6. AUSTRALIAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION CODE OF CONDUCT

6.1 INTRODUCTION

This case study examines the Code of Conduct (the Code) administered by the Australian Pharmaceutical Manufacturers Association Inc. (APMA). APMA represents the interests of those companies engaged in the research, development, manufacture, marketing and export of pharmaceutical products, which by regulation, must be supplied under a prescription.

This case study, in conjunction with a case study of the Proprietary Medicines Association of Australia (PMAA) Code of Practice, provides insights into the development and operation of self-regulation in a health and safety oriented industry. This case study draws no conclusions about the scheme, beyond acknowledging perceived benefits and shortfalls and is merely intended to highlight key features of the Pharmaceutical product industry and the industry's approach to self-regulation.

The following sections describe the market for prescription drugs and the market failure which has lead to the need for a Code of Conduct. Section 6.3 describes the present system of self-regulation and a brief history of the establishment of the APMA scheme. Finally section 6.4 discusses some features of the market that make the APMA's approach to self-regulation more or less effective.

6.2 THE MARKET FOR PRESCRIPTION MEDICINES

The Commonwealth Government via its health and industry policies has a major impact on the market for pharmaceutical products. These policies include a pre-market assessment of pharmaceutical products in order to assess their risk to the community.[1] Certain medicines which the Therapeutic Goods Administration (TGA) considers have a high level of risk associated with their use must be registered with the TGA. Highest risk medicines can only

[1] Therapeutic goods are divided broadly into two classes - drugs and devices. Unless exempt, any product for which therapeutic claims are made must be entered on the TGA's computer data base as either 'registered' goods or 'listed' goods before they may be supplied in, or exported from Australia. Medicines assessed, as having a higher level of risk must be registered (not listed). The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data.

be supplied by a pharmacist on receipt of prescription from an approved medical practitioner. These prescription medicines are the focus on the APMA Code.

The majority of prescription-only medicines are subsidised under the Pharmaceutical Benefits Scheme (PBS). Consumers of prescription medicines often pay considerably less than the actual cost of the medicine, in many cases substantially less. On average patients pay only 19 per cent of the cost of their prescriptions.[2] Another consequence of the PBS is that the Government, as the sole purchaser of PBS medicines, can exert considerable market power over the price it will pay suppliers. The price suppression varies with the type of drug. The Government has less ability to exert monopsony power for the purchase of unique or breakthrough drugs as the monopoly position of the pharmaceutical company allows it to charge a price close to the world price. On the other hand the PBS when purchasing drugs which have close substitutes can be very effective in obtaining a significant discount off the world price. The Industry Commission (1996) estimated that the Government's use of market power under the PBS saves taxpayers around $860 million per year.

6.2.1 The Pharmaceutical Industry

Australia is a small part of a global pharmaceutical industry. Australasian sales were estimated to be in the order of $US3.7 billion or around one per cent of the world market in 1998 (APMA 2000). The global industry is dominated by large multinational corporations which enjoy economies of scale in the development of research intensive products. The development of these products involves considerable investment risk which often pays off with high returns which are protected by patents. The APMA reports that over the last ten years pharmaceutical research has brought more than 300 new medicines to Australian patients. In 1998 alone 36 new medicines were made available to Australians.

Most multinational pharmaceutical companies have operations in Australia. In addition, there are a number of local pharmaceutical companies which supply prescription medicines. In 1997-98, twenty companies supplied around 75 per cent of all prescriptions processed by the PBS — five of these companies supplied around 30 per cent of all PBS prescriptions (APMA 2000).

The patent protection available to many new pharmaceutical products in conjunction with a relatively small number of industry participants provides the industry with a degree of market power. However, the extent to which this market power can be exploited is reduced by the

[2] In 1998-99, just under 128.9 million prescriptions were dispensed. The total cost of the PBS was $3.67 billion. The Commonwealth Government contributed $3.07 billion to the total cost and patient contributions totalled $601 million (APMA 2000).

existence of alternative medicines or treatments which are often close substitutes for the patented product — in many instances these products are also subject to patent. The Industry Commission in its 1996 review of the industry suggested that the patent system itself could promote competition in the industry as:

> Granting monopoly positions to products through the patent system promotes product competition over time by rewarding innovation through investment in R&D (IC 1996, p.12).

And

> Even where no substitutes exist patented products provide incentives for rival companies to develop close substitute products (IC 1996, p. 12)

To some extent the industry's market power is constrained by the monopsony power of the Government through its price negotiations under the PBS. In fact to a large extent the PBS takes price out of the equation for prescribers and their patients.

The removal of price as a marketing option means that pharmaceutical companies must resort to other measures to have their medicines rather than another company's medicine prescribed. Advertising and promotion are two tools which can draw attention to the qualities and attributes of a particular company's products compared to substitute products. The Therapeutic Goods Act restricts the advertising and marketing of prescription medicines to health care professionals. The conduct of pharmaceutical manufacturers in undertaking this advertising and promotion is the subject of the APMA Code of Conduct.

6.2.2 Demand for prescription-only pharmaceutical products

The demand for prescription-only pharmaceutical products is a derived demand. Consumers/patients seek out the services of a medical practitioner because they are unwell or alternatively wish to remain well. The medical practitioner has a number of ways of providing the required service one of these ways is to prescribe medication.

Because of the substantial subsidy and the large range of drugs available under the PBS medical practitioners will endeavour whereever possible to only prescribe drugs listed on the PBS. As a consequence, Australia's private prescription market is extremely small. The Industry Commission reported that 'In most cases, manufacturers are faced with supplying through the PBS or not supplying at all' (IC 1996, p. 88).

Prescribing medication is a complex task. It requires years of training and ongoing research and education to keep abreast of the continual developments in medications as well as their effectiveness and side effects etc. Patients cannot be expected to be aware of all of these intricacies and, to a large extent, they rely heavily on their medical practitioner to supply the

most appropriate medication. Thus the demand for a particular prescription pharmaceutical product rather than another is in large part driven by the medical practitioner's prescription decision. As pharmaceutical companies cannot effect this decision through pricing strategies they will seek out other means such as advertising and inducements to bring their drugs to the forefront of the medical practitioner's mind.

6.2.3 Nature of market failure(s)

As outlined in chapter 1, economic theory tells us that in most circumstances the normal operation of a market will produce an outcome for the community that maximises society's welfare. However, in some instances certain aspects of the markets operation can cause it to fail to achieve a desired outcome. In these circumstances regulation by government or by the industry itself may be necessary. This section considers the market failure(s) which have lead to the need for a Code of Conduct in the prescription-only pharmaceutical industry.

The TGA classifies prescription medicines as high-risk pharmaceutical products. Medical practitioners as prescribers of these products need to have a thorough understanding of their attributes. If the wrong drug or the wrong amount of a drug is prescribed the consequences for a patient could be life threatening. Thus, from a patients perspective it is crucial that the information medical practitioners receive about the drugs they prescribe is as accurate as possible. The risk of misleading information about a pharmaceutical product leading to adverse effects on a patient's health can be quite high.

From a medical practitioner's perspective staying abreast of recent developments in medicine is a time consuming business which involves assimilating large volumes of complex information on diseases, their treatment and side effects. Medical practitioners use a range of tools to keep up to date including through subscriptions to medical journals and through membership of medical associations.

Pharmaceutical companies through their advertising, promotion and contributions to medical journals can also play an important role in keeping medical practitioners up to date with the latest information on developments in pharmaceutical products. However, as discussed above, this information can also play an important role determining the demand for various prescription medicines. In an unregulated unfettered market, pharmaceutical companies could have an incentive to use inducements or provide information in a form which will sway a medical practitioner to choose one medicine over another, and thus increase the demand for that product even though it may not be the most appropriate medicine for a patient.

Asymmetric information (the unequal possession of information) among market participants can lead to inefficient outcomes in the market for pharmaceutical products as well as in the

market for health. Market failure associated with asymmetric information increases the risk and uncertainty associated with prescribing high risk medicines. Information asymmetry can lead to too over or under provision of certain medicines and poorer health outcomes for patients.

There are a number of options for intervention in the prescription-only pharmaceutical product market to address these market failures. Options to help address the information failure include:

- government or industry directly vetting all information, education and promotional activity undertaken by pharmaceutical companies or their representatives — the costs associated with this option may be high; and
- government or industry establishing and enforcing standards for advertising and promotion — the Code is one example of this means of intervention.

The lack of a market determined price for prescription medicines, particularly medicines which have close substitutes, which are supplied under the PBS further the compounds the information asymmetry problem as suppliers of similar products cannot encourage use of their product by changing its price.

6.3 THE PRESENT SYSTEM OF SELF-REGULATION

6.3.1 Background

Promotion or advertising of prescription-only products to the general public is prohibited under Commonwealth, State and Territory legislation. However, advertising and promotion of prescription-only products to medical professionals is permitted. The APMA Code sets the standard of conduct for companies engaged in the advertising and marketing of prescription products.

The APMA Code of Conduct (APMA Code) was first introduced in 1960 but has undergone numerous revisions since this date (the 13th edition was introduced in January 2000).

As the APMA Code governs the marketing of goods which cannot be sold directly, by law, to the public, it is very much an industry Code of Conduct. Consumer protection is served by setting standards that govern the quality of product information provided to the health care professionals who advise consumers.

6.3.2 Objectives of the Code

APMA's vision and mission provide insights to the objectives of the Code. Its vision is to:

> To be recognised as a valued contributor to Australia's health and social wellbeing and economic success.

Its mission is:

> To create a favourable environment for the profitable growth of the prescription pharmaceutical industry, in a socially responsible manner for the benefit of the Australian community.

Although the objective of the Code are not specifically outlined, the Preface to the 13th edition of the Code states the industry undertakes to:

1. Provide medicines that conform to the highest standards of safety, efficacy and quality;
2. Ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience; and
3. Use professionalism in dealing with health care professionals, public health officials and the general public.

The first of these undertakings is covered by legislation. For example, the TGA under the authority of the *Therapeutic Goods Act 1989* requires that pharmaceutical products with a high level of risk must be registered (not listed) on the Australian Register of Therapeutic Goods. The degree of assessment and regulation these products undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data.

However, the Code's Preface argues that while it is possible to legislate effectively for the testing, manufacture and control of medical products, appropriate standards for marketing conducts, which essentially covers undertakings two and three, cannot be defined by legislative means. And:

> For this reason, responsible manufacturers have concurred in the promulgation of the Code of Conduct and submitted to its constraints (APMA 1999, p.5).

Similarly the Preamble to the Code states:

> The Code owes its origin to the determination of the Australian Pharmaceutical Manufacturers Association Inc. to secure universal acceptance and adoption of high standards in the marketing of prescription products for human use (APMA 1999, p.7).

These statements indicate that the objective of the Code is closely linked to overcoming the information failures associated with the prescription and use of high-risk pharmaceutical products.

6.3.3 Development of the Code

The APMA Code has been in operation for more than 30 years (in one form or another). The Code is based on the provisions of the International Federation of Pharmaceutical Manufacturers Associations.

The Code, while predominantly monitored by APMA, does involve the TGA, the Australian Medical Association, the Royal Australian College of General Practitioners, and others in its complaints body and it the monitoring and review process.

The APMA is currently is currently investigating with the ACCC the possible authorisation under the Trade Practices Act of the 13th edition of the Code.

6.3.4 Code coverage

The APMA is the professional and trade association representing 54 companies that are engaged in the research, development, manufacture, marketing and export of prescription-only pharmaceutical products. Together APMA's member companies account for approximately 95 per cent of the prescription-only market in Australia. Only three major Australian manufacturers of pharmaceutical products have chosen to remain non-members of the APMA. However, the APMA actively encourages non-members to abide by the Code. If a non-member subject to a complaint refuses to abide by the Code the APMA reserves the right to refer the matter to the TGA or the ACCC.

Acceptance and observance of the Code is a condition of APMA membership. In 1999 the TGA required that any new prescription-only product approved for marketing in Australia must comply with the provisions of the Code whether the supplier is a member or not. The TGA also requires that all promotional material for registered goods must comply with the requirements of the Code.

The Code covers: journal advertising; reference advertising; television advertising; materials used by representatives; brand name reminders; product starter packs; trade displays; travel and sponsorship; educational material; communications with the general public; and relations with health care professionals.[3] The 13th edition of the Code has introduced a number of

[3] Educational material covers any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims. Health care

amendments, of particular significance is the introduction of a new section which covers information which can be obtained from Australian pharmaceutical Internet sites.

6.3.5 Funding of the Code

APMA membership subscriptions are based on a member's turnover. These subscriptions fund the operations of the APMA including the Code. Monetary sanctions for non-compliance with the Code are also used to fund the Code's administration.

According to APMA the benefits of a flexible, industry developed and administered scheme far outweigh the financial cost of self-regulating.

6.3.6 Administration and operation of the Code

The administration of the APMA Code is supervised by the Code of Conduct Committee (Code Committee). The Code requires that Committee have twelve members with full voting rights with the following credentials:

- the Chair or Deputy Chair — a lawyer with trade practices experience;
- a representative from the Australian Medical Association;
- a representative of the Royal Australian College of General Practitioners;
- a representative of a recognised patient support group;
- a representative of the Australian Society of Clinical and Experimental Pharmacologists and Toxicologists;
- a representative of a Consumers' Organisation (currently from the Consumers Health Forum);
- three APMA industry representatives; and
- two APMA medical/scientific directors.

In addition to these full members the Code allows for non-voting advisers and observers. Advisers are:

- the Code of conduct Secretary;
- the APMA Chief Executive Officer or delegate; and

professionals include members of the medical, dental, pharmacy or nursing professions and any other person who in the course of their professional activities may prescribe, supply or administer a medicine.

- the APMA Manager of Scientific and Technical Affairs.
- Observers are a representative of the TGA and a member of the APMA marketing Committee.
- A meeting of the Committee requires a quorum of six full members — two of these members must be representatives from the APMA.

Complaints

Complaints to APMA regarding the promotion of a product may be made by anyone including Government, a member of APMA or a medical practitioner. Complaints should be submitted to the APMA in writing, however, this requirement is less stringently enforced if the complaint is from a medical practitioner. The company at the centre of the complaint is then given the opportunity to comment on the complaint. The Code Committee, which maintains a significant degree of independence from APMA in its decision making, will then rule on the matter. Complaints against non-members will be referred to the subject company along with an invitation to have the dispute resolved by APMA.

The APMA Code allows for a range of penalties and sanctions to be imposed on members that breach the Code. When a promotional item or activity is deemed by the Code of Conduct Committee to breach the Code it is immediately required to be withdrawn from use. In addition to this, fines of up to $30,000 may be imposed if considered appropriate by the Committee, and suspension or expulsion from APMA membership is also a possible outcome.

A further punishment for members found in breach is the publication of the Code Committee's findings. A summary of all APMA Code breaches are published in the APMA Annual Report as well as in medical journals on a six monthly basis.

Over the Code's thirty year life no member of the APMA has been expelled for a breach of the Code and there has only been one occasion when a member in breach of the Code was suspended.

The most recent information on complaints dealt with under the Code relates to the year ending 30 June 1999. In that year the Code Committee met a total of ten times to evaluate 36 (new) complaints lodged with APMA. Of these complaints two were withdrawn prior to review, one was referred to the PMAA, and one complaint was dealt with by a non-member and a decision on another complaint was deferred. Of the 31 remaining complaints considered by the Code Committee, 21 were found to be in breach of one or more sections of the Code. (Four of the complaints found to be in breach of the Code related to the same

activity.) Five of the 21 complaints were the subject of appeal (see below), in two cases the appeal was partly upheld.

Immediate withdrawal of the material in breach of the Code was the most common sanctions imposed by the Committee. However, other sanctions which were often used in conjunction with withdrawal included corrective letters or advertisements, letters of apology and fines. Fines were imposed on four businesses. One company after appeal was fined $35,000 for four breaches of the Code. Two companies were fined $10,000 each and a third company was fined $5,000.

APMA members made 13, of the 21 complaints found to be in breach of the Code. The TGA and a State government health commission made another three complaints. Only five of the 21 complaints were made by medical practitioners or health service providers.

APMA advised Tasman that historically the bulk of complaints have come from APMA members. However, the number of medical practitioner complaints has risen over the last three years. This increase reflects an APMA campaign to improve general practitioners knowledge of the Code and the complaints procedure.

Table 5 illustrates the source and number of complaints received by the APMA and how some of the complaints have been dealt with before being evaluated by the Code of Conduct Committee.

Table 5: **APMA complaints, 1996–97 to 1998–99**

	1996–97	*1997–98*	*1998–99*
Received from Government	4	1	5
Received from APMA members	37	37	23
Received from external parties	9	12	9
Total complaints received	*50*	*50*	*37*
Withdrawn prior to review	6	10	2
Referred to the PMAA	–	–	1
Returned for re-submission	1	–	1
Dealt with by non-member	–	–	1

Sources: APMA Code of Conduct Annual Reports for 1997, 1998 and 1999.

Table 6 illustrates the number of complaints evaluated by the Code of Conduct Committee from 1996–97 to 1998–99.

Table 6: **Complaints evaluated by the Code of Conduct Committee, 1996–97 to 1998–99**

	1996–97	*1997–98*	*1998–99*
Breached Code of Conduct	26	32	21
Not in breach of Code of Conduct	17	7	10
Deferred for further consideration	–	–	1
Held over to next year	–	2	–
Held over from previous year	–	1	2
Under appeal at the end of previous year	–	–	2

Sources: APMA Code of Conduct Annual Reports for 1997, 1998 and 1999.

Appeals

A company found in breach of the Code may appeal against the findings and/or the sanction imposed. The appeal must be lodged in writing and a bond of $5,000 must be submitted to the APMA on lodgement. The Appeals Committee membership consists of four full time members comprising:

- An independent chairman or deputy chairman;
- Two representatives from the Colleges and/or Societies from the therapeutic class of the product;
- one APMA Association Representative; and
- one APMA Medical or Scientific Director.

The Code of Conduct Secretary and the APMA Chief Executive Officer or delegate act as advisers to the appeal Committee but have no voting rights.

Monitoring Committee

Another aspect of the APMA Scheme is the work of the Monitoring Committee. The APMA considers that the monitoring activity acts as a safety net for the Code. The need for a Monitoring Committee was identified in a Trade Practices Commission review of pharmaceutical self-regulation in 1988. The TPC concluded that the complaints mechanism alone was not sufficient to ensure a high degree of compliance from their members. The

Commission suggested that a comprehensive monitoring program would complement the complaints mechanism and help stimulate fair competition.

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The Monitoring Committee reviews promotional material to ensure compliance with the provisions of the APMA Code, provides relevant advice on current marketing practices and trends to the APMA. The findings of the Monitoring Committee are primarily aimed at providing advice to members on the necessary changes that are required to comply with the Code rather than being a complaints generating mechanism. To date only one breach identified by the Monitoring Committee has gone close to being passed on to the Committee which examines complaints.

APMA member companies are required to submit to the Monitoring Committee selected types of promotional material used during a nominated three-month period for the product category under review. The Monitoring Committee, which includes representatives from the AMA, RACGP and an expert in the therapeutic category under review, reviews this material to determine whether it complies with the provisions of the Code of Conduct.

In the twelve months ended in June 1999 the Monitoring Committee reviewed a total of 50 pieces of journal advertisements associated with respiratory and alimentary products. The review found that 88 per cent of the respiratory product advertisements and 94 per cent of alimentary products complied with the Code. Companies were advised of the potential breaches of the Code, however, the Code of Conduct Annual Report did not indicate whether action was taken to withdraw or correct any misinformation which may have been associated with the potential breach.

The Monitoring Committee also reviewed industry sponsored meetings for the period November — December 1998. The Committee provided advice to members on the most appropriate wording and format of invitations as well as the importance of an educational component at the meetings. Recommendations from the review were passed on to the Code of Conduct review. The review has subsequently lead to a strengthening of the Code's provisions relating to relationships with healthcare professionals. The APMA has advised the consultant that further amendments to the Code may also arise out of this review of industry sponsored meetings.

6.3.7 Review of the Code

The APMA Code requires that a review of the provisions of the APMA Code be conducted every three years. This review is conducted by APMA after it seeks advice from members, the ACCC, the TGA, the AMA, and other interested parties on possible amendments. Presently APMA is reviewing the nature and level of sanctions available to the Code Committee, with a view to improving their effectiveness

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

6.4.1 Overall effectiveness in addressing market failure(s)

The APMA's Code of Conduct has undergone and continues to undergo a process of change and refinement over its 30-year life. The fact that virtually all of Australia's pharmaceutical companies are a party to the Code enhances its ability to operate effectively. The relatively small number of annual complaints received by the Complaints Committee in conjunction with the Code's wide industry coverage suggests that the information imbalance between pharmaceutical companies and medical practitioners is being addressed effectively.

The Code has been the subject of two external reviews. In 1992 the World Health Organisation evaluated various countries' pharmaceutical promotion Codes of Conduct against ethical criteria for medicinal drug promotion. The APMA code scored the highest rating of all codes reviewed. The ACCC, then the Trade Practices Commission, also reviewed the Code (TPC 1992). The Commission positively acknowledged the Code's scope, operation and administration. The Commission has authorised the Code on public benefit grounds.

One difficulty with the operation of any Code covering advertising or promotional material is that once a breach occurs it can be difficult to nullify its effect. Withdrawal of the material in breach stops the mis-information from reaching new parties but cannot change impressions or decisions made prior to withdrawal. Corrective letters or advertisements can help change impressions formed by the breach, however, their effectiveness relies on the misinformed reading the corrective material. If a corrective advertisement is considered the most appropriate sanction it is crucial that the correction is in a prominent position in a journal or other publication which, with some certainty, will be read by misinformed practitioners. For some companies the bad advertising associated with being forced to undertake corrective measures may be sufficient of a sanction. However, for other companies a fine in conjunction

with corrective action may be the most effective means of improving a code effectiveness in addressing market failure.

There has been some recent criticism of certain practices of pharmaceutical companies by the Royal Australasian College of Physicians. Nance (2000), amongst other things, reports that some companies are providing medical practitioners with expensive holidays as inducements under the guise of an educational event. While it is likely that inducements with a large entertainment component would be in breach of the Code there can be no certainty that a complaint will be lodged with the APMA. Nance suggests that medical practitioners benefiting from the inducement may not be aware that there is a conflict of interest. Thus an effective resolution of the breach can not be guaranteed.

As the complaints mechanism is currently the only mechanism for imposing sanctions, consideration may need to be given to strengthening the powers of the Monitoring Committee so that it can impose sanctions for non-compliance.

There has also been criticism[4] of the APMA Code with regards to amount and number of fines imposed as a sanction. In 1996-97, 26 complaints were upheld under the Code of which only three fines were imposed and none were for the maximum penalty of $30,000. Despite the criticism this trend has continued. In 1998-99, the Code Committee upheld 21 complaints — only 4 fines were issued. None of these fines were charged at the maximum rate as none were considered as a breach repetition or repeats of previous breaches.

However, given that the majority of companies operating in the pharmaceutical market are very large, the impact or sanctioning effect of even the maximum fine must be questioned. If fines are to be imposed as a deterrent or a punishment under a code its magnitude needs to reflect not only the severity of the breach but also the capacity to pay of the company in question. On the other hand there may be a trade-off between the size of the possible fine and the willingness of companies to submit themselves to self-regulation.

The APMA is currently reviewing the effectiveness of the current range of sanctions available to the Code Committee. Issues under consideration include increasing the amount of fines and the greater use of corrective letters and advertisements.

6.4.2 Product related factors influencing effectiveness

As outlined in section 6.2, the pharmaceutical industry is a global rather than a national industry. Most drugs and medicinal products sold in Australia are also sold in other countries around the world. While the products are the same or very similar government regulation of

[4] The Courier Mail, "Bad Medicine", 7 November 1998.

these products varies from country to country. The advertising and promotion of prescription-only medicines is a case in point. In Australia, the advertising and marketing of prescription-only medicines to the general public is prohibited. Consistent with the TGA's requirements the APMA Code requires that prescription-only products should only be promoted to healthcare professionals, any activity directed towards the general public which encourages a patient to seek a prescription for a specific product is unacceptable. However, in some other countries this restriction in promotion to the general public does not apply.

The recent growth in and access to Internet technology could threaten the effectiveness of regulations which govern the promotion of prescription-only medicines to the general public. Consistent with the Code of Conduct, Australia's pharmaceutical companies have ensured that their Internet sites, which have public access, do not promote prescription products. Recent amendments to the Code also require that the Australian sites do not make reference to other information sources or Internet sites that would be in breach of the Code.

This action ensures that Australian pharmaceutical companies, which are members of the PMAA, comply with the spirit of the Code. However, the Code like Australian black letter law cannot regulate activities outside of Australia and the general public can readily access promotional material on prescription medicines from pharmaceutical sites developed outside of Australia. The development of e-commerce also exacerbates the risk that the general public may be able in some instances to obtain drugs the TGA has registered as being of high risk without a prescription. Thus technological developments could threaten a number of aspects of pharmaceutical regulation including the level and quality of information available to the general public.

On the other hand, the APMA is currently considering options for a system of quality accreditation for Australian pharmaceutical related Internet web sites, which could improve the quality of information available to the public. This system, which is still in the early stages of development, could provide consumers and medical practitioners with some means, such as a logo, which allows them to identifying that the information on a particular Internet site is accurate and complies with the Australian regulatory environment.

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

As outlined in section 6.2.1 the prescription-only pharmaceutical products market has a number of characteristics that reduce the level of competition between firms. Of particular importance is the patent system, which provides companies with a degree of monopoly power over the new products they develop. A company's monopoly power will be at its greatest

where the patent protects a unique or breakthrough drug, which is the only effective treatment for a debilitating or fatal illness. Some market power can also be exerted if a company has developed and patented a drug which has fewer side effects than its substitutes. At the other extreme there is fierce competition in the market for drugs which are out of patent. In practice most pharmaceutical companies produce drugs across the competition spectrum. Even in the market for a pharmaceutical product which currently has no substitutes there is often fierce competition between the companies to, as quickly as possible, develop a close substitute. Thus across the market as a whole there is fairly fierce rivalry. Because of the nature of the product and the PBS, competition between companies to have medical practitioners prescribe one medicine rather than another is based on non-price factors. Promotion of the attributes of a company's products is a crucial factor in this non-price competition.

Historically the bulk of complaints of breaches of the Code have come from APMA members. This reflects the intense competition between companies supplying substitute products. Companies must be continually alert to the claims made by their competitors about products. Importantly many of the pharmaceutical companies' employees have the research and scientific training necessary to assess whether a competitor's claims regarding a particular drug are false or misleading. The APMA has advised Tasman that its members jealously guard the Code and are continually on the outlook for breaches by their competitors. Observance of the Code helps keep the playing field level but also helps ensure that the often complex information medical practitioners receive about prescription-only medicines is accurate.

6.4.4 Commonality of producer and consumer interests and effectiveness

An industry's ability to develop and operate an effective system of self-regulation will be enhanced if there is an overlap between consumer and producer interests. Clearly patients as consumers of pharmaceutical products have a strong interest in being prescribed a medicine which is the most appropriate to their medical condition. Inappropriate prescription can reduce patients' quality of life and in the extreme be fatal. Accurate information on the attributes of prescription medicines will assist medical practitioners to prescribe appropriately for their patients.

In addition to impacting on patient health and welfare misleading information provided by a pharmaceutical company can have spillover effects onto the profitability and reputation of all pharmaceutical companies as well as medical practitioners. Thus, pharmaceutical companies as a whole have a strong incentive to self-regulate to ensure that information provided to medical practitioners is as accurate as possible.