin supplements will stimulate appetite or growth;

6.1.4 contain claims that good looks, good health and long life can necessarily be attributed to the use of vitamin supplements.

6.2 An advertisement relating to vitamin supplements shall contain:

6.2.1 the trade name and pharmaceutical form (if applicable) of the goods;

6.2.2 a statement of the indications for use of the goods;

6.2.3 a statement that vitamin supplements can be of assistance only if the dietary vitamin intake is inadequate.

7. CLAIMS

An advertisement for the use of therapeutic goods shall not contain:

7.1 any reference to a dose of drug in excess of a therapeutic dose;

7.2 any reference to alcohol as a medicine, or to beverages containing alcohol as thereby having medicinal properties;

7.3 any reference claiming that a course of eye exercises will restore more effective eyesight;

7.4 other than for medical devices, any claims that it is a stimulant by use of the word "stimulant" or words of a similar import; except for "appetite stimulant" (other than vitamins);

7.5 any matter which would lead persons to believe, from the symptoms described, that they are suffering from any serious ailment or that harmful consequences may result from the therapeutic good not being used;

7.6 any claim or statement that it is a universal panacea, infallible, unfailing, magical, miraculous, a certain, guaranteed or sure cure;

7.7 any claim or statement that it is effective in all cases of a condition;

7.8 any claim or statement that it will be immediate or instantaneous or of an exaggerated rapidity in action or the goods possess unique or absolute properties other than as permitted in writing by the Secretary of the Commonwealth Department of Human Services and Health;

7.9 any claim or statement that it is more efficacious or more safe because it occurs naturally;

7.10 any claim or statement that implies that the goods are safe or that their use cannot cause harm, except where the representation is approved in writing by theSecretary of the Commonwealth Department of Human Services and Health;

7.11 any claim or statement that the goods will effect rejuvenation, or regeneration of the human body or any part of it, or in any way arrest or reverse the ageing process, except as provided for in the clause of this Code relating to "Prohibitions" —sun screening.

8. PROFESSIONAL RECOMMENDATION

An advertisement for therapeutic goods shall not contain any implication that:

8.1 it is recommended or used generally by medical practitioners, dentists, pharmacists, nurses, dietitians or physiotherapists or by any person using a title implying that such person is so qualified or registered;

8.2 it is recommended or used by or emanates from hospitals or groups or associations representing or purporting to represent any branch of medicine or the sufferers from any disease;

8.3 the announcer or any person conveying a therapeutic claim is a professional worker as set out in 8.1 hereof;

8.4 the announcement is being made from the premises of a professional worker (as set out) or from a hospital, by virtue of the set or background; or

8.5 the advertised article is recommended or originates as set out in 8.1 or 8.2 of this section, by use of the words indicating prescription.

9. TESTIMONIALS

Use of testimonials will not be approved except where objective evidence can be given to support them, in that the person giving the testimonial did indeed use the product over the period claimed and achieved the results so claimed, and where accepted medical evidence is not in conflict with the testimonial given.

10. SAMPLES

An advertisement for therapeutic goods (other than therapeutic devices and sunscreening preparations) shall not contain any offer of a sample.

11. CLEARANCE

(a) All advertisements, other than those referred to in Clause 11(b) shall be subject to prior clearance by PMAA.

(b) Advertisements which are not subject to prior clearance by PMAA (but which, nevertheless, must comply with the spirit and content of the Code) are those which contain the name of a retailer or retailers offering the subject products for sale, contain information about the price or prices at which such products are offered for sale and which contain no other matter except one or more of the following -

(i) the brand name or names of the products offered for sale;
(ii) the type and/or style of the products offered for sale;
(iii) a photographic or other reproduction of the product offered for sale;
(iv the location and/or times at which the products are offered for sale; and
(v) other matter as is reasonably necessary to enable potential purchasers to identify the retailer or retailers on whose behalf the advertisement is published.

Addendum

This addendum forms part of the Code.

COMPLAINT PROCEDURES

Any person or organisation may complain about advertisements believed to be in breach of this Code. Written complaints may be submitted direct to the publisher of the advertisement, or to:

PMAA Complaints Panel
Level 4, 140 Arthur Street
North Sydney NSW 2060

ADMINISTRATION OF CODE

All advertisements submitted for approval are subject to an approval fee. Details can be obtained from the PMAA.

Subsequent to obtaining PMAA approval for compliance with the Therapeutic Goods Advertising Code, advertisers may be required to submit their advertisements to the relevant media body prior to media acceptance for publication/broadcast.

The relevant media bodies are as follows:

Federation of Australian Commercial television Stations (FACTS)
44 Avenue Road
Mosman NSW 2088
Fax 02 9969 8147

Federation of Australian Radio Broadcasters Limited (FARB)
Suite 10 Garden Mews
82-86 Pacific Highway
St Leonards NSW 2065
Fax 02 9906 5254

Australian Publishers Bureau (APB)
10th Floor
98 Arthur Street
North Sydney NSW 2060
Fax 02 9954 9105

Outdoor Advertising Association of Australia Inc (OAAA)
51A Hill Street (PO Box 481)
Roseville NSW 2069
Fax 02 9416 5316

Australian Cinema Advertising Council (ACAC)
51A Hill Street (PO Box 481)
Roseville NSW 2069
Fax 02 9416 5316

AIR MEDIA

Under Schedule 2 (Part 2) of the BROADCASTING SERVICES ACT 1992, the Secretary of the Department of Health and Family Services delegated his power to approve the text of proposed advertisements for commercial radio and television relating to medicines to the PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA INCORPORATED (PMAA).

The PMAA will approve scripts for radio and television as follows:

> For "medicines" as defined by the Broadcasting Services Act 1992 (i.e. drugs within the meaning of the Therapeutic Goods Regulations for human use).

CONFIDENTIALITY

Except as provided below, the PMAA accepts scripts and supporting material on a strictly confidential basis and therefore will not divulge or discuss their contents with anyone outside the PMAA Secretariat other than when participating in the review or appeals processes.

MATERIAL REQUIREMENTS

On all scripts for radio and television, and copy for print advertisements, space should be left at the bottom of each page in order that any stamp by the PMAA or any written comments may be inserted without obscuring any of the script.

Each advertisement submitted for approval should be accompanied by a copy of the label, carton and any package insert used in conjunction with the packaging and distribution of the goods. Where the labelling text is printed directly upon a container, a statement of its wording will suffice. If the active ingredients are not shown on the label, details of these should also be supplied.

Advertisements should be submitted to the PMAA Advertising Services Office. When the advertisement is approved the original script/copy will be held by the PMAA and a copy stamped "Approved" will be returned to the advertiser.

Television materials should be submitted in a form that allows the relationship of visual and audio - one to the other - to be readily understood and to clearly indicate the intended interpretation.

PMAA Advertising Services Office
Level 4, 140 Arthur Street
North Sydney NSW 2060
(Private Bag 938, North Sydney NSW 2059)
Ph 02 9955 7205
Fax 02 9957 6204

REVIEW PROCEDURES

Schedule 2 (Part 2) of the BROADCASTING SERVICES ACT 1992 gives any advertiser the right to appeal to the Minister for Communications and the Arts against a decision of the PMAA not to approve an advertisement for medicines.

As an integral part of the PMAA advertising approval process, PMAA makes available to advertisers a "review process" which involves the PMAA Complaints Panel. The review process is available to any advertiser that may wish to appeal against a decision of PMAA not to approve an advertisement. An advertiser for broadcast media may elect to use the Complaints Panel "review process" before considering a formal complaint to the Minister for Communications and the Arts,

If, after full discussion with the advertiser or agency, the PMAA Advertising Services Manager forms the view that the PMAA could not approve the script of a proposed advertisement, the advertiser will be advised within 10 working days of the receipt of the application for approval.

At that stage the advertiser may decide to have the PMAA refer the script and supporting material to the Complaints Panel for review by giving written notice to the PMAA within 5 working days. Any additional written material provided to the Complaints Panel by the PMAA will also be provided to the advertiser.

If, within 5 working days of being advised of the PMAA's preliminary view, a notice is not received of the advertiser's intentions, the PMAA will make a final decision based upon the preliminary view.

Within 15 working days of the receipt of all formal documentation (or at the discretion of the Chairman, oral submissions) the Complaints Panel will advise the PMAA and the advertiser of the results of its review.

If the Complaints Panel review suggests the script should not be approved, the PMAA must, within 60 days of the receipt of the original application, proceed to a final decision and advise the advertiser accordingly.

If the Complaints Panel review suggests that the script in its original form (or with appropriate amendments) should be approved, the PMAA will take into account the Complaints Panel views, and must, within 60 days of the receipt of the original application, proceed to a final decision and advise the advertiser accordingly.