# MINTER ELLISON
LAWYERS



MINTER ELLISON BUILDING
44 MARTIN PLACE
SYDNEY NSW

POSTAL ADDRESS
GPO BOX 521
SYDNEY NSW 2001
AUSTRALIA

DX 117 SYDNEY

TELEPHONE (02) 210 4444
INTERNATIONAL +61 2 210 4444
FACSIMILE (02) 235 2711

OUR REFERENCE
JMO:OMG 10097131

YOUR REFERENCE

WRITER'S DIRECT LINE
(02) 210 4806

9 June 1995

Mr J P O'Neil
Senior Assistant Commissioner
Trade Practices Commission
Benjamin Offices
Chan Street
BELCONNEN ACT 2617

**BY FACSIMILE: 06 264 2803**

Dear Sir

**Application No A90549 - Authorisation of the Proprietary Medicines Association of Australia Inc Code of Practice dated 27 January 1994**

On behalf of the PMAA, we notify the Commission that the PMAA proposes to amend the Code of Practice (Application No A90549) to:

1. insert a new section 7 containing guidelines for consumer product information;

2. amend clause 5 to incorporate changes in guidelines for advertising to health care professionals;

3. incorporating a new section 10.1.2 concerning sanctions against a member by the Complaints Panel for breaches of clause 7.3 of the Code; and

4. make consequential changes to clauses 8.4, 9.2.7, 9.2.12 and Appendix 2 to accommodate the new provisions for consumer product information.

Copies of the proposed amended provisions, and the background papers to the proposed amendments are attached.

We note that if we do not hear from the Commission within 10 days, this will constitute advice that the amendments are not significant and would not materially alter the circumstances of the authorisation granted by the Commission.

Yours faithfully
**MINTER ELLISON**

Odette M Gourley

# PMAA Code of Practice

## AMENDMENT FOR CONSUMER PRODUCT INFORMATION (CPI)

### Background paper #1

**Introduction**
From 1 July 1995 sponsors of all new Schedule 3 products will be required to provide Consumer Product Information (CPI)

TGA has agreed with PMAA's proposal that CPI for S3 products be subject to a self regulatory process, rather than the evaluation currently required for CPI for S4 products. This enables sponsors to notify TGA that CPI developed is in accord with Schedule 13 of the Therapeutic Goods Regulations and the Australian Guidelines for the Registration of Drugs Vol 2. Non Prescription Drugs (AGRD2)

**Code amendments**
PMAA's Code of Practice requires amendment to underpin the self-regulatory management of CPI for S3 products and to provide guidance for members on :

- CPI content
- Inappropriate techniques in provision of CPI, and
- Complaint handling.

The proposed new Clauses in the Code are as follows :

| | |
|---|---|
| Clause 7 | Consumer Product Information |
| Clause 7.1 | Background |
| Clause 7.2 | CPI content |
| Clause 7.3 | Techniques considered inappropriate in provision of CPI |
| Clause 7.4 | Complaint handling - CPI |
| Clause 10.1.2 | Sanctions (CPI) |

Consequent to the new Clauses, some pre-existing Clauses have required minor amendments to accommodate the handling of complaints for CPI. Those pre-existing Clauses affected are:

| | |
|---|---|
| Clause 8.4 | Clause 9.2.7 |
| Clause 9.2.12 | Appendix 2 |

A copy of the revised version of the Code is attached for your review. The proposed amendments are highlighted in italicised bold print.

**Recommended by Committee of Management**
The PMAA Committee of Management has recommended the above changes to members for adoption.

# PMAA Code of Practice

## AMENDMENT RE : ADVERTISING TO HEALTH PROFESSIONALS

### Background paper #2

PMAA's Code of Practice (Clause 5) has been expanded to provide further clarification for Members concerning the requirements for advertising OTC medicines to healthcare professionals.

A new Clause 5.5 clarifies the requirements for advertising to healthcare professionals. The clause contains new minimum requirements for advertising for Schedule 2 products, which contain a therapeutic claim.

This requirement arises from requests from TGA that advertising for all OTC medicines directed to healthcare professionals contain disclosure of active ingredients. Precedent exists in consumer print advertising, where active ingredient disclosure is required for all therapeutic goods.

Disclosure of active ingredient is already required by the PMAA Code of Practice for advertising directed to healthcare professionals for Schedule 3 products. PMAA considered that the same requirement for advertising of Schedule 2 products was reasonable, to address TGA's concerns that pharmacists particularly were made more aware of the ingredients in products which may have a similar name to other products on the market, with different ingredients.

The minimum requirements for advertising Schedule 2 products to healthcare professionals, is proposed as follows:

- Brand name of the proprietary medicine
- AAN of the active ingredient(s)
- Approved indication(s) for use

**Consequential amendments**
A new Clause 5.5 has been inserted. The numbering of Clause 5 has been reformatted so that the pre-existing Clauses 5.4 and 5.5 now become Clauses 5.3 and 5.4 respectively.

**Recommended by Committee of Management**
The PMAA Committee of Management has endorsed the amendment and recommend to the PMAA membership that the amendment be adopted.

**5.5 Advertising to Healthcare Professionals (Contd)**

***Excluded from the scope of this Code are advertising and promotional activities relating to prescription (Schedule 4) products. These activities fall under the APMA Code of Conduct.***

***Advertising for OTC medicines, directed to healthcare professionals must comply with the body of the PMAA Code, as well as this Clause, 5.5.***

***Information in Advertising***
***Advertising for Schedule 2 Proprietary/OTC Medicines where a therapeutic claim is made and where it is directed to healthcare professionals, shall contain the following information as a minimum:-***

* ***the brand name of the Proprietary Medicines***
* ***the Australian Approved Name(s) of the active ingredient(s)***
* ***approved indication(s) for use***

***Advertising for Schedule 3 medicines shall comply with Clause 5.5.1.***

**5.5.1 Advertising of Schedule Three Items**

◆ **Background**

With the introduction of the Therapeutic Goods Regulations adopted on 15/2/91, Proprietary Medicines classified as Schedule 3 cannot legally be advertised directly to the general public throughout Australia.

Schedule 3 Proprietary Medicines are described in the Standard for Uniform Scheduling of Drugs & Poisons as:

> "Schedule 3 - Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental or veterinary practitioners."

Consequently their sale to the general public requires the personal involvement of the pharmacist to ensure the Proprietary Medicine is suitable for the customer and that the customer is informed on the correct method of use. Schedule 3 Proprietary Medicines must be stored in pharmacy in areas to which the public does not generally have access. Promotional or advertising material relating to Schedule 3 Proprietary Medicines must not be visible to the public.

With this background, it is clear that the advertising of such Proprietary Medicines should be informative where possible, should be directed to healthcare professionals only and must not be directed to pharmacy assistants or other non-qualified personnel. Since only Professional Advertisements* are permitted, Schedule 3 Proprietary Medicines do not strictly fall within the ambit of the Therapeutic Goods Advertising Code of the Media Council of Australia. However, as set out in clause 5.1.2, this Code picks up and extends the provisions of the Therapeutic Goods Advertising Code.

**5.2 Comparative Advertising (Contd)**

- Points of comparison should be based on facts which have been previously substantiated and reflect the body of scientific evidence or experience at the time the advertisement is published.

Techniques which may be considered inappropriate and contrary to the provisions of this Code include the following examples:

- It should be clear with what the advertised Proprietary Medicine is being compared and upon what basis.

- Claims of superior or superlative status should be expressed in terms which accurately reflect the extent and the nature of the evidence available to substantiate them.

- Advertisements should not describe or show the Proprietary Medicines of a competitor as broken or defaced, inoperative or ineffective. The only exception is where the description or depiction is based upon the outcome of fair comparative tests to which the advertiser's Proprietary Medicine also has been subjected and the results of such tests are stated.

**5.3 ADVERTISING IN NON-BROADCAST ELECTRONIC MEDIA**

All Members shall submit electronic media advertising to PMAA for preclearance. In addition to broadcast electronic media preclearance, Members shall obtain preclearance of advertising through closed circuit video or audio networks in locations such as pharmacies, retail stores or doctors' surgeries.

**5.4 ADVERTISING IN CONSUMER PRINT, OUTDOOR AND CINEMA MEDIA**

All Members shall submit copy for consumer print/outdoor/cinema advertising to PMAA for preclearance to ensure compliance with the Therapeutic Goods Advertising Code. On receiving PMAA approval, companies shall submit advertising copy to the Australian Publishers' Bureau, Outdoor Advertising Association of Australia or Australian Cinema Advertising Council, as appropriate, for final clearance and provision of clearance number.

***5.5 ADVERTISING TO HEALTHCARE PROFESSIONALS***

***The intent of this Clause is to ensure that all promotion and advertising of proprietary medicines directed to healthcare professionals, encourages rational use of medicines, does not mislead and contributes to PMAA's overall aim of promoting responsible self medication.***

***Advertising material directed to healthcare professionals does not require prior approval by PMAA's preclearance service. Preclearance is only required for consumer advertising in broadcast media, and other consumer media as detailed in Clause 5.3 and 5.4. Companies must therefore satisfy themselves that any material they produce aimed at healthcare professionals complies with the Code.***

***Complaints regarding advertising or promotion of any OTC medicines directed to healthcare professionals will be adjudicated through PMAA's Complaints Handling Process outlined in Clause 9.***

## 7. *CONSUMER PRODUCT INFORMATION*

### *7.1 Background*

***From 1 July 1995 all new Schedule 3 products will be required to develop Consumer Product Information (CPI).***

***Existing Schedule 3 products will be required to have CPI available by 1 January 2004. Companies will be encouraged to progressively develop CPI during the interim period.***

### *7.2 CPI Content*

***Members shall ensure that all CPIs developed for their products comply with Schedule 13 of the Therapeutic Goods Regulations and the Australian Guidelines for the Registration of Drugs Vol.2. Non-Prescription Drug Products (AGRD2).***

***Schedule 13 requires that CPI is:***

- ***written in English***
- ***clearly legible***
- ***written in language that will easily be understood by patients***
- ***consistent with product information about the product***

***CPI must include the following :***

***Identification***

***What the product is used for and how it works***

***Advice before using the product***

***How to use the product properly***

***Further information***

***Unwanted effects***

***In case of overdosages***

***Storage conditions***

***Where to go for further information***

***Further details of the information required can be found in Schedule 13 and AGRD2. The Usability Guidelines and Glossary of Terms provide additional guidance.***

### *7.3 Techniques considered inappropriate in provision of CPI*

***CPI is not an advertising or promotional tool and as such should be confined to factual information concerning the product and its use.***

***As a consequence, the following techniques are considered contrary to the provisions of the Code :***

- ***inclusion in CPI of any form of comparison with other product(s), unless such comparision is consistent with approved PI;***
- ***attempts to use CPI as a direct/indirect form of advertising for the product.***

### *7.4 Complaint Handling - CPI*

***If on initial review of the complaint, the Executive Director believes that Schedule 13 has been breached, the complaint will be referred to the Compliance Branch, TGA, for resolution.***

***If however, the breach relates to Clause 7.3 above, the Executive Director will refer it to the Complaints Panel. Where the Panel is to hear a complaint concerning a CPI, an ad hoc observer will be co-opted onto the panel to provide expertise in the area in the area of writing CPI.***

***For details on the complaint procedure with regard to CPI, refer to Clause 9.***

## PART B: MANAGEMENT OF THE CODE

### 8. ADMINISTRATION OF THE CODE

**8.1** The administration of the Code shall be:

- supervised by the Executive Subcommittee* (refer Appendix 3, Rule 5.1)
- co-ordinated by the Executive Director, and
- monitored and reviewed by the Marketing & Ethics Subcommittee*.

**8.2** The Marketing & Ethics Subcommittee will appoint a Code of Practice Complaints Panel to participate as and when necessary in the administration of the Code in accordance with Sections 9, 10 and 11 of the Code. Members of the Complaints Panel shall hold office for one year and shall be eligible for re-appointment.

**8.3** The Marketing & Ethics Subcommittee shall ensure that the external members of the Complaints Panel nominated are independent of the Association and its Members, of high public standing and with demonstrated experience and ability in the respective areas of expertise they bring to the Complaints Panel.

**8.4** The Complaints Panel shall comprise a lawyer with trade practices experience; a practising member of the RACGP; a community pharmacist, being a member of the PSA; three members of the Committee of Management (on a rotating membership); a representative from a broad-based representative consumer/community organisation and, as an observer, a representative from the Department of Human Services and Health.

The Chair of the Complaints Panel shall be the lawyer with trade practices experience or his/her alternate, also a lawyer with trade practices experience.

The Marketing & Ethics Subcommittee may, after consultation and agreement, appoint an alternate to officiate in the absence of a member.

The Executive Director and other representatives of the PMAA Secretariat shall be entitled to attend meetings of the Complaints Panel as advisers.

***When the Complaint concerns CPI, the Panel will include an observer with expertise in the writing of CPI.***

Where Code complaints are heard, any Committee of Management member sitting on the Complaints Panel will be excluded if a conflict of interest or confidentiality arises, and shall be replaced by another member of the Committee of Management, failing whom another representative of a Member of the Association co-opted by the President. The Complaints Panel will only be convened to hear and make findings and determinations on complaints/disputes. The quorum for the Complaints Panel shall be five, two of whom shall be external members.

**8.5** To ensure that the Code accurately reflects current community standards and values, the Marketing & Ethics Subcommittee shall regularly (and at minimum annually) review the Code. The Marketing & Ethics Subcommittee, in consultation with the external members of the Complaints Panel, shall consider ways in which the Code should be amended and/or updated and shall formulate recommendations to the Executive Subcommittee.

## 9. COMPLAINT PROCEDURE

*For the purposes of the Complaint Procedure. "Member" includes non-member companies agreeing to be bound by the Code (refer definition of "Member").*

### 9.1 POLICY

It is the policy of the Association that all complaint procedures will be administered in accordance with general principles of fairness.

### 9.2 COMPLAINT HANDLING

(refer Appendix 2 for diagrammatic representation of Complaint Process)

9.2.1 The following procedure shall apply in the event of the Association receiving a complaint concerning the advertising and/or promotion of Proprietary Medicines by a Member.

9.2.2 The Executive Director shall ensure that written notification is given to the Association of all complaints against a Member.

9.2.3 The Executive Director shall on receipt of written notification of the complaint consider whether the Advertising Codes of the Media Council of Australia may have been breached. Where this likelihood exists, the Executive Director shall determine whether the complainant has independently approached the Advertising Standards Council and/or the Media Council of Australia. If not, the Executive Director will ensure that the Advertising Standards Council is made aware of the complaint. However, the Association will retain the right to consider the complaint in relation to the PMAA Code and to apply sanctions, where appropriate.

9.2.4 The Executive Director shall ensure all complaints are acknowledged in writing within seven working days of receipt and are dealt with as expeditiously as possible.

9.2.5 The Executive Director shall ensure that the details of the complaint are notified to:

- the Chief Executive of the Member which is the subject of the complaint; and
- the Executive Subcommittee.

9.2.6 The Member that is the subject of the complaint shall be given full details of the nature of the complaint. The Member will provide references/information as deemed by the Executive Director to be necessary. The Member shall also be invited to state whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be considered necessary.

9.2.7 If ***the complaint concerns advertising/promotion,*** the Executive Director, after considering all information provided and making such further inquiry as necessary, forms the opinion that a breach of the Code may have occurred, he/she may notify the complaint to the Complaints Panel. ***If the complaint concerns CPI, and the Executive Director forms the opinion that a breach of Clause 7.3 of the Code may have occurred, the Executive Director will automatically refer the complaint to the Complaints Panel for resolution.***

**9.2 Complaint Handling (Contd)**

**9.2.8** Upon resolution of the complaint, the Executive Director shall confirm in writing to the Chief Executive of the Member which was the subject of the complaint, the finding and actions agreed on to resolve the matter. The Executive Director shall also so notify the complainant and the Executive Subcommittee.

**9.2.9** If the Executive Director considers that no breach may have occurred, he/she shall so advise the complainant. If the complainant is dissatisfied, the complainant may nevertheless require the Executive Director to convene a meeting of the Complaints Panel to hear the complaint. The Executive Director shall so inform the complainant.

**9.2.10** If the Executive Director is unable to achieve a satisfactory resolution and/or compliance with the Code, he/she shall convene a meeting of the Complaints Panel to consider all information and responses to date and to make such further inquiry as is necessary or desirable. The Executive Director shall keep the Parties* to the complaint informed as to the stage of the complaint investigation procedure.

**9.2.11** Should a complaint concern a Member represented by a person who is a member of the Complaints Panel, the person shall, for that investigation, disqualify himself or herself and the President shall co-opt another member of the Committee of Management to act as a pro-tempore member of the Complaints Panel.

**9.2.12** The Complaints Panel shall consider all information provided before making any decision. Parties to the complaint shall be given the opportunity to provide further information and/or make submissions to the Complaints Panel. ***Where the Complaints Panel is hearing a complaint about CPI, the Panel may elect to refer an issue to the CPI Quality Assurance Reference Group for comments, prior to the Panel completing its deliberations.***

**9.2.13** Upon completion of the Complaints Panel's investigations, which shall be completed within 21 working days of the Executive Director convening a Panel meeting, the Executive Director will notify the parties to the complaint of the Complaints Panel's findings and determinations.

**9.2.14** Should the Complaints Panel consider that no breach of the Code has occurred, it shall so advise the Executive Director. The Complaints Panel shall provide to the Executive Director in writing, reasons for its opinion.

**9.2.15** If the Complaints Panel, after considering all information provided, forms the opinion that a breach of the Code has occurred, it shall determine appropriate sanctions as provided for under Section 10 of this Code and so inform the Executive Director.

**9.2.16** In the case where a breach of the Code has occurred, the Complaints Panel will advise the Executive Director of its findings and determination. The Executive Director shall notify the parties to the complaint within seven working days.

**9.2.17** The parties to the complaint shall be advised of the appeal procedures contained in Section 11 of this Code.

## 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 Failure of the offending Member to comply with either or both 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 and 10.1.1.2.

10.1.1.4 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.

***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.***

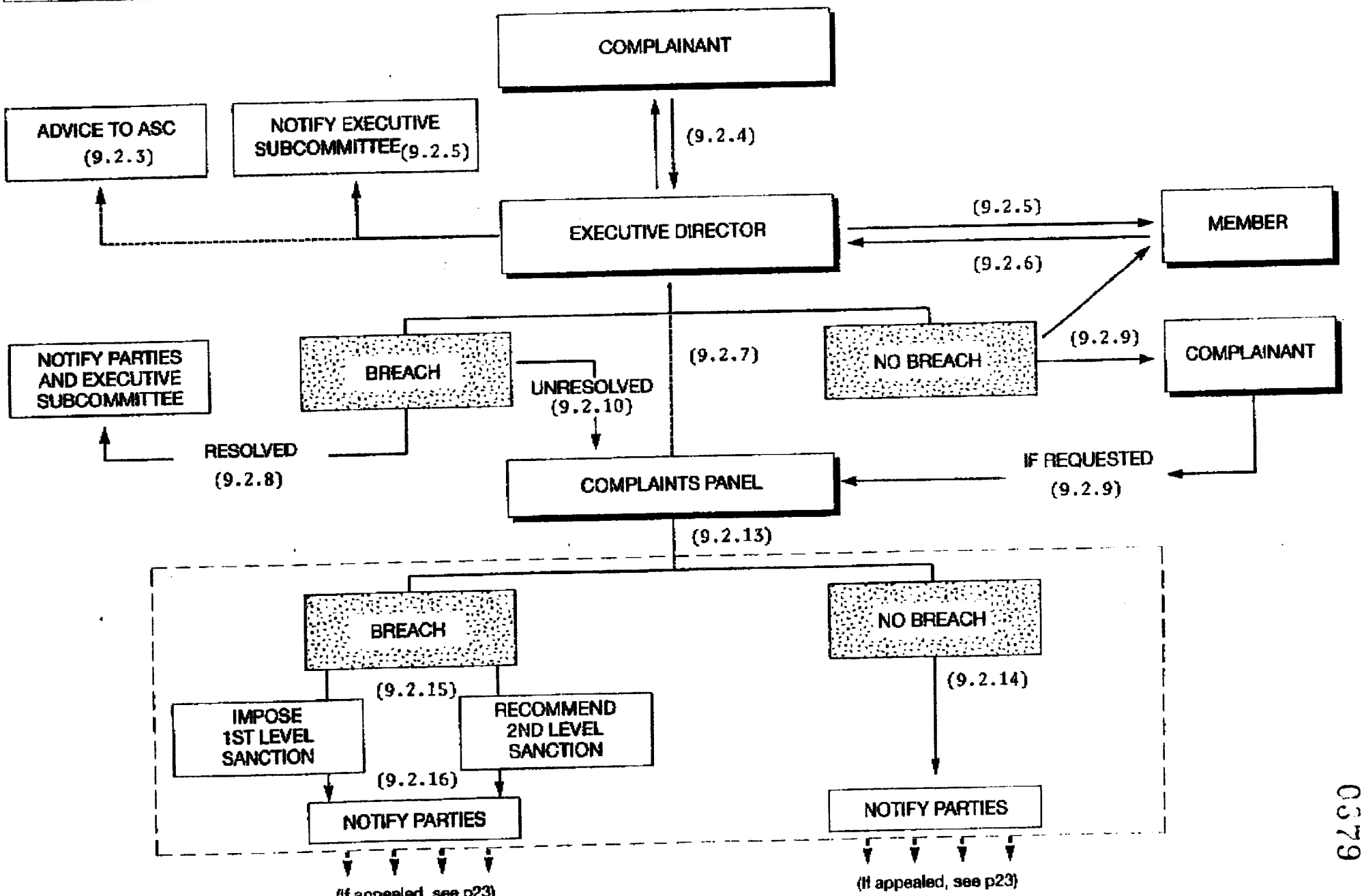
***10.1.2.2 That corrective measures be taken to redraft the CPI in accordance with the findings of the Panel.***

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

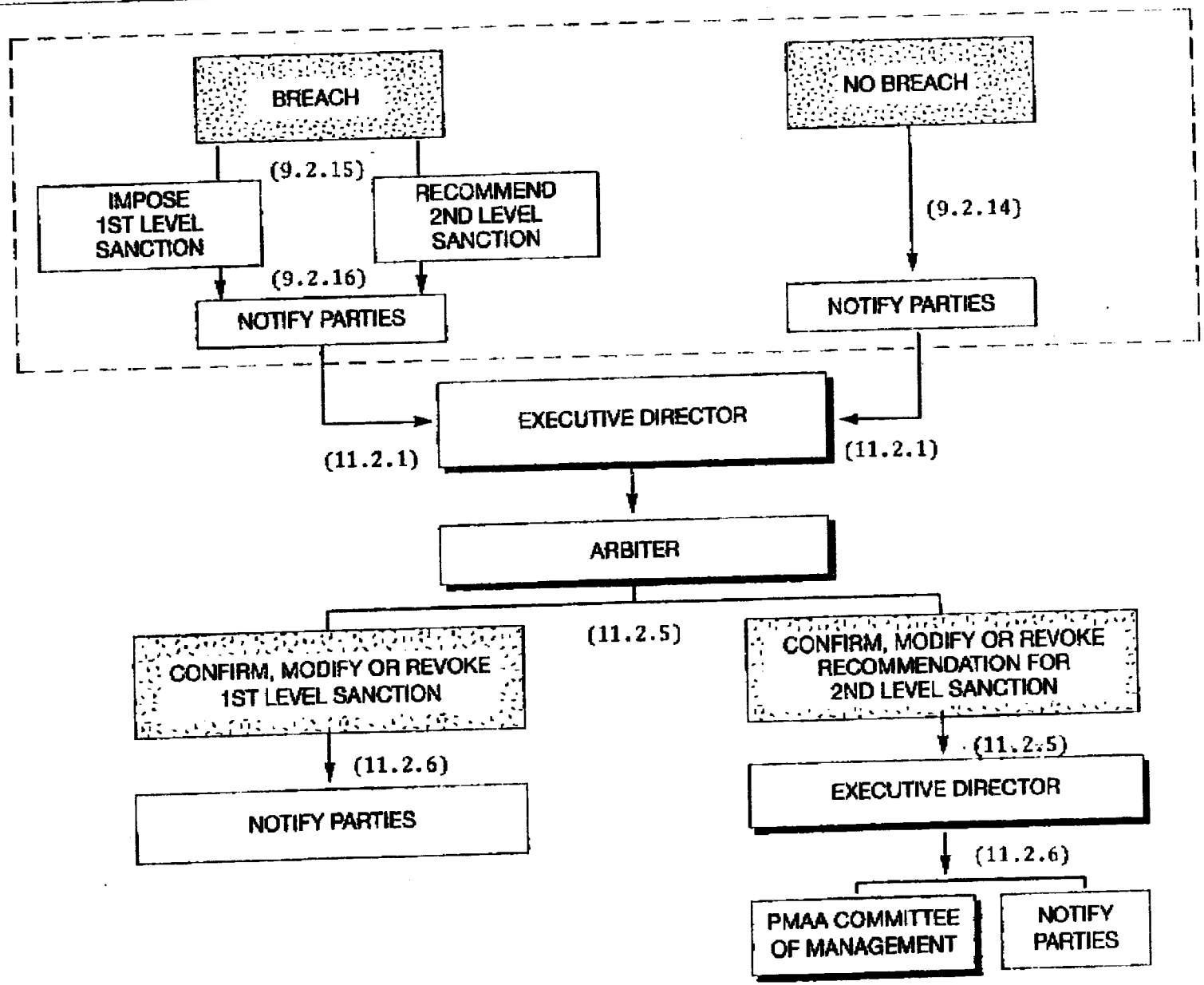
***10.1.2.4 That the matter be referred to TGA as a breach of Schedule 13.***

# COMPLAINT PROCESS

APPENDIX 2

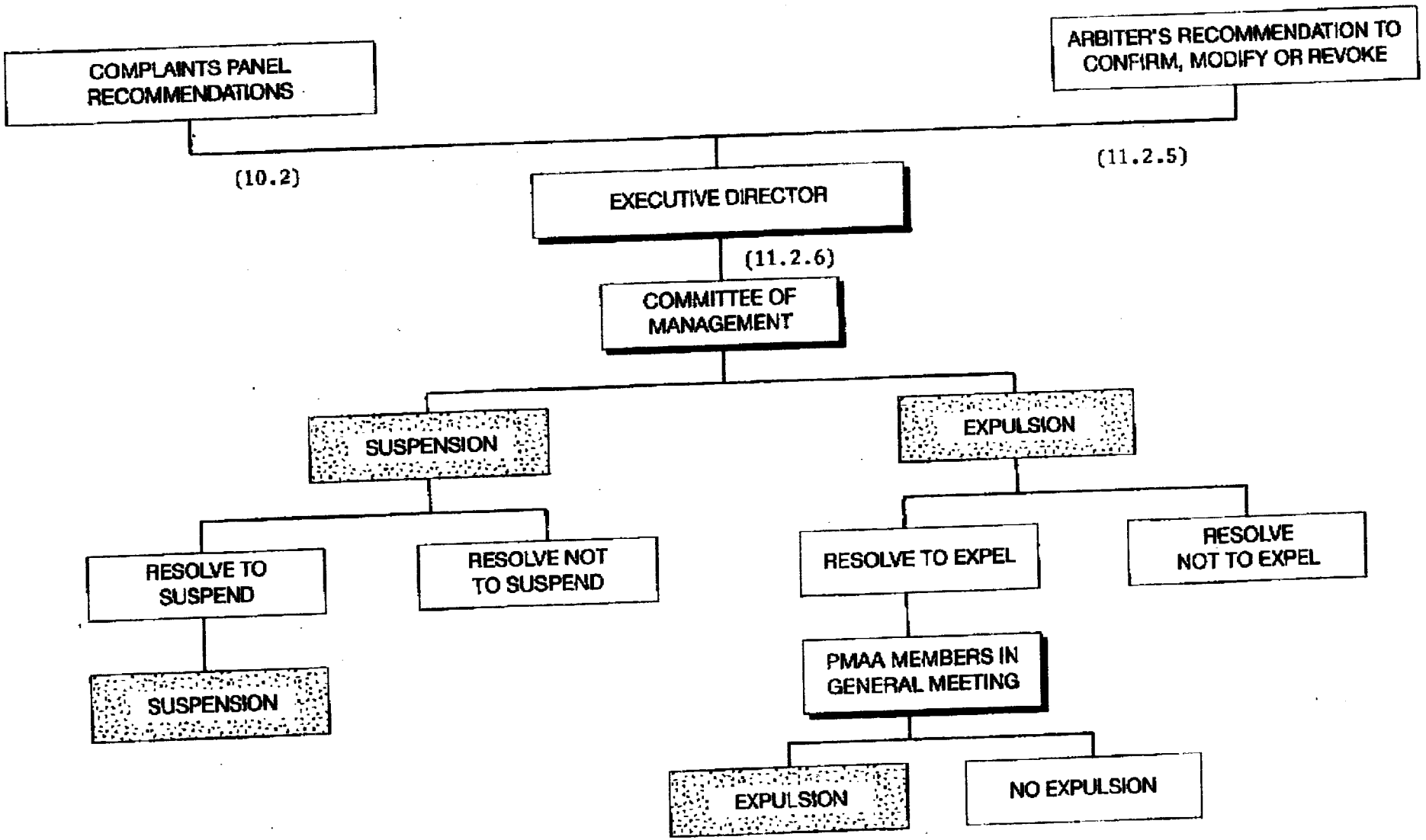


# APPEAL PROCESS



# APPEAL PROCESS - SECOND LEVEL SANCTIONS

APPENDIX 2 contd.






09/06 '95 17:19 ☎2352711