7. PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA CODE OF PRACTICE

7.1 INTRODUCTION

This case study examines the Code of Practice (PMAA Code) administered by the Proprietary Medicines Association of Australia (PMAA). The PMAA represents companies that manufacture or sponsor non-prescription consumer healthcare products. The PMAA Code does not apply to medicines that by law must be prescribed by a medical practitioner.

This case study, in conjunction with a case study of the Australian Pharmaceutical Manufacturers Association (APMA) Code of Conduct which covers prescription-only medicines, provides insights into the development and operation of self-regulation in a health and safety oriented industry. The case study draws no conclusions about the scheme, beyond acknowledging perceived benefits and shortfalls and is merely intended to highlight key features of the industry and its approach to self-regulation.

The following sections describe the market for non-prescription medicines and the market failure that has lead to the need for a Code of Practice. Section 7.3 briefly describes the present system of self-regulation and a brief history of the establishment of the PMAA scheme. Finally section 7.4 discusses some features of the market that make the PMAA approach to self-regulation more or less effective.

7.2 THE MARKET FOR NON-PRESCRIPTION CONSUMER HEALTHCARE PRODUCTS

7.2.1 Supply of non-prescription consumer healthcare products

Before any therapeutic product can be marketed in Australia, the *Therapeutic Goods Act 1989* requires that it be reviewed and either registered or listed on the Australian Register of Therapeutic Goods (ARTG). There are approximately 50,000 separate products on the ARTG with some 3000 being added each year. A substantial proportion of these therapeutic goods would fall into the category of proprietary medicines, which includes complementary medicines, although others would fall into the category of prescription only medicines and medical devices.

The PMAA Code defines proprietary medicines to mean:

> … 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 medial prescription and which are used for the purpose of or in connection with:
>
> – preventing, diagnosing or alleviating a disease, ailment, defect or injury in man;
>
> – influencing, inhibiting or modifying a physiological process in man;
>
> – testing for a physiological condition or the susceptibility of man to a disease or ailment; or
>
> – destroying or inhibiting micro-organisms that may be harmful to man.

Following this definition proprietary medicines essentially cover all medicines which are not prescription-only medicines and are purchased directly by consumers. Thus for the purposes of the PMAA Code proprietary medicines would include complementary medicines which are also known as 'traditional' or 'alternative' medicines. Complementary medicines include vitamin, mineral, herbal, aromatherapy and homoeopathic products.

Thus as outlined in section 7.3, complementary medicines are essentially covered by two self-regulatory codes of conduct. The PMAA Code which is the subject of this case study and the Complementary Healthcare Council of Australia (CHC).

Following the PMAA Code's definition proprietary medicines would include therapeutic goods listed or registered on the ARTG and which are available without prescription. For example, herbal products, vitamins, sun screen preparations, medicated soaps, dietary supplements, certain cosmetics and hair and skin care products, baby care products, heat rubs, paracetamol, and pharmacist only medicines.

The range of products which are covered by the non-prescription pharmaceutical medicines industry is an indication of the market's diversity. For example, the healthcare products covered by this case study are supplied from a range of industries including the:

- Dairy products manufacturing n.e.c. (ANZSIC 2129) — primary activities include the manufacture of health beverages as well as infants and invalids milk based products (in powder form) — such products would be covered if their manufacturer made a therapeutic claim;
- Medicinal and Pharmaceutical Product Manufacturing (ANZSIC 2543) — primary activities include the manufacture of medicines, herbal medicines, pharmaceutical preparations, vitamin products, barrier creams and feed supplements;
- Soap and other detergent manufacturing (ANZSIC 2545) — primary activities include the manufacture of soap products (including medicated soaps), toothpastes and disinfectants; and

- Cosmetic and Toiletry Preparation Manufacturing (ANZSIC 25346) — primary activities include the manufacture of sunscreen preparations, face lotions, depilatories and hair shampoos.

In additional the retail outlets for these products include pharmacies, supermarkets and health food shops.

There is no available data which summaries the precise industry structure or size of the market for non-prescription consumer healthcare products. However, the APMA in an overview of the pharmaceutical industry in Australia states that the Australian pharmaceutical industry comprises approximately 120 companies producing both prescription and over the counter medicines. In 1998-99 these companies had a turnover of more than $6 billion (APMA leaflet). As the APMA membership of 54 companies represents approximately 95 per cent of the prescription-only market in Australia we can infer that the bulk of the remaining 120 companies (66) operate in the non-prescription consumer healthcare products industry. In addition, a number of the 54 companies associated with the APMA also supply non-prescription medicines. However given the diverse range of products covered by the PMAA code, this group of 'pharmaceutical' companies will only represent a proportion of the business which are likely to supply consumers with healthcare products which could come within the Code's ambit. For example, many complementary medicines will be supplied by herbalists and other practitioners of alternative medicine. Thus participants in the industry can be expected to range from large multi-national companies to very small businesses supplying a range of complementary medicines.

While there is a relatively large number of participants in the market for non-prescription healthcare products it should be borne in mind that the diversity in the nature of product categories within categories can lead to market segmentation. In addition, like prescription-only medicines, the industry has a strong reliance on patents to protect products, which have required an extensive investment in research and development. Both of these characteristics can reduce the level of competition.

On the other hand, the extent to which this market power can be exploited is reduced by the existence of alternative medicines or treatments. In addition, once a product has been assessed by the Therapeutic Goods Administration (TGA) and listed on the ARTG there are no major barriers to entry into the market for new or substitutive products which are developed locally or imported.

As a consequence of these factors the market for virtually all non-prescription consumer healthcare products is competitive. Competition is based on price but also on the quality and other attributes of the products. The information provided to consumers by way of

mainstream and other forms of advertising is an important factor in achieving or maintaining market share.

7.2.2 Demand for non-prescription consumer health care products

There is a strong and growing demand for non-prescription consumer healthcare products.

The Consumer Health Forum (1999) reports that the over-the-counter (non-prescription) medicine sector — which includes herbal products — is growing more strongly than the pharmacy market as a whole. Recent estimates of the value of scanned retail sales of proprietary medicines indicate strong growth in retail sales. AZTEC (2000) reports that in 1999 the retail value of electronically scanned sales of 29 categories of propriety medicines was valued at $1,331 million — this sales value represents an increase of more than 10 per cent on the previous year. However, as many small pharmacies, health food shops and herbalists would not use scanning technology AZTEC estimates must be considered as a conservative estimate of the growing demand for non-prescription medicines.

Complementary medicines are growing in popularity in Australia, a 1996 study estimates that around 50 per cent of the population choose to use complementary or alternative therapies (MacLennan, Wilson and Taylor 1996).

The Consumer Health Forum suggests that consumers are choosing to use complementary therapies and other non-prescription medications so that they have a greater control over their health conditions and the options for treatment.

Consumers' sensitivity of demand to a change in the price of non-prescription medicines will vary between product categories and in many instances from consumer to consumer. For some products categories demand may be relatively inelastic — that is the quantity of the product demanded by consumers will not decrease significantly if the price increases. This situation will arise when the product demanded is a necessity, infant milk formulas are likely to be in this category of product. On the other hand, the demand for some non-prescription medicines may be very elastic — that is the quantity of the product demanded will decline sharply if the price of the product increases. Products which are luxury goods are likely to fall into this category.

Demand for certain non-prescription medicines and healthcare products will also vary significantly between groups of consumers. For example, some consumers would not choose to use certain complementary medicines regardless of their price. Whereas other consumers may treat some types of complementary medicines as a complete alternative to western

medicine and be prepared to purchase some complementary medicine even if the price increased dramatically.

Another factor which impacts on the demand for non-prescription medicines is the number of substitute products. There are very few non-prescription healthcare products which have no substitutes. On the other hand, for some consumers the level of product differentiation used by suppliers in the sector can act to reduce the apparent number of substitute products.

7.2.3 Nature of market failure(s)

As outlined in earlier chapters, regulation by government or by an industry itself may be necessary if the unfettered operation of the market fails to produce an outcome for the community that maximises society's welfare. This section considers the market failure(s) which have lead to the need for a Code of Practice in the proprietary medicines industry.

The non-prescription medications and other healthcare products, which are the subject of this case study, are not designated as high-risk by the TGA. Nonetheless many are complex products which if taken to excess or used inappropriately can lead to a less than desirable health outcome for the consumer or a family member. In addition because consumers are not always aware of the safety, quality or efficacy of certain products they could self-prescribe medicines which are not effective for their medical condition or worse still adversely impact on their health.[1] On the other hand, suppliers of these products generally have a good understanding of the safety and quality of their products, as well as the most appropriate use of the product and its side effects. This imbalance of information between consumers and suppliers can cause the market to fail to maximise community welfare. Such an imbalance is termed an asymmetric information market failure.

Firms which are aware of this information imbalance may choose to address the market failure and provide more information which can potentially increase their market share. On the other hand, less reputable firms may choose to take advantage of the existing information asymmetry by providing incorrect, persuasive or misleading information to encourage consumers to use their products.

In Australia there has been a history of consumer misuse of some certain non-prescription medicines such as analgesics. In some instances this may have been due to a lack of consumer information about the medicine.

[1] In large part this lack of information has lead to the TGA requiring that therapeutic goods be evaluated for safety and quality and that certain therapeutic goods be also evaluated for efficacy.

False or misleading information or advertising by one producer in the non-prescription consumer healthcare market can have negative spillover (externality) effects that go beyond the disreputable firm. For example, misinformation about one product can create consumer dissatisfaction, which can adversely impact on firms producing substitute products or on the entire consumer healthcare industry. Firm owners can attempt to overcome this externality through branding their products or through their association with like-minded businesses, which operate within a model of self-regulation.

Thus the potential for less reputable firms to provide false or misleading advertising of products which could potentially cause harm to consumers and other suppliers' reputations are factors that have lead to the development of self-regulatory Codes for businesses supplying non-prescription medicines.

7.3 THE PRESENT SYSTEM OF SELF-REGULATION

7.3.1 Background

A myriad of regulation governs the manufacture, sale and promotion of consumer healthcare products. While the primary focus of this case study is the market conditions which make the PMAA's self-regulatory code more or less effective, it is necessary at the outset to understand the interrelation with other forms of regulation, including formal "black letter" regulation.

The *Therapeutic Goods Act 1989* and its accompanying regulations are the principal legislative control over the manufacture, supply (including for export) and marketing of consumer healthcare products. The Act, which is administered by the TGA[2], creates a substantially uniform national system of controls on therapeutic goods.[3] The TGA is also responsible for ensuring that the Therapeutic Goods Advertising Code (TGAC) is administered by the Therapeutic Goods Advertising Code Council (TGACC).

The TGAC was initially a self-regulatory code developed by the former Therapeutic Goods Advertising Code Council which acted under the authority of the Media Council of Australia. However, the Code is now the subject of co-regulation between the TGA and key stakeholders (consumers, healthcare professions, advertisers and industry associations

2 The TGA is a Government regulator funded entirely by industry on a cost recovery basis.

3 New South Wales and Victoria have introduced complementary legislation and, it is understood by the Department of Health and Aged Care that the other States and Territories will do so shortly.

including the PMAA and Complementary Healthcare Council of Australia (CHC)).[4] Box 2 outlines the history behind the move to co-regulation.

Box 2: **Co-regulation of the advertisement of certain healthcare products**

The Therapeutic Goods Advertising Code (TGAC) was initially a self-regulatory code developed by the former Therapeutic Goods Advertising Code Council which acted under the authority of the Media Council of Australia (MCA). However, the Code is now the subject of co-regulation. The Code was authorised by the Australian Competition Tribunal in 1988.

In 1991 a number of the Code's clauses were adopted into the Therapeutic Goods Act's regulations. However, the MCA continued to be responsible for its administration, and review.

In 1996 the MCA ceased its operations and the PMAA applied to the ACCC to take over the Council's role. However, as the PMAA's membership did not cover all products covered by the TGAC, the Trade Practices Commission (now the ACCC) required that a collegiate be formed between the PMAA and the Complementary Healthcare Council of Australia CHC (then the Nutritional Foods Association of Australia). This collegiate submitted and subsequently received authorisation of the TGAC.

However, the authorisation was the subject of an appeal to the Competition Tribunal. During the appeal hearings it became clear that the industry coverage through the collegiate's membership was not sufficient to bind all industry participants. As neither association had the power to bind non-members to decisions and compliance with sanctions imposed under the TGAC, the collegiate withdrew its authorisation application. The collegiate recognised that the successful operation of the Code required the underpinning of black letter law and negotiations commenced with the TGA. In December 1997 the Therapeutic Good Regulations were amended to both underpin the Code's content and the collegiate's system of controlling advertising.

The new Therapeutic Good Regulations gave the Complementary Healthcare Council of Australia authority to provide approval of advertisements for complementary medicines that are to appear in mainstream print media. The PMAA was given authority to provide approval of advertisements of all other non-prescription healthcare products that are to appear in mainstream print media advertisements. The PMAA under a previous delegation was also given authority to approve or not approve advertisements to consumers to be presented in the broadcast media for all non-prescription healthcare products, including complementary medicines.

Source: TGACC (1999).

4 The CHC is the peak body representing the complementary healthcare industry in Australia.

All advertising of therapeutic medicines, which carry therapeutic claims to consumers, must by law comply with the requirements and standards of the TGAC. Advertisement is broadly defined Therapeutic Goods Act as covering:

> Any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the [eligible therapeutic] goods.

This definition covers many forms of promotional communications, including product labels, which is directed at consumers by the sponsor of a product.

The Broadcasting Services Act and the Therapeutic Goods Act requires that all advertising for publication or broadcast in the mainstream media must go through a system of prior approval. These media are defined under the Therapeutic Goods Act:

> Mainstream print media means any magazine or newspaper for consumers containing a range of new, public interest items, advertorials, advertisements or competitions.

Other non-mainstream or 'below-the-line' media advertising must also comply with the Code but are not required under the TGAC to be formally approved. "Below-the-line advertisements" are deemed to be all advertisements that do not appear in mainstream media as defined by the Therapeutic Goods Administration's Regulations.

The responsibility for the approval of mainstream advertising has been delegated to two different associations — the CHC and the PMAA. The CHC has responsibility for approving the advertisements of complementary healthcare products in the mainstream print media, while the PMAA has responsibility for approving advertisements of all other therapeutic goods in mainstream print and broadcast media as well as all complementary healthcare products in broadcast media.

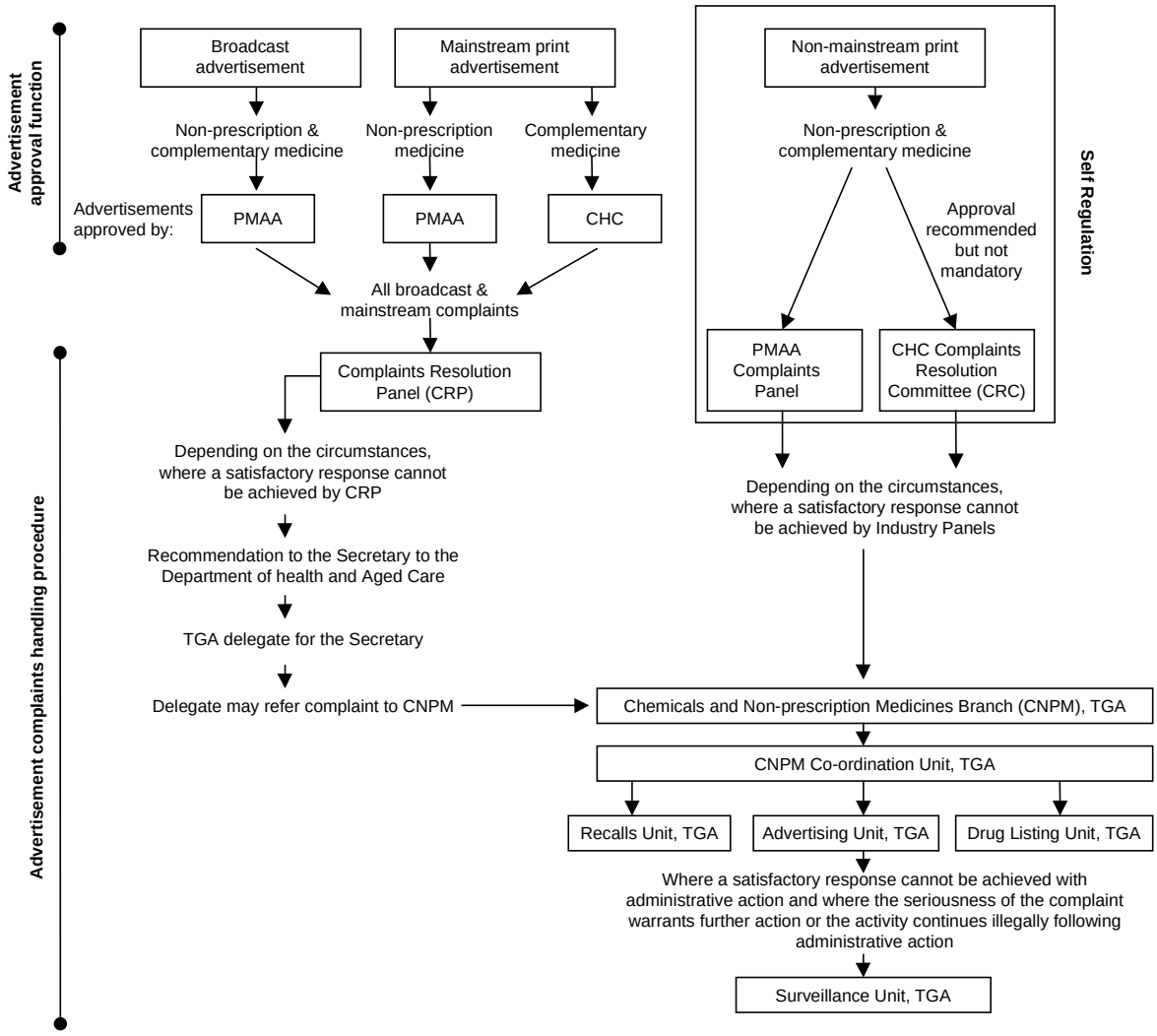
In addition under the Therapeutic Goods Regulations the TGACC which comprises representatives from industry associations, government, consumers, healthcare professionals and the advertising industry. The Council's functions include:

- ensuring that the Code reflects community standards;
- ensuring that there is uniformly across the different media;
- advising the Minister on amendments to the TGAC; and
- operating a Complaints Resolution Panel (CRP).

The PMAA and the CHC are both represented on the Council. Complaints about mainstream advertisements are handled by the CRP — under a co-regulatory arrangement. Complaints about non-mainstream advertising are handled by the PMAA and the CHC — under self-regulatory arrangements. This self-regulation complements the operation of the Complaints

Resolution Panel under the TGAC. The PMAA Code of Practice is the subject of this case study. Figure 2 outlines the approval and complaints procedures.

Figure 2: **The approval and complaints procedures for advertisements of non-prescription therapeutic goods**



Source: TGA and PMAA.

The PMAA requires that its members must comply with the TGAC as well as the PMAA Code. The PMAA refers mainstream media complaints about proprietary medicines it receives to the TGAC and non-mainstream complaints about complementary medicines to the CHC. However, many of the PMAA's members operate in the complementary market. The PMAA reserves the right to examine any complaints against a member company. Complaints against non-member companies who do not wish to participate in the PMAA complaints process may be referred to the TGA or ACCC for prosecution under the law.

7.3.2 Objectives of the PMAA Code

The PMAA Code aims to guide the industry by encouraging responsible consumer use of non-prescription medicines and health care products. This is done by setting rules and standards for advertising and promoting products, and determines relevant information for package labels. Section 3 of the PMAA Code states that it 'intended to establish the basic parameters which guide Members in the conduct of their business and particularly in matters of advertising and promotion of proprietary medicines.

Specifically the Code seek to assist Members to:

- responsibly inform consumers about proprietary Medicines which are available;
- uphold a high standard in the communication of information about proprietary medicines;
- ensure that all claims made for proprietary Medicines are accurate, balanced and based on sound and objective scientific considerations; and
- ensure that such information is communicated in a way which promotes the responsible use of Proprietary Medicines.

The PMAA Code sets out to address appropriate standards of commercial conduct generally and of advertising and promotional practices in particular. This reflects concern that the conduct of an individual member can reflect on both the PMAA's membership and the industry as a whole.

7.3.3 Development of the Code

The PMAA Code was authorised under the *Trade Practices Act 1974* in January 1994 and it came into force on 18 February 1994. It was introduced in an effort to promote consumer confidence in proprietary medicines.

The PMAA must notify the ACCC of any changes that it proposes to make to the Code. After notification the ACCC will advise the PMAA if any proposed amendments would require separate authorisation on the ground that they are significant and could materially alter the circumstance of any previous authorisation granted by the Commission.

7.3.4 Code coverage

The PMAA Code covers all its members. Acceptance and observance of the PMAA Code's provisions are binding and are a condition of membership. It is a condition of the Code that

members must ensure that any agent acting on their behalf are fully conversant with the provision of the Code.

In 1998-99 the PMAA had a total of 62 members. Membership of the PMAA is divided into two categories — Ordinary and Associate Membership.

Ordinary Members are those companies that manufacture or sponsor consumer healthcare products. The association had 38 Ordinary Members in 1998-99.

Associate Members are those firms, agencies, consultants and other businesses that provide services to the industry, such as advertising, public relations, regulatory consultancy, cartage and industry statistics. In 1998-99 the association had 24 Associate members.

As outlined in Figure 2, co-regulation governs the advertising of therapeutic goods in the mainstream media. However, section 5.3.2 of the PMAA Code also requires that PMAA members submit all mainstream advertising material, including advertisements for complementary products, to the PMAA for approval to ensure compliance with the PMAA Code. In addition signatories to the PMAA Code are encouraged but not required to face an approval system for advertisements that are not captured by the Therapeutic Goods Advertising Code.

Further companies manufacturing proprietary medicines that are not members of the PMAA are invited to accept and observe the PMAA Code.

The standards applied under the PMAA Code mirror and then extends those applied under the TGAC for mainstream advertisements. For example unlike the TGAC, the PMAA Code prohibits the promotion to the general public of any prize competition which is conditional on the purchase of a proprietary medicine.[5]

7.3.5 Funding of the Code

Self-regulation under the PMAA Code is intended to be funded on a user pays basis. Industry complainants must pay a fee of $1000 if a complaint is to be heard by the Complaints Panel and a further $5000 is levied if the complaint goes to appeal. The PMAA admits that the scheme is currently not operating on a cost recovery basis and the PMAA through membership subscriptions continues to subsidise the Complaints Panel.

[5] Disinfectants (not including those with antiseptic claims), unscheduled vitamin and mineral preparations and unscheduled therapeutic goods for external use are exempted from this requirement.

7.3.6 Administration and operation of the Code

The administration of the PMAA Code is supervised by the Executive Subcommittee, which is appointed by the PMAA Committee of Management. The Subcommittee comprises but is not limited to the Association's President, two Vice Presidents and the Immediate Past President. The Code is co-ordinated by the Executive Director of the PMAA and is Marketing and Ethics Subcommittee which is also appointed by the Committee of Management.

Complaints and appeals

The PMAA Code includes a dispute resolution scheme, which establishes redress for consumer or competitive complaints. The advertising rules are a measure intended to encourage the responsible use of therapeutic goods without encouraging excess consumption by consumers.

The Code of Practice Complaints Panel (Complaints Panel) is the body responsible for hearing complaints and ruling on breaches of the PMAA Code. The Complaints Panel is appointed by the Marketing & Ethics Subcommittee of the PMAA and is Chaired by a lawyer with experience in trade practices law, and includes a representative from the Royal Australian College of General Practitioners (RACGP), a community pharmacist, three industry representatives, a consumer representative and a non-voting observer from the Commonwealth Department of Health and Aged Care.

Complainants need to lodge their complaint in writing with the Executive Director of the PMAA who will then determine if the complaint is likely to contravene government legislation, its accompanying regulations, or other industry based codes. However, the PMAA retains the right to examine any complaint whether there is a breach of other regulation or not.

When a complaint originates from outside the industry, the complainant need simply notify the Executive Director of a possible breach; however, if the complaint comes from an industry representative then certain procedures must be followed. First, the parties must engage in dialogue in an attempt to resolve the dispute themselves. If this can not be done then they may approach the PMAA seeking resolution. An administrative lodgement fee is charged to the complainant (if the complaint is upheld, the offender is liable for the fee), which is designed to cover the cost of running the scheme. Complainants must also provide a solid argument as to why the complaint should be upheld, and in certain cases they will be required to provide medical/scientific evidence to support their claim. Companies who are the subject of a complaint have the opportunity to respond.

Although the system makes provision for anybody to lodge a complaint, the PMAA deals predominantly with complaints by competing firms. However, PMAA has received several complaints in the past from consumers and from healthcare professionals concerned about the standards of a particular advertising campaign.

Under the PMAA Code sanctions (authorised by the ACCC) are applied against any member company found to have breached the Code. If the Complaints Panel finds that a breach has occurred it is classified as either a Minor Breach (a breach of the PMAA Code that has no safety implications), a Moderate Breach, a Severe Breach, or a Repeat Breach. Once classified these breaches carry a range of fines, from nil for a minor breach to $50,000 for a Repeat Breach. Sanctioning a member can also involve forcing a retraction and/or corrective statement, discontinuance of an advertising campaign, or the cessation of PMAA membership. All complaints and the Complaints Panel's findings are published in the Association's Annual Report.

In 1998–99, a total of seven complaints were lodged under the PMAA Code of Practice and all were initiated by industry competitors (Table 7). All seven complaints reviewed by the PMAA Complaint Panel were found to be in breach of the Code. Only one determination made by the Panel was appealed. This determination was modified by finding the two serious breaches to be a single less severe breach for which a fine of $5000 was imposed. Another single less severe breach was found for which a $5000 fine was also imposed (PMAA 1999).

In comparison, three complaints where lodged in 1997–98 and seven complaints in 1996–97. Of the three complaints lodged in 1997-98, two were initiated by industry competitors and one by a consumer. Of these complaints, one was brought against a non PMAA member company and in the absence of the company's consent to be bound by the determination of the Panel, the Panel would not determine the complaint. One of the complaints was dismissed and one complaint resolved by the Panel was appealed but the determination was upheld and the fine imposed was reduced.

Of the seven complaints lodged in 1996-97, five complaints were received from industry competitors; one from the Therapeutic Goods Administration and one complaint was received from a consumer and two State Health Departments. Three of the complaints were dismissed and the other four complaints were satisfactorily resolved by the Panel.

Table 7: **Outcomes of complaints lodged under the PMAA Code of Practice, 1996–97 to 1998–99**

1998–99: A total of 7 complaints lodged under the PMAA Code of Practice

Complaint	*Complainant*	*Outcome*	*Appeal*	*Appeal outcome*
1	Industry competitor	One minor breach, two less severe breaches and two sever breaches of the Code. Written undertaking to discontinue use of the promotional material and to issue a corrective statement. $5000 fine imposed.	No	
2	Industry competitor	One minor breach and two serious breaches of Clause 5.1.3 of the Code – the claims found in breach not to be repeated.	Yes	The determination of the Panel was modified by finding the two serious breaches to be a single less severe breach for which a fine of $5000 was imposed. Another single less severe breach was found for which a $5000 fine was imposed.
3	Industry competitor	The Panel found two breaches and resolved that the claims found in breach should not be repeated in the present or similar form.	No	
4	Industry competitor	Severe breaches of clauses 4.4 and 5.1.3, fine of $5000 imposed.	No	
5	Industry competitor	Less severe breach of clause 5.1.3 – undertaking in writing to discontinue use of the expression found to be in breach.	No	
6	Industry competitor	Less severe breach of clause 5.2.	No	
7	Industry competitor	Minor breach of clause 6.1.5 – required to publish a corrective advertisement.	No	

(continued next page)

Table 7: **Outcomes of complaints lodged under the PMAA Code of Practice, 1996–97 to 1998–99** (continued)

1997–98: A total of 3 complaints lodged under the PMAA Code of Practice

Complaint	*Complainant*	*Outcome*	*Appeal*	*Appeal outcome*
1	Industry competitor	Dismissed.		
2	Industry competitor	In the absence of the defendant's consent to be bound by the determination of the PMAA Complaint Panel, the Panel would not determine the complaint.	No	
3	Consumer	Written undertaking to discontinue use of particular wording: issuing of an approved corrective advertisement in each publication in which the advertisement appeared; and a find of $5000 imposed.	Yes	Panel's determination was upheld. The fine imposed by the Panel was reduced to $2000.

(continued next page)

Table 7: **Outcomes of complaints lodged under the PMAA Code of Practice, 1996–97 to 1998–99** (continued)

1996–97: A total of 7 complaints lodged under the PMAA Code of Practice

Complaint	*Complainant*	*Outcome*	*Appeal*	*Appeal outcome*
1	Consumer and two State Health Departments	Letter box supply to households of sample ceased by company. Issue referred to Marketing & Ethics Subcommittee for Code of Practice clarification.	No	
2	Industry competitor	Corrective worded advertisement prepared and agreement sought to refrain from further use of such a claim in future advertising.	No	
3	Industry competitor	Advertising withdrawn prior to complaint hearing, a corrective worded advertisement prepared and agreement sought to refrain from using such claim in future advertising.	No	
4	TGA	Dismissed.	No	
5	Industry competitor	Dismissed.	No	
6	Industry competitor	Dismissed.	No	
7	Industry competitor	Letter from defendant stating compliance to refrain from using the claim statement. No further distribution of leaflets and posters to consumers and 30 days given to cease distribution of promotional material.	No	

7.3.7 Review of the Code

The PMAA Code is reviewed annually by the PMAA's Marketing & Ethics Subcommittee. These reviews are designed to provide recommendations on ways to improve the scheme so as to reflect changing community standards. As the standards for approval of advertising closely mirror those in the TGAC amendments to the TGAC can also impact on the PMAA Code.

The Therapeutic Goods Advertising Code Council has recently reviewed the TGAC and in April 2000 the Minister Senator Grant Tambling launched the revised Code. The Minister (2000) in announcing the launch stated that:

> A key component of the review was the development of guidelines for evidence required to support claims made by manufacturers for non-prescription medicines.
>
> …..Backed by the full weight of legislation, the new advertising Code clearly establishes the principles to be followed. The overriding principle is that the promotion of medicinal products should be truthful, valid and not misleading,"
>
> … The changes will enable manufacturers to make a wider range of claims, without compromising public safety. Consumers will benefit from a greater level of confidence about the claims made for medicines

The PMAA anticipates that some changes to its Code will be needed in the near future to reflect the amendments to the TGAC.

7.4 FEATURES OF THE MARKET THAT MAKE SELF REGULATION MORE OR LESS EFFECTIVE

7.4.1 Overall effectiveness in addressing market failure(s)

The PMAA Code operates in a market which is already heavily regulated. As outlined above, the Code's main areas of interest, promotion and advertising, are also subject to regulation under the Therapeutic Goods Act.

In the case of mainstream print and broadcast advertising the approval procedures are mandatory and are undertaken via a system of co-regulation with the TGA. Complaints against mainstream print and broadcast advertising are also subject to co-regulation and are initially heard and usually resolved by the Complaints Resolution Panel. However, although non-mainstream advertising must comply with the TGAC and the PMAA Code, there is no provision in the co-regulatory process for the initial hearing of these complaints. This non-mainstream complaints procedure is a major focus of the PMAA Code.

Over the last three years there have only been 17 complaints and four of these complaints were dismissed. This level of complaints is extremely low when the wide variety of products and promotional material subject to the PMAA Code's regulations is taken into account. The low level of complaints provides an indication that the Code's provisions are dealing with the market failures identified in section 7.2.3. Nonetheless some breaches are occurring. As discussed in Chapter 6, once a breach occurs it can be difficult to nullify its effect. Withdrawal of the in breach material stops the mis-information from reaching new parties and corrective advertisements and the like can help change impressions formed by the breach. However, the effectiveness of this action relies on the misinformed reading the corrective material.

Avoiding potential breaches through a pre-clearance or approval procedure similar to that required for mainstream and broadcast advertising could help further reduce the number of complaints but this is a costly option, from a self-regulation perspective. Random checking of member firms' advertising material, in a fashion similar to the Monitoring Committee arrangements under the APMA Code discussed in chapter 6, would be an alternative to pre-clearance arrangements. Such random monitoring could help ensure that the low level of complaints reflects the industry's effectiveness in dealing with market failures rather than the complacency of competitors or a lack of consumer knowledge about their rights under the Code.

In regard to sanctions the Complaints Panel rarely hands down maximum penalties for breaches of the Code. Over the three years of complaints reviewed and summarised in Table 7 above, the maximum monetary sanction imposed for a severe breach was $5,000; this is well below the $40,000 limit. The PMAA agues that while these fines are an important deterrent to rouge behaviour, the main sanction (and deterrent) available to the Complaints Panel is publication of the offence and termination of membership.

As discussed in Chapter 6, to be effective fines should reflect not only the severity of the breach but also the market circumstances. As many companies in the market for proprietary medicines have large turnovers (and profits) it is not clear that a $5,000 fine would have much of a sanctioning or deterrent effect.

7.4.2 Product related factors influencing effectiveness

Like the APMA Code discussed in Chapter 6, the recent growth in and access to Internet technology and e-commerce and the increasing globalisation of the pharmaceutical industry has the potential to undermine the effectiveness of regulations designed to overcome

information asymmetries associated with advertising and promotion of complex medicinal products.[6]

While PMAA members' Internet sites in Australia must comply with the Code; Australian consumers can now access medications and information about medications, including some prescription-only medications through the Internet. Many of the companies supplying medications via e-commerce are not operating in Australia and are thus not necessarily complying with TGA regulations or the PMAA's industry self-regulation. There can be no guarantee that the information consumers obtain over the Internet or on the information provided with medications purchased over the Internet is accurate. This situation creates a potential risk to consumers and can also undermine the competitive position of the local industry.

7.4.3 Impact of nature and extent of competition between firms on effectiveness

Reflecting the competition between companies supplying substitute proprietary medicine products, the majority of complaints about breaches of the PMAA Code were made by members of the PMAA that are competing against the company subject to the complaint. Thus the level of competition in the market for non-prescription consumer healthcare products has contributed to the effectiveness of the PMAA Code.

7.4.4 Commonality of producer and consumer interests and effectiveness

Reputable producers of non-prescription medicines have an interest in ensuring that their customers consider that their products are effective and safe. As outlined above, false or misleading information or advertising by one producer in the non-prescription consumer healthcare market can have negative spillover (externality) effects that go beyond the disreputable firm. For example, mis-information about one product creates consumer dissatisfaction, which impacts on substitute products or on the entire consumer healthcare industry. The threat of these negative spillovers creates a strong incentive for firms to be associated with an effective form of industry self-regulation.

[6] The World Health Organisation has also identified the tension between the benefits of the Internet for disseminating and obtaining information on medical products and the differences in regulations covering advertising, promotion and sale of medical products in its member states. Accordingly the Fiftieth World Health Assembly requested that the Director-General convene a WHO ad hoc working group to formulate recommendations on cross-border promotion and sale of medical products using the Internet (WHA 1998).

Commonality of interest has led a substantial number of Australia's non-prescription consumer healthcare suppliers to form industry associations. Both the PMAA and the CHC mandate compliance with their respective association's self-regulatory Code.

The PMAA Code sets out to address the externality problem by setting standards of commercial conduct generally and of advertising and promotional practices in particular. This reflects concern that the conduct of an individual member can reflect on both the industry and the PMAA's membership as a whole.

While the commonality of producer interests has contributed to the effectiveness of the PMAA's self-regulation in dealing with the market failure, some competing firms have chosen to remain unassociated. However, it appears that these firms also maintain the standards set by the Code. Nonetheless, their decision to remain outside the association means that self-regulation may not always effectively deal with the industry's information problems. As outlined in Box 2, incomplete industry coverage in the past led to the TGAC becoming a co-regulatory Code.