ASMI
CODE OF PRACTICE

Australian Self Medication Industry Inc. Revised March 2013

Code of Practice

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Note: 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 enquiries, comments from ASMI members and determinations made by the ASMI Complaints Panel

Preface

Authorisation of the then PMAA Code of Practice by the Trade Practices Commission (TPC) was granted on 27 January 1994 and came into force on 18 February 1994.

This authorisation applies to:

- ASMI and its members from time to time;
- all future proposed amendments to these arrangements which ASMI provides to the Commission and which the Commission considers are not significant and will not materially alter the circumstances of any authorisation granted in respect of these arrangements.

The Commission further required that:

- the public and healthcare professionals be advised of the existence of the Code and the complaint process;
- the Executive Director circulate to the Complaints Panel and to the Marketing & Ethics Subcommittee monthly summaries of all complaints received and their disposition.

The Commission will adopt the following procedures with respect to future amendments of the Code:

- ASMI will notify the Commission of amendments it proposes to make to the Code;
- The Commission will advise ASMI if it considers the proposed amendments are significant and would materially alter the circumstances of any authorisation granted by the Commission.
- both the proposed amendments and the Commission's advice to ASMI concerning those amendments will be placed on the public register of authorisation applications maintained by the Commission, subject to the Commission's power to, on request, exclude material from the public register.
- The Commission has agreed that no time limit be imposed on the authorisation, subject to regular ASMI reviews of the Code.

The significant changes to the Code that were made in 2012/2013 mean that the authorisation no longer applies to the Code.

NOTE: This preface does not form part of the Code.

1. Definitions

In this Code of Practice:

"Advertisement/Promotion" means any form of communication including by means of:

(i) Any form of publication, display, notice, catalogue, leaflet, booklet, letter (whether circular or addressed to a particular person) or other document;
(ii) Any educational event or training material;
(iii) Any packaging materials (including labels, cartons, direction folders, and other packaging components bearing printed matter);
(iv) Any words inscribed on any article;
(v) Any exhibition of a photograph or film;
(vi) Any sound recording, radio, television, digital media or spoken word.

"Awareness Activity": A communication to consumers which, without advertising or promoting any specific product, provides information in relation to health and conditions or diseases for which a Pharmacist Only Medicine may be available.

"Branded Advertising" This type of advertising is also referred to as direct to consumer advertising and is only permissible for unscheduled, schedule 2 and schedule 3 (listed in appendix H of SUSDP) products.

"Broadcast media" means any radio or television broadcast for consumers. It excludes broadcasts only available to healthcare professionals and information available on the internet.

"Consumer Advertisement" means an advertisement as defined and covered by the Therapeutic Goods Advertising Code**:**

'"Advertisement" in relation to therapeutic goods as defined in the Therapeutic Goods Act 1989 includes any statement, pictorial representation or design, however made, that is intended whether directly or indirectly to promote the use or supply of the goods'

"Consumer Medicine Information (CMI)" is confined to factual information concerning all Pharmacist Only Medicines (Schedule 3) and their use. The purpose is to help consumers use medicines appropriately and supplement and support the counselling activities of doctors, pharmacists and other caregivers. CMI is not an advertising or promotional tool. CMI must comply with Schedule 13 of the Therapeutic Goods Regulations 1990 and must be consistent with Product Information (within the meaning of section 9D(5) of the Therapeutic Goods Act 1989).

"The Association" means the Australian Self Medication Industry Incorporated.

"Code" means the ASMI Code of Practice, and includes (unless the context requires otherwise) the Therapeutic Goods Advertising Code.

"Committee of Management" means the Committee as specified in Part IV of the Rules of the Association, which has been elected to control and manage the affairs of the Association.

"Complaints Panel" means the ASMI Code of Practice Complaints Panel.

"Direct to consumer advertising" – This type of advertising is more commonly referred to as branded advertising and is only permissible for unscheduled, schedule 2 and schedule 3 (listed in appendix H of SUSDP) products. See definition of branded advertising above.

1. Definitions *continued*

"Discredit" means injure the reputation of or destroy confidence in the product/industry.

"External Use" in relation to any medicine or related product means for application to the anal canal, ear, eye, mucosa of the mouth, nose, skin, teeth, throat or vagina, where local action only is required and where extensive
systemic absorption will not occur, but this shall not apply to nasal drops, nasal inhalations, nasal sprays, teething applications, throat lozenges, throat pastilles, throat sprays or throat tablets.

"Generic Information" means information as defined in section 42B of the *Therapeutic Goods Act 1989*.

"Healthcare professional" includes a person that meets the description of a healthcare professional in section 42AA(1), (2), (3) of the *Therapeutic Goods Act 1989*.

"Hospitality" means the provision of travel costs, accommodation, food or beverages.

The **"industry"** means the basic manufacture and/or formulation and/or importation and/or basic or applied research into and/or the registration and/or marketing of non-prescription consumer healthcare products.

"Mainstream Print media" means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

"Marketing & Ethics Subcommittee" means the committee appointed by the Committee of Management to, *inter alia*, monitor and review the ASMI Code of Practice.

"Member" means any Ordinary or Associate member as defined by the ASMI Rules. For the purposes of this Code, "Member" also includes any consenting non□member company, which has agreed to be bound by all or part of the provisions of the Code.

"Non-prescription consumer healthcare products" means products for health/personal care that may be purchased directly by consumers. These include, but are not limited to, products which are available to the public without medical prescription and which are used for the purpose of or in connection with:

- preventing, diagnosing or alleviating a disease, ailment, defect or injury in humans;
- influencing, inhibiting or modifying a physiological process in humans;
- testing for a physiologic condition or the susceptibility of man to a disease or ailment; or
- destroying or inhibiting micro□organisms that may be harmful to humans.

"Off Site Location" means any area of a retail outlet that is not the normal shelf placement site for therapeutic goods. Within grocery outlets, off site locations are defined as anywhere in the store that is beyond the Health & Beauty section. In Pharmacy, off site is defined as anywhere outside the store. For other distribution channels, promotional displays that appear other than in the routine placement area for therapeutic goods would be defined as off site.

"Parties" means for the purpose of the complaint and appeal processes, both the complainant and the company, which is the subject of a complaint.

"**Prize competition**" means a contest for a prize, where purchase is a condition of entry.

1. Definitions *continued*

"Quality Use of Medicines" means:

- Selecting diagnostic and treatment options wisely based on the best available evidence and the consumer's needs;
- Choosing suitable therapeutic products if this is considered necessary; and
- Using therapeutic products safely and effectively.

"Rules" mean the Rules of the Association for the time being in force.

"Specified media" means:

(a) mainstream media within the meaning of section 42B of the *Therapeutic Goods Act 1989*; or
(b) cinematography film; or
(c) displays about goods, including posters:
    (i) in shopping malls
    (ii) in or on public transport; and
    (iii) on billboards.

"Stakeholders" means healthcare professionals, pharmacy assistants, other non-healthcare professional persons and consumers.

"**The Association"** means the Australian Self-Medication Industry Incorporated.

"Therapeutic Goods" is as per the definition in the Therapeutic Goods Act 1989.

"Unfair" means not equitable or honest or impartial or according to the Rules.

Note: The first use of a defined term is underlined and marked with an asterisk (*).

2. Introduction

2.1 The Association* is the corporate representative and advocate for manufacturers of non-prescription consumer healthcare products*.

2.2 As an integral part of Australia's healthcare system, the Association, through its Members*, is committed to the Quality Use of Medicines* and positively encouraging responsible use and extending the role of self--medication in Australia and to making available to the public, quality non-prescription consumer healthcare products which are both safe and effective when used as directed.

2.3 The Association promotes the concept of good health incorporating Quality Use of Medicines based on genuine consumer health needs and supported by the ethical conduct of all parties.

2.4 In this commitment, the Association's Members recognise that, whilst non-prescription consumer healthcare products can bring substantial social and economic benefits to the community, the advertising and promotion of these products should be responsible and balanced.

2.5 For these reasons, the Association has developed and promulgated this Code of Practice which requires Members to submit to its provisions as an act of self-discipline.

2.6 The Association's Members recognise that this Code of Practice has as its primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which the Association and its Members engage, the effectiveness of which is assessed through the eyes of the relevant community.

2.7 Recognising that the conduct of an individual Member can reflect upon both the industry* and the Association's membership as a whole, the Code* sets out to address what are deemed to be appropriate standards of commercial conduct generally and of advertising and promotional practices in particular.

2.8 Acceptance and observance of its provisions are binding and a condition of membership of the Association.

2.9 Members also acknowledge that the Code itself is to be applied in spirit, as well as in the letter, so that high ethical standards are followed throughout the industry.

2.10 Members shall ensure that all agents acting on their behalf are fully conversant with the provisions of this Code. Manufacturing companies of non-prescription consumer healthcare products outside the Association are invited to accept and observe this Code.

2.11 The Association commits to collaborate with relevant Stakeholders* in Code of Practice monitoring, updating, education and compliance.

3. Objectives of the Code

3.1 This Code is intended to establish the basic parameters which guide Members in the conduct of their business and particularly in matters of advertising and promotion of non-prescription consumer healthcare products.

3.2 Specifically, in relation to non-prescription consumer healthcare products, the Code seeks to assist Members to:

3.2.1 Responsibly inform consumers about the products which are available;

3.2.2 Uphold a high standard in the communication of information about the products;

3.2.3 Ensure that all claims made for the products are accurate, balanced and based on sound and objective scientific considerations;

3.2.4 Ensure that such information is communicated in a way which promotes the responsible use of the products.

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PROVISIONS OF THE CODE

PART A: THE CODE AND ITS APPLICATION

4. Principles of Practice

4.1 Members shall not engage in any unfair* or unconscionable conduct or commercial practice.

4.2 Members shall at all times ensure that they are familiar with, and comply with, the relevant provisions of Commonwealth and/or State Acts, Regulations or other legal instruments which pertain to the functions and operations in the industry.

4.3 Members shall at all times comply with provisions of:

4.3.1 the Therapeutic Goods Advertising Code;

4.3.2 and such other Codes as are from time to time developed and/or endorsed by the Association.

4.4 A Member shall ensure that all relevant persons, including representatives employed by the Member are aware of the requirements of this Code and the responsibilities inherent in membership of the Association.

4.5 Members will cooperate with the Association in the investigation of problems which may from time to time arise with respect to the safe use of non-prescription consumer healthcare products.

4.6 Members will cooperate to whatever extent they are reasonably able in programs conducted by the Association, either on its own or in collaboration with Government authorities, which are aimed to educate the user or the consumer in the safe and proper use of non-prescription consumer healthcare products.

4.7 Members will assist the Association and/or Government authorities and industry bodies to the full extent that they are able in consideration of any existing regulations or voluntary schemes aimed at achieving quality use of medicines (QUM).

4.8 Members will draw to the attention of the Association any information which may lead to improvement in standards of correct and safe use of non-prescription consumer healthcare products.

4.9 Members may, by virtue of belonging to other industry associations, be required also to conform to codes of practice of such other associations.

4.10 Requests from individual members of the public for advice of a diagnostic nature must always be refused and the inquirer recommended to consult an appropriate healthcare professional*.

4.11 Requests for information on non-prescription consumer healthcare products must be answered in a balanced way to avoid the risks of raising unfounded hopes or fears in the public mind as to the results of the use of such medicines.

Explanatory Notes

4. Principles of Practice

4.4 Members are responsible for the behaviour of their employees and agents. Members should therefore ensure that appropriate training is available and that all relevant persons understand the Code and comply with its requirements. It is especially important that representatives who have direct contact with Healthcare Professionals are made aware of the importance of maintaining the professional independence of Healthcare Professionals.

5. Advertising and Promotion

5.1 General principles

5.1.1 This section of the Code applies to Members whose non-prescription consumer healthcare products are promoted to healthcare professionals, consumers, or both.

5.1.2 Nothing in this Section of the Code of Practice shall be construed as replacing, diminishing or precluding requirements of The Therapeutic Goods Advertising Code in relation to consumer advertisements* of non-prescription consumer healthcare products. This section of the Code of Practice applies to all advertisements/promotions* for non-prescription consumer healthcare products.

5.1.3 Information and medical claims about non-prescription consumer healthcare products must be current, accurate, balanced, and must not mislead either directly, by implication, or by omission. 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.

5.1.4 Furthermore, information and claims must, when made, have been substantiated, such substantiation being provided without delay upon request. A member unable or unwilling to provide a reference in substantiation of a claim, should refrain from citing it. An abstract or summary of unpublished data should be identified as such when cited.

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

5.1.6 No Member will promote to consumers any prize competition* which is conditional on their purchase of a non-prescription consumer healthcare product. Disinfectants (other than those with antiseptic claims), unscheduled vitamin and mineral preparations, unscheduled fibre supplements and unscheduled therapeutic goods* for external use* are exempted from this clause.

5.1.7 Encouragement or support of unsolicited sampling of a placebo of therapeutic goods for internal use, by other than a healthcare professional, is prohibited.

5.1.8 Advertisements/promotions must not offer any personal incentive to a healthcare professional, pharmacy assistant, or other non-healthcare professional sales person, to recommend or supply therapeutic goods.

5.1.9 Advertisements/Promotions directed to Stakeholders, must be ethical and consistent with Quality Use of Medicines. Such advertisements/promotions should be able to withstand public scrutiny and should not discredit*, or be likely to discredit, the Industry, the Association or Members.

Explanatory Notes

5.1 General Principles

Non-healthcare professional sales staff is a broad definition which includes health food store and grocery channel staff, for example.

5.1.3 Information that may be considered false or misleading includes the following examples:

- literature references, or quotations or claims that are more favourable than has been demonstrated by the body of clinical evidence or experience;
- information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions;
- citing of data previously valid but made obsolete or false by subsequent findings;
- suggestions or representations of uses, dosages, or indications not approved by the Commonwealth Department of Health and Ageing.

5.1.2 Compliance with the Therapeutic Goods Advertising Code

Techniques which may be considered inappropriate and contrary to the provisions of the Code because they may be likely to persuade consumers to use a product which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser, include the following examples:

- Promotion to sales assistants, or to any healthcare professional, of prize competitions which are in any way related to sales to consumers of non-prescription consumer healthcare products.
- Distribution of samples to the public or issue of any coupon or voucher in connection with the distribution of samples.
- Encouragement or support of advertising of recommended “cut price” deals to the general public.
- Examples of ticketing which may constitute a breach of that Code include: "special"; temporary "value"; "discount”; "get it while it lasts"; or similar forms of ticketing.

This does not, however, preclude “every day low price” policies. Lowering of prices to meet competitive challenge may be implemented, but it must not be communicated to the general public via ticketing or similar promotional techniques.

- Encouragement or support of cooperative retail press advertisements where recommended prices are featured in a manner which may be likely to persuade consumers to purchase a non-prescription consumer healthcare product in a larger quantity than is sufficient to meet the reasonable needs of the purchaser.
- Encouragement or support of promotional displays in off-site locations within reach of the public which may be likely to persuade consumers to purchase a non-prescription consumer healthcare product in a larger quantity than is sufficient to meet the reasonable needs of the purchaser, e.g. dump bins, gondola ends (shared or full), dispensers, impulse bars at check out or other known impulse areas.

Free standing off-location displays should only be placed in the appropriate category aisles, and should display stock as it is on shelf, that is neatly stacked not jumbled. Shelf extensions such as dispenser units may only be displayed in the appropriate category aisles.

5. Advertising and Promotion *continued*

5.2 Comparative Advertising

5.2.1 Advertisements containing comparison with other advertisers, or other non-prescription consumer healthcare products shall also comply with the terms of this section.

5.2.2 Advertisements and promotional material should not describe or show the non-prescription consumer healthcare products 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 product also has been subjected and the results of such tests are stated.

Explanatory Notes

5.2 Comparative Advertising

Techniques which may be considered inappropriate and contrary to the provisions of this Code are:

- Where it is unclear with what the advertised non-prescription consumer healthcare product is being compared or upon what basis.

Or

- Claims of superior or superlative status which are not expressed in terms which accurately reflect the extent or the nature of the evidence available to substantiate them.

5. Advertising and Promotion *continued*

5.3 Specific Requirements For Advertising And Promotion To Consumers

5.3.1 Approval of advertisements

Members and non-members shall submit copy for advertisements to consumers in specified (which includes mainstream) and broadcast media* to the appropriate bodies (eg. ASMI and CHC) for approval in accordance with the delegations under the Therapeutic Goods Regulations 1990 and the Broadcasting Services Act 1992. On approval Members shall submit advertising copy to FreeTV Australia, the Federation of Australian Radio Broadcasters (FARB), Commercial Radio Australia (CRA) or the Australian Cinema Advertising Council (ACAC) where applicable.

Explanatory Notes

5.3 Advertising/Promotion to Consumers

This section relates to all consumer advertising of non-prescription consumer healthcare products.

5.3.1 Approval of advertisements

All consumer advertising in specified and broadcast media must be approved by the appropriate industry association. Advertisements for Complementary Healthcare Products (other than devices) in mainstream print media* are required under the Therapeutic Goods Act and Regulations to be submitted to:

Advertising Services
Complementary Healthcare Council
PO Box 104
DEAKIN WEST ACT 2600
Ph: (02) 6260 4022
Fax: (02) 6260 4122
Email: chc@chc.org.au

Advertisements for all other therapeutic goods (other than devices) in mainstream print media and all therapeutic goods (other than devices) in broadcast media are required under the Therapeutic Goods Act 1989 and Regulations, and the Broadcasting Services Act, to be submitted to:

Advertising Services
Australian Self-Medication Industry
Level 22, 141 Walker Street
NORTH SYDNEY NSW 2060
Ph: (02) 9955 7205
Fax: (02) 9957 6204
E-mail: asmiadvertising@asmi.com.au

Promotional material including internet content, which falls outside of the definition of specified and mainstream media such as shelf wobblers, in store posters and mobiles, do not require approval but must never the less comply with the provisions of this Code.

For a definition of mainstream and specified media* please see “Definitions”.

Minimum Requirements

Clause 6 of the TGAC contains minimum requirements for advertisements of therapeutic goods and these are:

This clause, other than paragraphs (b), does not apply to:

- Advertisements for unbranded therapeutic goods
- Labels

This clause does not apply to retail advertisements displaying only the name/picture of the goods and/or price and/or the point of sale, provided the advertisement does not contain a claim for therapeutic use.

5. Advertising and Promotion *continued*

Advertising of Pharmacist Only Medicines (Schedule 3)

5.3.2 Direct to Consumer Advertising of Pharmacist Only Medicines (Schedule 3)

5.3.2.1 For those Pharmacist Only Medicines (Schedule 3) for which advertising is permitted, all advertisements and promotional activity should comply with this Code and the Therapeutic Goods Advertising Code and advertising shall be submitted for approval as provided for in clause 5.3.1 of this Code.

5.3.2.2 For those Pharmacist Only Medicines (Schedule 3 substances) not permitted to be advertised to the general public, advertisements should be directed to healthcare professionals only and must not be directed to pharmacy assistants or other non-qualified personnel.

Explanatory Notes

5.3.1 Approval of advertisements - *continued*

An advertisement for therapeutic goods shall contain:

(a) The trade name of the goods
(b) A reference to the approved/permitted indication(s) for the use of the goods
(c) Where applicable, a list of ingredients or the following statement prominently displayed or communicated:

ALWAYS READ THE LABEL

except in the case of direct marketing and Internet marketing, where the catalogue or Internet communication must contain a full list of active ingredients

(d) Words to the following effect, prominently displayed or communicated:

USE ONLY AS DIRECTED

And, for claims relating to symptoms of diseases or conditions,

IF SYMPTOMS PERSIST SEE YOUR DOCTOR/HEALTHCARE PROFESSIONAL

(e) or, in the case of schedule 3 therapeutic goods listed in Appendix H of the Standard for the Uniform Schedule of Drugs and Poisons, words to the effect of

YOUR PHARMACIST'S ADVICE IS REQUIRED

(f) In the case of therapeutic goods that are able to be lawfully advertised and are available only from, or on the recommendation of, a health professional (except in the case of S2 and S3), the following displayed or communicated:

YOUR [APPROPRIATE HEALTHCARE PROFESSIONAL] WILL ADVISE YOU WHETHER THIS PREPARATION [PRODUCT NAME] IS SUITABLE FOR YOU/YOUR CONDITION

Advertising of Pharmacist Only Medicines (Schedule 3)

5.3.2 Direct to Consumer Advertising* of Pharmacist Only Medicines (Schedule 3)

Except for those Pharmacist Only Medicines (Schedule 3 substances) for which direct to consumer advertising is permitted, promotional or advertising material relating to Pharmacist Only Medicines (Schedule 3) must not be visible to the public.

5. Advertising and Promotion *continued*

5.3.3 Awareness Activities and Pharmacist Only Medicines (Schedule 3) (Not permitted to be advertised to consumers)

5.3.3.1 Awareness Activities* must be current, accurate, balanced, and must not mislead either directly, by implication, or by omission. Any 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 Awareness Activity is conducted.

5.3.3.2 Awareness Activities must be ethical and consistent with Quality Use of Medicines. Such Activities should be able to withstand public scrutiny and should not discredit, or be likely to discredit, the Industry, the Association or Members.

5.3.3.3 Awareness Activities must not contain language which is alarmist.

5.3.3.4 If management options are referred to, the Awareness Activity must not unduly emphasise particular options or the need to seek treatment.

5.3.3.5 The language used should be appropriate and able to be readily understood by the audience to which it is directed.

5.3.3.6 Sponsor company or distributor identification is permissible.

5.3.3.7 Awareness Activities may include generic information* which details the condition, conditions or class of condition for which Pharmacist Only Medicines (Schedule 3) have become available or where new indications for existing Pharmacist Only Medicines (Schedule 3) have been approved.

5.3.3.8 Awareness Activities must clearly emphasise the role of the Healthcare Professional in recommending actual products, and direct consumers to their Healthcare Professional for further information.

5.3.3.9 An Awareness Activity must contain one of the following cautionary statements or words to the same effect.

"Consult your pharmacist and/or doctor"
"Seek your pharmacist's and/or doctor's advice"
"Ask your pharmacist and/or doctor for advice about suitable products for you"
“Ask your pharmacist and/or doctor for the best management options for you”

Explanatory Notes

5.3.3 Awareness Activities

Awareness Activities may provide information, promote awareness and educate the public about health, disease and their management.

Certain Schedule 3 medicines may not be advertised to consumers. Despite this, it is permissible to provide information to consumers in relation to their health and conditions or diseases for which such non-advertisable medicines are available, provided that no specific medicine is advertised or promoted. Provision of such information is referred to as an “Awareness Activity”.

Awareness Activities can provide relevant information to consumers and enhance their awareness that medicines are available without a doctor's prescription, and can direct them to seek further information from their doctor or pharmacist about those medicines.

Objectives

The need to create such awareness may arise from the availability of new OTC medicines, or rescheduling which has enabled medicines which had been previously restricted to prescription only use, to be available without a prescription.

Accordingly, Awareness Activities should:

- inform consumers of the availability of Pharmacist Only Medicines (Schedule 3);
- emphasise that such medicines may only be used on the recommendation of, or after consultation with, a pharmacist or medical practitioner;
- convey information of an educational, rather than promotional nature;
- refer consumers to their pharmacist or doctor for further information, thus promoting better communication between consumers and health professionals; and
- focus on building consumer awareness that certain (unidentified) medicines are available.

Companies sponsoring Awareness Activities are encouraged to provide pharmacists with educational material.

The Role of the Healthcare Professional

The role of the Healthcare Professional as an adviser to the consumer is very important.

Once the consumer is aware of the availability of an (unidentified) Pharmacist Only Medicine (Schedule 3) for a particular condition or symptom, the suitability of available products, and the possible need for a doctor's diagnosis, will need to be assessed by the Healthcare Professional. If a suitable product is available, information about the product, its correct usage, dosage and precautions, will be required at the point of purchase when the patient is most receptive to this type of information.

Awareness Activities simply indicate the availability of (unidentified) Pharmacist Only Medicines (Schedule 3) for certain conditions and communicate basic information.

The role of the pharmacist as adviser at the point of purchase is crucial, as is the doctor’s role, and neither should be usurped by Awareness Activities. Rather, their roles should be enhanced.

The requirements for Awareness Activities clearly limit the scope of allowable claims, ensuring no identification of Pharmacist Only Medicines.

The provision of information to consumers via Awareness Activities about some Pharmacist Only Medicines (Schedule 3) provides a means of informing them of the availability of medicines and directing them to pharmacists and doctors for further discussion.

5. Advertising and Promotion *continued*

5.3.4 Advertising and promotion to children

Only those therapeutic goods listed in Appendix 5 of the Therapeutic Goods Advertising Code may be advertised to minors.

Explanatory Notes

5.3.4 Advertising and promotion to children

For therapeutic goods not listed in Appendix 5, techniques which may be considered inappropriate and contrary to the provisions of the Code, include the following examples:

- Encouragement or support of the positioning of non-prescription consumer healthcare products where they are readily accessible to children.
- Direction of advertising of non-prescription consumer healthcare products to children, except for those listed in Appendix 5 of the TGAC.
- Advertising of non-prescription consumer healthcare products in a manner which is likely to lead to its use by children without parental supervision.

5. Advertising and Promotion *continued*

5.4 Specific Requirements for Advertising and Promotion To Healthcare Professionals

5.4.1 Minimum requirements for advertisements
Unscheduled and Pharmacy Medicines (Schedule 2)

Advertisements for unscheduled and Pharmacy Medicines (Schedule 2) directed to healthcare professionals, shall contain the following information as a minimum:

- the brand name of the products
- the Australian Approved Name(s) of the active ingredient(s)
- a statement of the indication for use of the goods
- For multi-ingredient products, the advertisement shall contain reference to at least the first four principal active ingredients and the statement “For full active ingredients, see the label”.

Pharmacist Only Medicines (Schedule 3)

Advertisements for Pharmacist Only Medicines (S3) shall comply with any applicable conditions of registration.

Advertisements of Pharmacist Only Medicines (Schedule 3) must include in addition to the above:

- a succinct statement of the contra-indications, clinically significant precautions and side-effects (unless the product is included in Appendix H of the SUSDP i.e. can be advertised by brand to consumers)
- dosage and method of use
- the name of the supplier and the city, town or locality of the registered office
- a clear and unambiguous statement for healthcare professionals to review the full PI (if more extensive than the above) before recommending, and alerting them to the availability of the full PI from the manufacturer on request.

5.4.2 Brand name reminder advertisements

5.4.2.1 A brand name reminder advertisement (one containing only a brand name or branding device) i.e. conveying no claims or promotional statements, is not required to include any further information.

5.4.2.2 Advertisements which convey only purchasing details/information for the pharmacist and which communicates no claims or benefits of the goods does not require any further information.

Explanatory Notes

5.4 Specific Requirements for Advertising and Promotion to Healthcare Professionals

The intent of this Clause is to ensure that all promotion and advertising of non-prescription consumer healthcare products directed to healthcare professionals, encourages Quality Use of Medicines, does not mislead and contributes to ASMI's overall aim of promoting responsible self- medication.

Advertising material directed to healthcare professionals does not require prior approval by ASMI's approval service. Approval is only required for consumer advertising in broadcast media, and other consumer media including media directed to pharmacy assistants as detailed in Clauses 5.4.1. 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 non-prescription consumer healthcare product directed to healthcare professionals will be adjudicated through ASMI's Complaints Handling Process outlined in clause 9.

Excluded from the scope of this Code are advertising and promotional activities relating to prescription (Schedules 4 and 8) products. These activities fall under the Medicines Australia Code of Conduct.

Advertising for non-prescription consumer healthcare products, directed to healthcare professionals must comply with the body of the ASMI Code of Practice, as well as this Clause.

6. Relationships with Stakeholders

6.1 General

Interactions between Members and Stakeholders, must be ethical and consistent with Quality Use of Medicines. All interactions should be able to withstand public scrutiny and should not discredit, or be likely to discredit, the Industry, the Association or Members.

In addition to these general requirements, Members must comply with the following specific requirements.

6.2 Hospitality and entertainment

The provision of hospitality* to Stakeholders must be appropriate to the occasion, reasonable in the circumstances and of modest value.

Any entertainment must be appropriate to the occasion and reasonable in the circumstances.

6.3 Research and education grants

The provision of financial support to Stakeholders for the purposes of research and/or education must not be conditional upon, or provided in the expectation of, the Stakeholder recommending or supplying therapeutic goods.

Publication of research results must identify the researcher and the financial sponsor of the research.

6.4 Sponsorship of third party educational events

Where a Member provides financial support for an educational event conducted by a third party, that support must be declared in a manner appropriate to the circumstances. The declaration may be made by either the donor or the recipient of the financial support and the Member is responsible for ensuring this is done appropriately.

6.5 Funding of patient groups

Where a Member provides financial support to a patient group, that support must be declared in a manner appropriate to the circumstances. The declaration may be made by either the donor or the recipient of the financial support and the Member is responsible for ensuring this is done appropriately.

6.6 Provision of product samples to Healthcare professionals

Members may provide samples of non-prescription consumer healthcare products to Healthcare Professionals with the permission of the Healthcare Professional.

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7. Consumer Information

7.1 Consumer Medicine Information (CMI)*

7.1 CMI content

7.1.1 Members shall ensure that all CMI's developed for their products comply with Schedule 13 of the Therapeutic Goods Regulations1990.

7.1.2 No member shall attempt to use CMI as a direct/indirect form of advertising for the product.

7.1.3 Complaint handling - CMI

If on initial review of the complaint, the Executive Director believes that Schedule 13 of the Therapeutic Goods Regulation 1990 has been breached, the complaint will be referred to the Chemicals and Non-Prescription Medicines Branch, TGA, for resolution.

If however, the breach relates to Clause 7.1 above, and does not relate to Schedule 13 of the Therapeutic Goods Regulation 1990, the Executive Director will refer it to the Complaints Panel*. Where the Complaints Panel is to hear a complaint concerning a CMI, an ad hoc observer will be coopted onto the panel to provide expertise in the area of writing CMI.

For details on the complaint procedure with regard to CMI, refer to Clause 10.

7.2 Consumer-focussed labelling

7.2.1 Members shall ensure that all labels for non-prescription medicines (OTC and complementary) comply with the principles of consumer-focussed labelling as outlined in Therapeutic Goods Order No. 69A.

7.2.2 Members are strongly encouraged to use the Labelling Code of Practice and accompanying guidelines to help achieve the objectives of consumer-focussed labelling.

Explanatory Notes

7.1 Consumer Medicine Information

Background

Since 1 July 1995 all new Pharmacist Only Medicines (Schedule 3) are required to develop Consumer Medicine Information (CMI)*.

Existing Pharmacist Only Medicines (Schedule 3) as at 1 July 1995 will be required to have CMI available by 1 January 2004. Companies will be encouraged to progressively develop CMI during the interim period.

7.1.1 CMI content

Details of the information required can be found in Schedule 13 and AGRD2. The "Writing about medicines for people - Usability Guidelines for Consumer Medicine Information, 2nd Edition" are to be referred to for additional guidance.

7.1.2 CMI is not an advertising or promotional tool and as such must 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 CMI of any form of comparison with other product(s), unless such comparison is consistent with approved PI;
- attempts to use CMI as a direct/indirect form of advertising for the product

7.2 Consumer-focussed labelling

The Therapeutic Goods Order No. 69A requires product labels be designed in accordance with the principles of consumer-focussed labelling.

The principles of consumer-focussed labelling enable the label to be designed in such a way that consumers can:

(a) Choose an appropriate medicine on their own;
(b) Use the medicine safely and effectively;
(c) Readily find the information they need, understand it and act on it appropriately; and
(d) Access further information, if they want to know more about the medicine.

Products with labels that have been designed in accordance with the document entitled "Labelling Code of Practice: Designing medicine labels for people", published by Communications Research Institute of Australia Inc. in April 2004 should achieve this aim.

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PROVISIONS OF THE CODE

PART B: MANAGEMENT OF THE CODE

8. Administration of the Code

8.1 The administration of the Code shall be:

- supervised by the Committee of Management*
- coordinated 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 reappointment.

As a condition of appointment all members of the Complaints Panel must enter into a confidentiality agreement regarding the deliberations of the Complaints Panel in the form determined by the Marketing & Ethics Subcommittee. This confidentiality agreement will not apply to the determinations of the Complaints Panel.

8.3 The Marketing & Ethics Subcommittee shall ensure that the external members of the Complaints Panel 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 Industry members, being members of Committee of Management or Chief Executive Officers of Member companies or their nominee on a rotating membership; a nominee from a broad--based representative consumer/community organisation and, as a non-voting observer, a representative from the Department of Health and Ageing.

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 appoint an alternate to officiate in the absence of a member.

When the Complaint concerns CMI, the Complaints Panel will include a non-voting observer with expertise in the writing of CMI.

A member of the Complaints Panel having an interest in the subject matter of a complaint or likely to have a conflict of confidentiality in hearing the complaint, may not sit to hear that complaint unless the parties* to the complaint otherwise agree but shall be replaced by an alternate having the same qualifications for appointment as the member. The Complaints Panel will be convened only 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.

Chief Executive Officers of Member companies or their nominees (being employees of Member companies) may, unless a party to a particular complaint objects, by arrangement with the Executive Director and upon signing a confidentiality agreement in the form determined under section 8.2 of this Code, attend as an observer any meeting of the Complaints Panel, except where confidential information has been provided to the Complaints Panel.

8. Administration of the Code *continued*

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 and other Stakeholders identified by the Subcommittee, shall consider ways in which the Code should be amended and/or updated and shall formulate recommendations to the Committee of Management.

8.6 To ensure that all Stakeholders are aware of complaint procedures and previous decisions about complaints, the Executive Director after removing any confidential information, shall publish determinations of the Complaints Panel , determinations of the Arbiter and the relevant advertisements on the public section of the ASMI website.

Once determinations are published, ASMI shall also publish and keep up to date on its website in the Member's section a tabulation listing:

- Complaint number and date of determination hyperlinked to the determination
- Company name
- Product and claims/conduct the subject of the complaint
- Panel findings, classification of breaches and sanctions
- Appeal outcomes hyperlinked to Appeal determination

Because the integrity of the complaints handling mechanism depends on the Complaints Panel and the Arbiter operating independently of the Association, it is inappropriate for the Executive Director and staff (who provide administrative support) to comment on their decisions.

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 Procedure – General

9.2.1 A complainant is not precluded from resorting to litigation but the Complaints Panel must not consider a complaint while its substance is the subject of pending court proceedings.

9.2.2 A party to a complaint must notify the Executive Director immediately upon becoming aware of any court proceedings concerning the substance of the complaint.

9.2.3 Upon receiving a complaint concerning the advertising or promotion by a Member of a non-prescription healthcare product, the Executive Director must

(a) notify the Committee of Management; and

(b) if the complaint is in writing, consider whether the Therapeutic Goods Advertising Code may have been breached. Where this likelihood exists, the Executive Director must ascertain whether the complainant has approached the Complaints Resolution Panel. If not, the Executive Director must ensure that the relevant authority is made aware of the complaint. However, ASMI retains the right to consider the complaint in relation to the ASMI Code and to apply sanctions, where appropriate.

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

9.2.5 The Executive Director must ensure that details of the complaint are notified to the Chief Executive of the Member whose conduct is the subject of the complaint.

9.2.6 The Executive Director may, from time to time, make available for the guidance of Members, copies of previous determinations of the Complaints Panel and of the Arbiter (excluding confidential matters). Complaints Panel members and the Arbiter may receive such material to assist them in making their determinations. Non-members proposing to make complaints or responding to complaints may receive such material for the purposes of their conduct of the complaint or of their response to the complaint.

9.2.7 Prior decisions, although of instructive and persuasive value, are not binding on the Panel or the Arbiter.

9. Complaint Procedure *continued*

9.3 Complaints From Consumers and Other Persons Outside The Industry

9.3.1 Complainants are encouraged to contact the Member concerned prior to lodging a complaint as a satisfactory solution may be immediately available.

9.3.2 Where a complaint is made by a consumer or other person outside the industry, the complainant may simply state the nature of the conduct to which objection is taken and give the reason(s) for the objection. Where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review.

9.3.3 The Member whose conduct is the subject of the complaint must be given full details of the complaint. The Member must provide such references and information as the Executive Director may require. The Member must respond to the complaint within 10 working days.

9.3.4 ASMI will provide to the complainant a copy of the Member's response. The complainant may deliver to ASMI within 5 working days any reply it wishes to make. ASMI will send a copy of the reply to the Member.

9.3.5 All material provided by the parties in accordance with the provisions of this Code will be considered by the Complaints Panel.

9.4 Industry-Generated Complaints

9.4.1 Informal procedures

9.4.1.1 Members are encouraged to seek to resolve their differences informally both before invoking the formal procedures described below and at any time before final determination of a formal complaint. No informal communications may be sent to ASMI nor communicated to the Panel or the Arbiter.

9.4.1.2 If the complaint is resolved by agreement after the initiation of the formal complaint process and before final determination of the complaint (whether by the Complaints Panel or by the Arbiter), the complainant (or, in the case of an appeal, the appellant) must inform the Executive Director immediately and the complaint will be treated as withdrawn.

9.4.2 Formal procedures

9.4.2.1 Industry-generated complaints should not be used simply as a competitive tool.

9.4.2.2 Subject to any contrary order of the Arbiter on Appeal, the unsuccessful party to an industry-generated complaint must reimburse ASMI its out-of-pocket expenses associated with the determination of the complaint (such as fees payable to the Panel Chair) unless the Panel determines that each party should contribute a specified proportion, in which case each party must contribute that proportion. This payment is separate from and in addition to any fine payable to ASMI in accord with the schedule of fines outlined in Clause 10.2.3.

9. Complaint Procedure *continued*

9.4.2.3 If the complaint is resolved by agreement after the initiation of the formal complaint process and before determination of the complaint by the Complaints Panel, the parties must bear ASMI's out-of pocket expenses associated with the complaint in such proportions as they may agree or, failing agreement, in equal shares.

9.4.2.4 Industry-generated complaints must be initiated by letter from the complainant to the respondent in hard copy and, to the extent practicable, electronically, stating that it is a formal complaint under the ASMI Code of Practice. Everything on which the complainant proposes to rely should be included because generally there will be no opportunity to add anything later. Therefore the formal complaint should:

- include a copy of the advertisement or promotional material in question
- include copies of any studies relied on;
- explain why it is said this Code has been contravened;
- specify the section or sections of this Code said to have been contravened; and
- identify the category of breach.

The formal complaint should not be sent to ASMI at this stage.

9.4.2.5 Any formal response which the respondent wishes to make to the formal complaint must be delivered to the complainant in hard copy and, to the extent practicable, electronically, within 10 working days of receipt of the hard copy of the formal complaint or within such further time as the complainant, acting reasonably, may allow. The formal response must state that it is a formal response under the ASMI Code of Practice. The formal response should contain everything on which the respondent wishes to rely because generally there will be no opportunity to add anything later. The formal response should not be sent to ASMI at this stage.

9.4.2.6 If the complainant is not satisfied with the formal response, the complainant may invoke the ASMI complaints resolution procedure by sending to ASMI 10 hard copies of both the formal complaint and any formal response and, to the extent practicable, one copy electronically, and state that it wishes the Panel to resolve the complaint. The complainant must, at the same time, also send one hard copy of this material and, to the extent practicable, one copy electronically, to the respondent.

9.4.2.7 Neither the complainant nor the respondent may send to ASMI or to any member of the Panel any informal correspondence between the parties.

9.4.2.8 If a formal response was delivered out of time, the complainant must nevertheless include copies of the response in the material provided to ASMI, and, if it objects to the Panel considering the response, must so state, with its reasons. In such a case, the Panel Chair must ask the respondent to show cause why the Panel should take the response into account. If and only if the Panel Chair decides that the response should be received despite being delivered out of time, the Executive Director must ensure the response is placed before the Panel for its consideration. The decision of the Panel Chair on this issue shall be final.

9. Complaint Procedure *continued*

9.4.2.9 Unless the Panel Chair has decided to place a late response before the Panel, the Panel must determine the complaint without regard to a late response.

9.4.2.10 The Panel must determine the complaint solely with regard to the formal complaint and any formal response that was made within time or placed before the Panel upon a decision of the Panel Chair pursuant to the previous paragraph. In exceptional cases, the Panel or the Panel Chair may allow further written material to be put before the Panel and may allow an opportunity to respond to it. The question whether a late response should be taken into Account cannot be considered an exceptional circumstance.

The Panel may invite both parties to the complaint to attend the Panel meeting either in person or electronically solely to answer any questions from the Panel directed to clarifying issues arising out of the formal complaint and the formal response. No new written material will be accepted at this stage nor will a party be permitted to introduce new arguments. Both parties are entitled to hear each other's answers. A transcript of the questions and answers will be made available to the Panel and, in the event of an Appeal, to the Arbiter.

9.4.2.11 Where the parties have determined that they do not wish to attend and once all members of the Complaints Panel have received from ASMI copies of the complaint and the response electronically and, to the extent unavailable electronically, in hard copy, they may consider and discuss complaints in a secure, password-protected online chat room on the ASMI website and, if all members agree to do so, may determine the complaint without meeting face to face. Where a member desires to ask a question of a party, as contemplated by clause 9.4.2.10, the Panel must meet face to face.

9.5 Panel Procedures For All Complaints

9.5.1 Should a complaint concern a Member represented by a person who is a member of the Complaints Panel, the person shall, for that complaint, disqualify himself or herself and another Industry member shall act as a member of the Complaints Panel.

9.5.2 The Complaints Panel shall consider all information provided in accordance with the provisions of this Code before making any decision. Where the Complaints Panel is hearing a complaint about CMI, the Complaints Panel may elect to refer an issue to the CMI Quality Assurance Reference Group for comments, prior to the Complaints Panel completing its deliberations.

9.5.3 Should the Complaints Panel consider that no breach of the Code has occurred, it shall so advise the Executive Director, with reasons.

9.5.4 Should the Complaints Panel consider that a breach of the Code has occurred, it shall determine appropriate sanctions as provided for under Section 10 of this Code and advise the Executive Director of its findings and determinations, with reasons.

9.5.5 Within seven working days of the Panel meeting, a Draft Determination will be provided to the parties to the complaint. Within five working days each party may notify the Panel Chair of any claimed inconsistencies and ambiguities in the draft determination and must at the same time notify the other party. (This is not an opportunity to re-argue the case but rather to point out some inconsistency or ambiguity in the reasoning.) Within three working days i.e. 3 days after a

9. Complaint Procedure *continued*

party has claimed an inconsistency either party may provide comment i.e. on the inconsistency claimed by the other party to the claimed by the other party to the Panel Chair, who will make any changes to the draft that the Panel Chair considers necessary to address any demonstrated ambiguities or inconsistencies. Within 5 working days i.e. after party 2 has commented on the claim by party 1 and vice versa the Panel Chair must then provide the Final Determination to the Executive Director who must notify the parties and the ASMI Committee of Management of the Complaints Panel's findings and determination, with its reasons.

9.5.6 If the Complaints Panel identifies a possible breach of the Code not raised by the complainant, the Complaints Panel may draw the possible breach to the attention of the Member (with sufficient particularity for the Member to understand the respect(s) in which a breach may be established) and may request a response from the Member. If the Complaints Panel finds a breach established, after having considered the Member's response in light of all other material before it, the Complaints Panel may classify the breach and impose sanctions pursuant to section 10 of this Code.

9.5.7 The Executive Director must ensure that the parties to the complaint are advised of the appeal procedures contained in Section 11 of this Code.

Annual Report

The Executive Director shall publish annually a report of all matters arising under Sections 10, 11 and 12 of this Code, including the names of the parties, the nature of the complaint, the stage reached and what sanctions, if any, have been imposed.

10. Sanctions

10.1 Breaches

10.1.1 Where a breach of the Code has been established, the Complaints Panel must first classify what kind of breach has occurred, in accordance with the classification set out below:

Minor Breach	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
Moderate Breach	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.
Severe Breach	a breach of the Code that has safety implications or will have a major impact on how consumers or healthcare professionals view the product or competitor products
Repeat Breach	when the same or 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.

10.1.2 After classifying the breach, the Complaints Panel must consider whether or not it will impose any sanctions. The Complaints Panel is not obliged to impose a sanction where breaches of the Code have been established.

10.1.3 In determining whether or not to impose a sanction and, if so, what that sanction should be, the Complaints Panel will consider all the circumstances of the case, including whether:

- publication has ceased;
- steps have been taken to withdraw the material published;
- corrective statements have been made;
- the breach was deliberate or inadvertent;
- the Member that is the subject of the complaint has previously breached the Code;
- there were or are safety implications; and
- the perceptions of healthcare professionals or consumers have been or will be affected.

10. Sanctions *continued*

10.2 Sanctions Able To Be Applied By The Complaints Panel

10.2.1 Undertaking to discontinue advertising

The Complaints Panel may require the Member to 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.

The Panel may require the undertaking to oblige the Member to cease publication in any media (until they can be supported) of an advertisement or of a particular claim or claims which, in the advertisement before the Panel, have been determined to constitute a breach of the Code.

Where a breach of 5.1.4 involving failure to provide substantiation is found, the Panel may direct the Member to provide substantiation to the complainant, within such time as the Panel may specify.

10.2.2 Retraction and/or corrective statements

The Complaints Panel may require the Member to issue retraction statements and/or corrective statements or advertisements and/or to use its best endeavours to retrieve advertisements found to be in breach on such conditions as the Complaints Panel specifies, as appropriate. The format, size, wording, mode of publication and method of distribution of such statements/advertisements shall be specified by the Complaints Panel in its determination and will in general conform to the original statement/advertisement. This does not preclude the party that is the subject of the complaint from suggesting amendments to the retraction or corrective statements and to the associated directions. Such suggested amendments must be made to the Panel Chair within five working days of receipt of the Draft Determination and must be notified to the other party at the same time. Within three working days the other party may provide any comment to the Panel Chair. The Complaints Panel through its Chair is under no obligation to accept the suggested amendments. Subject to the appeal process set out in the Code, the decision of the Complaints Panel is final. The time for lodging an appeal is unaffected.

10.2.3 Fines

The Complaints Panel may issue a fine to the subject company in accordance with the schedule of fines, detailed below. 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.

BREACH	FINES
Minor Breach	NIL
Moderate Breach	Maximum: $20,000
Severe Breach	Maximum: $40,000
Repeat Breach	Maximum: $50,000

10. Sanctions *continued*

10.2.4 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 10.2.1, 10.2.2 and 10.2.3.

10.2.5 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 ACCC if deemed necessary.

10.2.6 A Member found in breach and directed to take remedial action is required to demonstrate to ASMI that such action has been taken. This may include providing details of mailing lists used and confirmation of media space bookings for corrective statements.

10.2.7 One or more of the following sanctions against a Member notified in writing may be applied by the Complaints Panel where breaches of Clause 7.1 of the Code have been established.

10.2.7.1 That the Member discontinue immediately distribution of the CMI.

10.2.7.2 That corrective measures be taken to redraft the CMI in accordance with he findings of the Complaints Panel.

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

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

10.2.8 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 Complaints Panel may request the complainant to show cause why the Complaints Panel should not impose a charge of $10,000 for vexatious use of the Code.

10. Sanctions *continued*

10.3 Sanctions Able To Be Applied By Committee of Management

10.3.1 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 10 of the Code.

10.3.1.1 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.

10.3.1.2 The expulsion of the Member from the Association, under the provisions of the Rules of the Association.

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

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

11. Right of Appeal

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 make every endeavour to comply with the ruling as soon as the Member receives the Draft Determination, 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

The appeal process will be conducted following the principles of fairness and equity for both parties to the appeal process. The appeal will have regard to section 9.3 and 9.4 of the Code of Practice.

11.2.1 A party dissatisfied with a Final 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 ASMI setting out the grounds for objection.

11.2.2 The unsuccessful party to an industry generated appeal must reimburse ASMI its out-of -pocket expenses associated with the determination of the appeal (such as fees payable to the Arbiter) and of the complaint (such as fees payable to the Panel Chair) unless the Arbiter determines that each party should contribute a specified proportion, in which case each party must contribute that proportion. This payment is separate from and in addition to any fines payable to ASMI in accord with the schedule of fines outlined in clause 10.2.3

11.2.3 If the complaint is resolved by agreement after the initiation of the formal complaint process and before determination of the complaint by the Arbiter, the parties must bear ASMI’s out-of pocket expenses associated with the complaint in such proportions as they may agree or, failing agreement, in equal shares.

11.2.4 The Committee of Management will be advised of the appeal lodgement within 7 working days.

11.2.5 The appeal shall be held not later than 28 days after receipt of the written appeal. The parties shall be advised of the date, time and place of the appeal meeting and any adjournment thereof.

11.2.6 The appeal shall be determined by an independent person (the “Arbiter”) appointed by the Marketing & Ethics Subcommittee with appropriate legal and trade practice expertise and not involved in any previous hearing of the particular complaint, sitting alone on an at□call basis. Parties to the appeal shall not introduce medical expertise to assist the Arbiter in deliberating the scientific or medical aspects of the appeal. The arbiter can request that the ASMI Executive Director appoint an independent scientific or medical expert to advise the arbiter in their deliberation.

11. Right of Appeal *continued*

11.2.7 Three copies of the written appeal shall be received by the Executive Director and a copy will be provided to both the company which lodged the original complaint and the Arbiter. The responding company will have 10 working days within which to provide three copies of any written response to the appeal to the Executive Director, should it so wish. The written response will be forwarded to the appellant company and to the Arbiter.

11.2.8 To avoid the appeal becoming a new hearing on fresh material, the materials to be considered by the Arbiter shall be confined to the evidence that was before the Complaints Panel; the determination and reasons of the Complaint Panel and any written submissions of the parties. In exceptional circumstances the Arbiter may decide to accept material that was not available when the complaint was heard by the Complaint Panel, such as new published material or changes to product registration.

11.2.9 The parties will indicate in writing whether they wish to attend and speak at the meeting. The party may appear in person or through representatives or both. The names and positions of the nominated persons are to be notified to the Executive Director prior to the date of the appeal meeting who will then inform the Arbiter prior to the meeting.

Chief Executive Officers of Member companies or their nominees (being employees of Member companies) may, unless a party to a particular complaint objects, by arrangement with the Executive Director and upon signing a confidentiality agreement in the form determined under section 8.2 of this Code, attend as an observer any appeal meeting, except where confidential information has been provided to the Arbiter.

11.2.10 At the appeal meeting referred to in 11.2.2 and 11.2.6 above, the Arbiter shall ensure proper consideration of the appeal, whilst not being bound by the rules of evidence. The Arbiter shall;

a) give the parties the opportunity to make oral representations. In the event of an oral representation, the following procedures shall apply;

- the party bringing the appeal will be heard first and that party shall be entitled to reply to any oral representations made on behalf of the other party;
- with the consent of the Arbiter proceedings may be adjourned for a short time between oral submissions;
- neither party may intervene during the other party's oral presentation, or direct questions to the other party;
- the Arbiter may ask questions of either party and may (but shall not be obliged to) ask a question of a party at the suggestion of the other party.

b) The Arbiter shall give due consideration to any written representations submitted by the parties prior to the meeting.

11. Right of Appeal *continued*

11.2.11 The Arbiter in reaching a determination may confirm, revoke or modify the decision of the Complaints Panel. The Arbiter may request the Complaint Panel to reconvene to reconsider the complaint in the event that:

a) a procedural error is identified by the Arbiter;
b) new technical or scientific information is presented.

The procedures of the Complaints Panel under these circumstances will be determined by the Chair of the Complaints Panel in consultation with the Executive Director. Upon such reconsideration the Complaints Panel may confirm, revoke or vary its previous determination (s).

11.2.12 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.

11.2.13 The Executive Director shall, as soon as practicable, inform the parties in writing of the Arbiter's decision, and shall also so inform the Committee of Management where the Arbiter recommends suspension or expulsion of a Member. The Executive Director shall not comment or engage in correspondence in relation to the substance of the decision or reasoning of the Arbiter.

12. Monitoring of Advertising

12.1 Objectives

To support compliance with the ASMI Code of Practice, the Promotional Monitoring Panel will pro-actively monitor selected promotional material of Members on a regular and ongoing basis.

12.2 Aims of the Monitoring Process

- To encourage compliance with the ASMI Code of Practice through the review of all printed, audiovisual, computer based and associated product related non-mainstream advertising materials in light of the provisions of the Code.
- To provide comment on compliance issues where requested
- To provide an ongoing mechanism for the identification of trends in health matters, marketing activities or changes in technology which may indicate the potential need for amendments to the Code of Practice
- To provide and publish statistical data on the rate of compliance.

12.3 Scope

All forms of promotional material which are not subject to the formal approval process may be reviewed by the Panel.

12.4 Membership Of The Promotional Monitoring Panel

The Marketing & Ethics Subcommittee will determine the composition of the Promotional Monitoring Panel which will include adequate representation from the medical and pharmacy profession, patient/ consumer groups and Industry.

The Chairperson of the Promotional Monitoring Panel will be independent of the Australian Self-Medication Industry and its member companies.

The Monitoring Subcommittee is comprised of the following members:-

Permanent Members:
Chairman – independent of ASMI and its member companies
One community pharmacist
One member from the medical profession
One member of the ASMI Secretariat
One member of a relevant patient or consumer support group

Rotating Members:
One Medical or Scientific Director of a member company without a conflict of interest
One Marketing Director of a member company without a conflict of interest.

12. Monitoring of Advertising *continued*

12.5 Protocol For The Activities Of The Promotional Monitoring Panel

This protocol delineates the activities of the ASMI Promotional Monitoring Panel (PMP), which is responsible for the examination of promotional materials, and linked activities within nominated therapeutic categories, with regard to compliance with the Code of Practice.

OPERATING PROCEDURES

Specific types of advertising materials will be requested of member companies from within the various therapeutic categories on a random basis.

Member companies will be required to submit to the PMP through the Secretariat, nine copies of the selected type of advertising material issued by the member over a period to be specified by the Committee, eg. 3 months, for the therapeutic category under review.

It is acknowledged that although the PMP has the right to request all types of promotional material during a review, companies will only be required to submit, within 15 working days of receipt of the request, all material of the type specified by the Secretariat. The Marketing & Ethics Subcommittee will, from time to time, determine the subject matter to be reviewed by the Monitoring Panel.

A written statement, signed by the company representative confirming that the supplied material constitutes all the selected material for the category under review will be required.

The Chairman of PMP and one member of the ASMI Secretariat will pre-sort material so that only material that makes promotional claims is sent to Panellists for review. In addition large pieces of material will not be sent to panellists but reviewed on the day of the PMP meeting.

The Secretariat will provide a copy of each piece of material to each member of the PMP at least seven (7) days prior to the meeting date, together with any other relevant information eg. consumer information, or other observations.

Meetings will be held quarterly to allow time for feedback to the companies and company response.

If, following the review of the submitted material, the PMP considers that there has been a failure to comply with the Code of Practice, the member in question will be contacted in writing by the Secretariat, supplied with the relevant portion of the Minutes, and asked to give, within 15 working days of receipt of the request, any answer, clarification or explanation deemed necessary. The PMP will consider the response and provide if necessary any further advice or comment to the company or refer the matter on to the Marketing & Ethics Subcommittee.

12. Monitoring of Advertising *continued*

12.6 Therapeutic Categories

Allergy Treatment (anti-histamines, steroid inhalers)
Pain relief, including arthritis and all paracetamol, aspirin and NSAID containing analgesics
Oral
Topical
Anti-microbial
Antiseptics and disinfectants
Cough/cold/flu
Throat lozenges, gargles, sprays
Cough mixtures
Decongestants
Expectorants
Combination products
Dermatological (include anti psoriatic, skin care)
Anti-dandruff shampoos
Anti-fungals, anti-virals, anti-bacterials, anti-parasitics
Acne preparations
Devices (include pregnancy test kits, tampons, condoms, lubricant, bandages and sports aids)
Complementary healthcare products
Herbals and Nutritionals (in combination or as single ingredient products)
Vitamins and minerals
Gastro-intestinal and urinary
Preparations for relief of heartburn (antacids, H2 antagonists)
Anti-diarrhoeals, anti-emetics, haemorrhoidal preparations, laxatives
Anti-helminthic
Miscellaneous
Ear drops
Eye drops
Oral Care
Smoking cessation
Sunscreen
Weight loss

12. Monitoring of Advertising *continued*

12.7 Promotional Categories

Press releases

Posters

Brochures

Pamphlets/leaflets

Catalogues

Direct mail

Point-of-sale materials: shelf wobblers, giant packs, mobiles, bins/display stands, etc. (Photographs to be submitted if impractical to submit original materials)

Detail aids

Education materials for retailers

Narrow-cast TV/radio

Digital media

Training materials

On pack promotions

Hospitality/Entertainment

Other

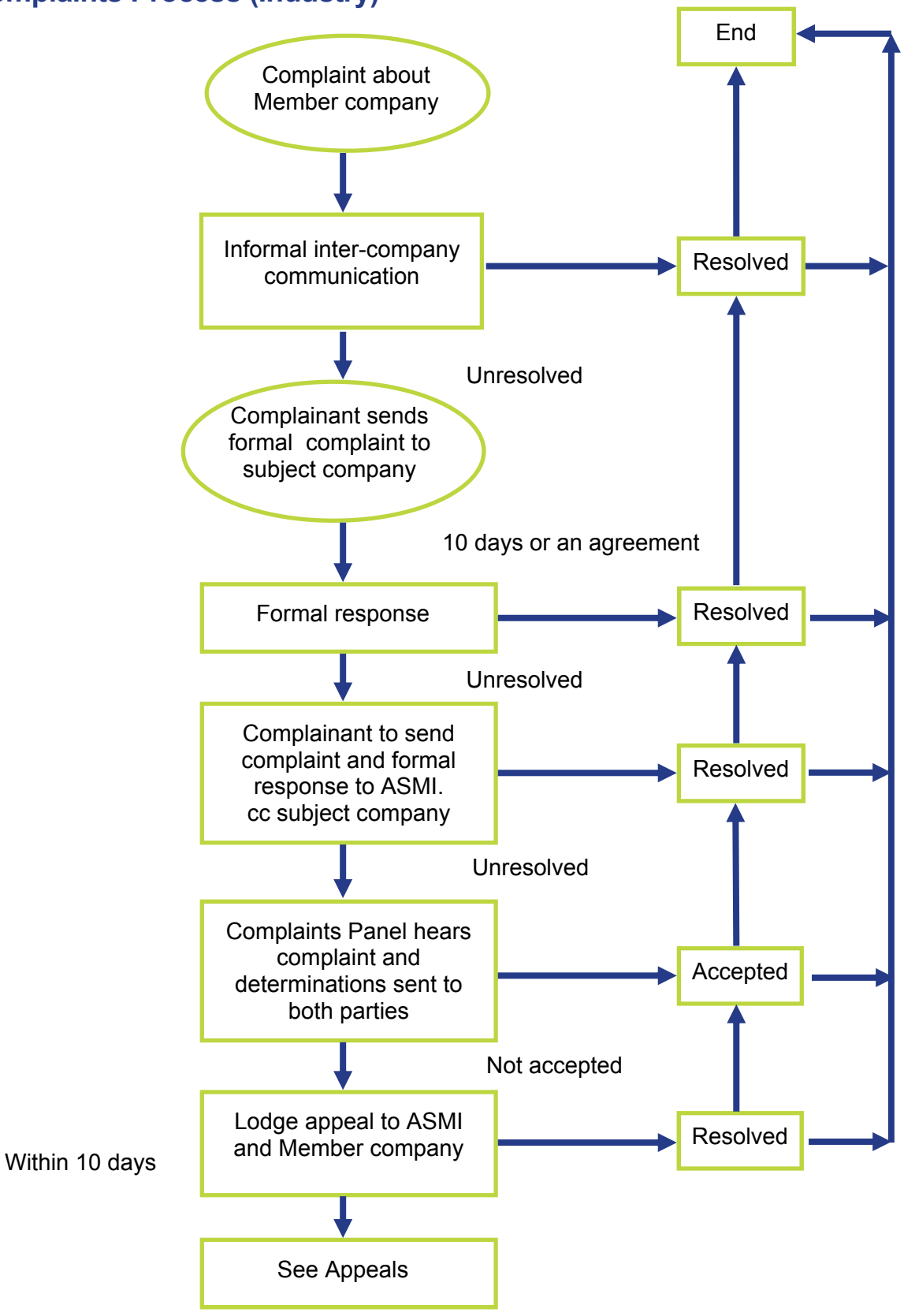
12.8 Reporting

The PMP will report to the Committee of Management as required. In addition, the PMP will issue an Annual Report for inclusion in the ASMI Annual Report. This Report will include the therapeutic categories and the type of material reviewed, the number of items reviewed, the number and type of problems detected, and the number of Code of Practice complaints generated.

In addition the Monitoring Panel will provide ongoing reports to the Marketing & Ethics Subcommittee on issues concerning the Code of Practice, which require review.

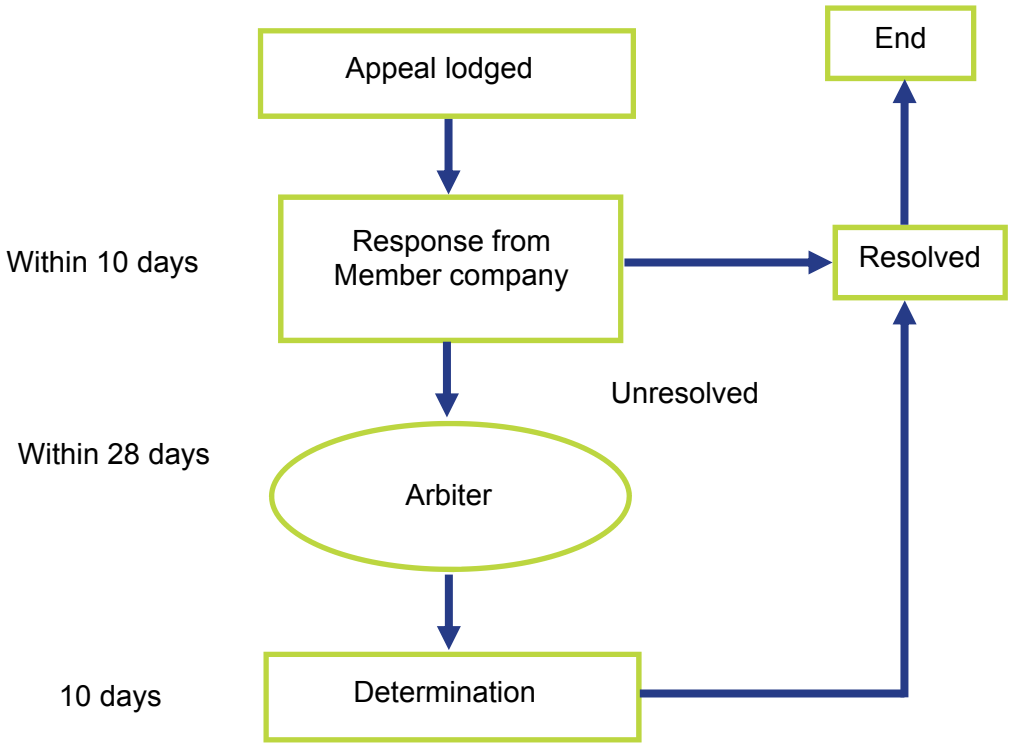
Flow Charts for Complaint Handling

Complaints Process (Industry)



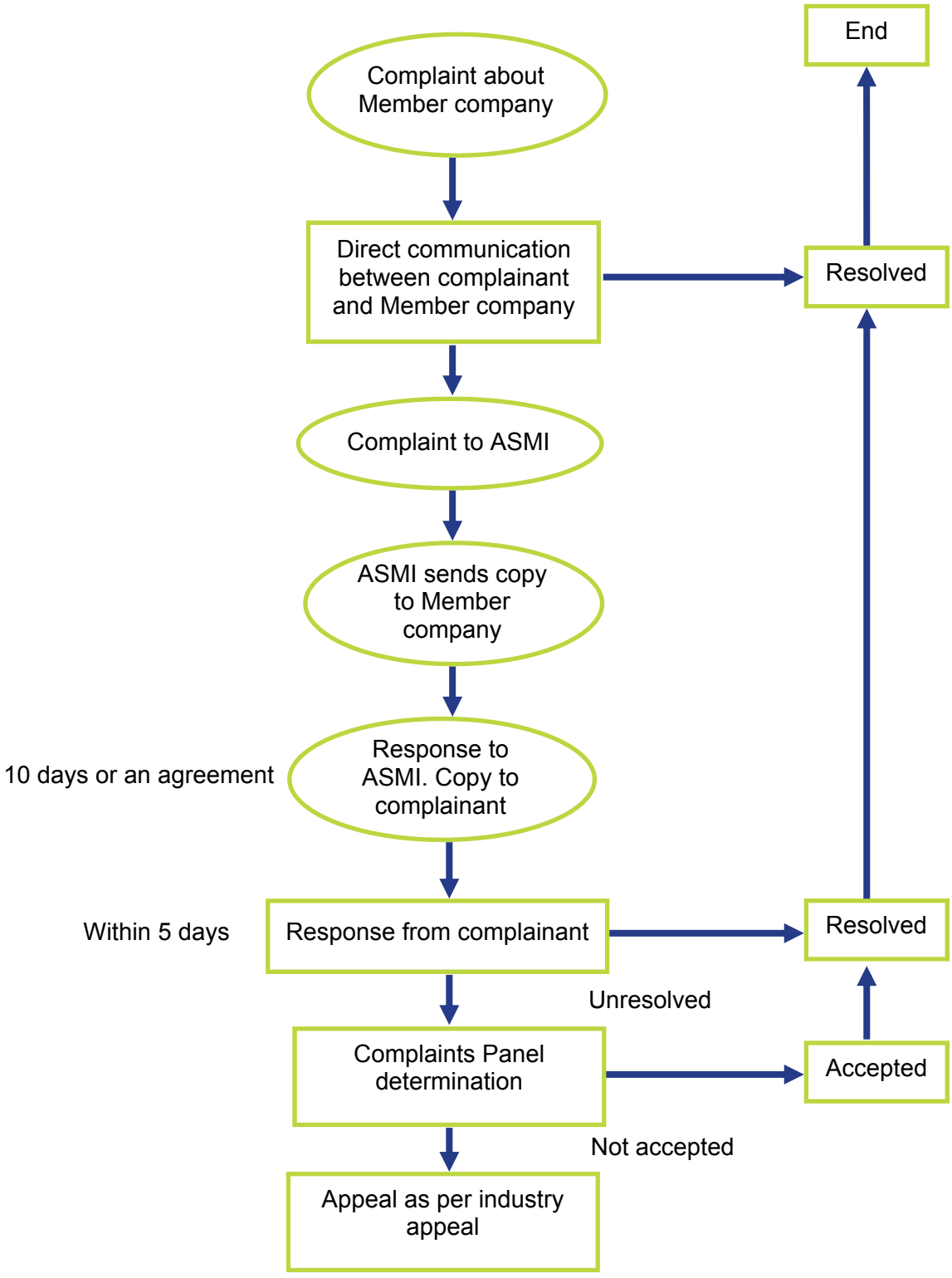
Flow Charts for Complaint Handling
continued

Appeals



Flow Charts for Complaint Handling
continued

Complaints (Non Industry Generated)



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