Determination

Applications for Authorisation

lodged by

Medicines Australia Inc

in respect of

A code of conduct for the promotion and marketing of prescription medicines by pharmaceutical manufacturers

Date: 14 November 2003

Authorisation Nos:	A90779 A90780	**Commissioners:** Samuel Sylvan Martin
Public Register No:	C2001/254	McNeill Willett

Executive Summary

The Applications

On 14 February 2001, the Australian Pharmaceutical Manufacturers Association (APMA) sought authorisation for the 13th edition of its Code of Conduct for pharmaceutical manufacturers (the Code).

APMA is now known as Medicines Australia. On 19 August 2002, Medicines Australia requested that the Commission suspend its consideration of the 13th edition of the Code, pending the completion of the 14th edition of the Code.

On 16 January 2003, Medicines Australia lodged an amended application seeking authorisation for the 14th edition of the Code.

The Code

The Code seeks to regulate the promotion of prescription medicines by pharmaceutical companies. Broadly, the Code can be divided into two categories:

- the regulation of the provision of information about prescription medicines to health care professionals and the public by pharmaceutical companies; and
- the regulation of the provision of benefits (financial and otherwise) to health care professionals by pharmaceutical companies.

The Commission's assessment

Public benefit

The Commission considers that the sections of the Code regulating the provision of information to healthcare professionals about prescription medicines generate a small public benefit by supplementing the provisions in the Act prohibiting false and misleading representations.

As regards the provision of benefits to healthcare professionals, the Commission concludes that, on the evidence available to it, without the Code, some if not many pharmaceutical companies would be likely to offer benefits to healthcare professionals that are banned by the Code and that this would lead to inappropriate prescribing by at least some healthcare professionals.

Having said this, the Commission considers that evidence available to it does not make clear the actual extent of inappropriate prescribing – and therefore the size of the corresponding potential public benefit. However, given the likely consequences of inappropriate prescribing for consumers, the Commission considers it prudent, for the purposes of assessing this application, to err on the side of caution – that is, to recognise a greater potential for inappropriate prescribing than might actually be the case. On these limited grounds, the Commission concludes that the Code potentially generates a not insignificant public benefit.

However, the Commission remains concerned about the enforcement of the Code. As such, in practice, it considers that only a small public benefit arises.

Anti-competitive detriment

The Commission considers that the Code generates minimal anti-competitive detriment. As indicated above, the sections regulating the provision of information largely supplement the TPA prohibition of false and misleading representations. In addition, the sections regulating the provision of benefits to doctors are unlikely to affect research and development by pharmaceutical companies by reducing their sales revenues.

Conclusion

Where the public benefit and detriment are of similar sizes, as is the case here, some uncertainty inevitably arises about whether the public benefit actually exceeds the detriment. In such situations, the Commission will generally not be satisfied that authorisation should be granted unless conditions can be imposed that substantially remove the uncertainty. This is what the Commission has done as regards Medicine Australia's application for authorisation.

These conditions are, broadly, as follows:

- that the expanded role of the Monitoring Committee with regard to the provision of benefits to doctors continues, and the results of its activities be made publicly available;
- that Medicines Australia publish full details of all breaches of the Code on its website; and
- that any amendments to the Guidelines accompanying the Code are provided to the Commission on an annual basis.

The Commission **grants** authorisation to the Code, subject to the conditions outlined above, for three years.

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1. Introduction

1.1. The Australian Competition and Consumer Commission (the Commission) is the Commonwealth agency responsible for administering the *Trade Practices Act 1974* (the TPA). A key objective of the TPA is to prevent anti-competitive conduct, thereby encouraging competition and efficiency in business. This results in a greater choice for consumers with regard to price, quality and service.

1.2. The TPA, however, allows the Commission to grant immunity from legal action for anti-competitive conduct in certain circumstances. One way in which parties may obtain immunity is to apply to the Commission for what is known as an 'authorisation'.

1.3. Broadly, the Commission may 'authorise' parties to engage in anti-competitive conduct where it is satisfied that the public benefit flowing from the conduct outweighs any public detriment from any lessening of competition. However, even if this is not the case, it may be still be possible for the Commission to grant authorisation where conditions can be imposed which, for example, reduce the public detriment so that it is less than the public benefit.

Revocation and substitution of authorisations

1.4. In addition, the Commission may grant an application by the holder of an authorisation to revoke its authorisation and grant a substitute authorisation where, in broad terms, the public benefit from the conduct proposed to be authorised (that is, under the substitute authorisation) outweighs the public detriment from any lessening of competition caused by that conduct.[1] Again, if appropriate, conditions may be imposed to achieve this outcome.

1.5. Before the Commission may grant an application to revoke an existing authorisation and grant a substitute authorisation, it must conduct the same public consultation process as it would conduct for a new application for authorisation.

Authorisation process

1.6. Upon receiving an application for the revocation and substitution of an authorisation, the Commission invites interested parties to lodge submissions outlining whether or not they support the application, and their reasons.

1.7. The Commission then issues a draft determination in writing, proposing either to grant the application (in whole, in part, or subject to conditions) or

[1] Subsection 91C (7) of the TPA. Before the Commission may grant an authorisation in these circumstances, it must be satisfied that it would be able to grant authorisation if the application were an original one, having regard to the relevant tests. In this instance, the relevant tests would be those contained in subsections 90 (6) and 90 (8) of the TPA. The Australian Competition Tribunal has observed in the past that these tests are, in substance, the same. Accordingly, the Commission will apply the same test to all of the proposed arrangements for which authorisation has been sought – namely, weighing the public benefit flowing from the conduct against the public detriment from any lessening of competition flowing from the conduct.

deny the application. In preparing a draft determination, the Commission will take into account any submissions received from interested parties.

1.8. Once a draft determination is released, the applicant or any interested party may request that the Commission hold a conference to enable them to orally express any concerns about the draft determination's operation and effect. The Commission will also invite interested parties to lodge written submissions on the draft determination.

1.9. The Commission then reconsiders the application, taking into account the comments made at the conference (if one is requested) and any further submissions received, and issues a written final determination.

The Applicant[2]

1.10. Medicines Australia was formerly known as the Australian Pharmaceutical Manufacturers Association (APMA). Medicines Australia is a national association representing the prescription medicines industry in Australia. Members are pharmaceutical companies that, according to Medicines Australia, represent over 90 per cent of the prescription market. Medicines Australia advocates on behalf of its members and consults with government and non-government organisations on issues of relevance to the industry.

1.11. Medicines Australia implements a Code of Conduct (the Code) for the advertising and promotion of pharmaceutical products; compliance with the Code is a requirement of membership.

The Applications

1.12. On 30 June 1977, the Trade Practices Commission (the Commission's predecessor) granted clearance[3] to the 4th edition of the Code pursuant to the then subsection 92 (2) of the TPA (C23698). On 1 July 1977, section 92 was repealed. Clearances granted under that section were deemed to be authorisations granted by the Commission.

1.13. The Code has undergone substantial revision since 1977. On 14 February 2001, APMA lodged applications A90779 and A90780 with the Commission seeking the revocation of clearance C23698 and its substitution with an authorisation relating to the 13th edition of the Code pursuant to section 91C of the TPA.

1.14. On 19 August 2002, Medicines Australia requested the Commission to suspend its consideration of the applications, pending the development of the

[2] Information about the Applicant was sourced from the Medicines Australia website at www.medicinesaustralia.com.au on 18 March 2003.

[3] From 1974 until 1977 businesses were able to apply to the Commission for 'clearance' of certain conduct. The Commission granted the clearance if the conduct did not have a significant effect on competition. The granting of a clearance deemed conduct not to be a breach of the Act. Unlike authorisation, clearance was available for conduct which might not breach the Act. In practice, it appears that the process was used to formally recognise that conduct which seemed unlikely to breach the Act did not, in fact, do so. Authorisation, on the other hand, was and is sought where conduct might breach the Act. Consequently, a more stringent test applies to granting authorisation; that is, whether the conduct is likely to generate public benefits outweighing any public detriment.

14th edition of the Code. The 14th edition of the Code was adopted by Medicines Australia on 3 December 2002.

1.15. On 16 January 2003, Medicines Australia lodged amended applications seeking revocation of clearance C23698 and its substitution with authorisations relating to the 14th edition of the Code. The applications were expressed to extend to all current and future members of Medicines Australia, pursuant to subsection 88 (10) of the TPA.

1.16. Medicines Australia has sought substitute authorisations to:

- make or give effect to a provision of a contract, arrangement or understanding where the provision is, or may be, an exclusionary provision within the meaning of section 45 of the TPA (A90779); and
- make or give effect to a provision of a contract, arrangement or understanding where the provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45 of the TPA (A90780).

1.17. Medicines Australia sought authorisation for a period of six years. In addition, it proposed that it provide the Commission with a copy of any amendments to the Code of Conduct during this period and that authorisation (if granted) should extend to those amendments unless the Commission considers that the amendments warrant review of the authorisation.

1.18. A copy of the Code is at Attachment A. Key provisions are outlined in section 4 of this determination.

Draft determination

1.19. The Commission issued a draft determination proposing to grant authorisation to the applications, subject to conditions, on 27 June 2003.

1.20. The Commission informed interested parties that they could request a pre-determination conference to discuss the operation and effect of the draft determination. No such conference was requested.

1.21. The Commission also invited interested parties to make further submissions on the draft determination. These submissions are outlined in section 4 of this determination and are discussed in detail, where relevant, in section 5 of this determination.

Amendments to the Code

1.22. As noted at paragraph 1.14, Medicines Australia requested that the Commission suspend its consideration of the 13th edition of the Code whilst it drafted the 14th edition of the Code. The 14th edition has been amended, in part to accommodate concerns raised with Medicines Australia in relation to the 13th edition of the Code in 2002.

1.23. Broadly, the Code was amended in the following ways:

- new provisions have been included regulating the selection of venues for educational functions;
- the amount and type of product information that must be included in all forms of promotional literature and material has been extended;
- representatives of pharmaceutical companies must not provide any kind of benefit (financial or otherwise) to doctors in order to gain access to them for the purpose of promoting products;
- sections of the Code regulating the provision of entertainment or hospitality to healthcare professionals have been significantly expanded to provide further and more specific guidance to pharmaceutical companies; and
- the maximum fine that can be imposed for a breach of the Code has been increased from $75 000 to $200 000.

Chronology of the amended applications

1.24. A chronology of the Commission's assessment of the applications in relation to the 14th edition of the Code is at Table 1 below.

Table 1: Chronology of the Commission's assessment

Date	Action
16 January 2003	Medicines Australia lodged amended applications in relation to the 14th edition of the Code.
4 February 2003	The Commission sought submissions on the amended applications from interested parties.
20 March 2003	The Commission invited Medicines Australia to comment on the issues raised by interested parties.
9 April 2003	Medicines Australia responded to the submissions from interested parties.
27 June 2003	The Commission issued a draft determination. Interested parties were informed that they could request a pre-determination conference, and were invited to lodge submissions on the draft determination.
14 July 2003	The date by which interested parties were required to request a pre-determination conference. No such conference was requested.
4 August 2003	The date by which interested parties were asked to lodge submissions on the draft determination.
8 August 2003	The Commission provided copies of the submissions from interested parties to Medicines Australia.

2 September 2003	Medicines Australia responded to the submissions from interested parties.
7 October 2003	Medicines Australia provided additional information to the Commission in relation to the activities of its Monitoring Committee.
14 November 2003	The Commission issued a final determination.

2. The Prescription Medicine Industry[4]

2.1. The prescription medicine industry is involved in the development and production of prescription medicines, and the supply of those medicines to the Australian public. Prescription medicines are those which may only be obtained on the instructions of a medical practitioner.

2.2. According to Medicines Australia, the Australian prescription medicine industry encompasses approximately 120 companies (some foreign owned) and employs more than 14 000 people.[5] 49 of these companies are members of Medicines Australia. Medicines Australia claims that its members represent over 90% of the prescription medicine market.

2.3. Medicines Australia does not represent the self-medication industry, which includes manufacturers of over-the-counter (OTC) medications and complementary therapies (the Australian Self-Medication Industry[6] represents this sector).

The regulation of therapeutic goods

State and Territory regulation

2.4. Legislation in each State and Territory regulates how therapeutic substances may be supplied.

2.5. For example, in New South Wales, a Poisons List proclaimed under the *Poisons and Therapeutic Goods Act 1966* allocates substances, including medicines, into different Schedules. Substances which are only available with a doctor's prescription are listed in Schedule 4; substances which may only be supplied by certain persons (such as doctors or pharmacists) are listed in Schedules 2 and 3. Medicines which are not scheduled may be sold anywhere (for example, at a supermarket).[7]

2.6. These Schedules largely comply with the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which ensures that scheduling decisions are broadly consistent across Australia. The SUSDP is administered by a committee of Commonwealth, state and territory government representatives known as the National Drugs and Poisons Scheduling Committee.[8]

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[4] The information about the prescription medicine industry in this section is sourced from: Productivity Commission *Evaluation of the Pharmaceutical Industry Investment Program* February 2003; Industry Commission *The Pharmaceutical Industry: Report No 51* May 1996; the Pharmaceutical Benefits Scheme website at www.health.gov.au/pbs; and Therapeutic Goods Administration *Medicines Regulation and the TGA* (December 1999).

[5] Medicines Australia website at www.medicinesaustralia.com.au.

[6] See www.asmi.com.au.

[7] NSW Health Pharmaceutical Services Branch *Guide to Poisons and Therapeutic Goods Legislation for Medical Practitioners and Dentists*, available from www.nsw.health.gov.au.

[8] This committee is established under Part 5B of the *Therapeutic Goods Act 1989* (Cth).

The Therapeutic Goods Act

2.7. Medicines[9] must be listed or registered on the Australian Register of Therapeutic Goods (ARTG) established under the *Therapeutic Goods Act 1989* (the TG Act) before they can be sold in Australia.

2.8. Higher risk products – for example, prescription medicines and OTC medicines such as analgesics and cough/cold preparations – must be registered on the ARTG. These products are rigorously tested to ensure their safety, quality and efficacy.

2.9. Lower risk products, such as complementary medicines, are listed on the ARTG. Listed medicines do not contain ingredients that are scheduled in the SUSDP. The TGA assesses these medicines with regard to quality and safety, but not with regard to efficacy (although manufacturers are required to have information substantiating any claims made about a product).

2.10. The manufacturers of all therapeutic goods must be licensed under the TG Act and their manufacturing processes must comply with the principles of good manufacturing practice. If these principles are not adhered to, the manufacturer's license may be revoked.

2.11. The Therapeutic Goods Administration (the TGA) is responsible for administering the TG Act.

2.12. The TG Act also regulates matters such as the advertising, labelling and appearance of registered therapeutic goods.

Promoting prescription medicines

2.13. The TG Act effectively prohibits manufacturers from directly promoting prescription medicines to the general public.[10] From 1 July 2005, the TGA will be replaced by a joint trans-Tasman agency. The Commission notes that direct-to-consumer advertising of prescription products is currently not prohibited in New Zealand. However, the Commission understands that there is currently no intention to remove the prohibition on such advertising in Australia when the joint agency commences operations.

2.14. The TG Act does, however, allow pharmaceutical manufacturers to promote prescription medicines to healthcare professionals, although the TGA requires that promotional material comply with the Code.[11]

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[9] Unless it can be demonstrated that they are not therapeutic goods – that is, that they are foods or cosmetics.

[10] Section 42C of the TG Act provides that a person must not insert an advertisement that is not an 'approved advertisement' in the mainstream media. An 'approved advertisement' is one that has been approved by the Secretary of the Department of Health and Ageing pursuant to regulation 5G of the Therapeutic Goods Regulations 1990. Direct-to-consumer marketing of prescription products is not approved. Non-prescription medicines may be marketed directly to consumers, subject to the provisions of the Therapeutic Goods Advertising Code and the Australian Self Medication Industry Code of Practice.

[11] Medicines Australia submission, 15 January 2003, p2.

2.15. In recent years, concern has been expressed about the relationship between doctors and pharmaceutical companies. In keeping with the transnational nature of the industry, this concern is not merely confined to Australia, and has resulted in the introduction of codes of conduct comparable to Medicines Australia's Code in the United States and the United Kingdom. Further, international bodies such as the World Health Organisation and the International Federation of Pharmaceutical Manufacturers Associations have also developed guidelines for the pharmaceutical industry in this respect.[12]

2.16. Within Australia, the Australian Medical Association (the AMA) has produced guidelines on the relationship between the pharmaceutical industry and doctors.[13] Broadly, these guidelines provide that the doctor's primary obligation is towards the patient, and considerations involving the pharmaceutical industry are appropriate only insofar as they do not intrude upon or distort that primary obligation.

2.17. With regard to hospitality and gifts, the guidelines provide that doctors should not accept, nor allow their prescribing habits to be influenced by, personal gifts from the pharmaceutical industry.

2.18. The AMA's Code of Ethics is also relevant. For example, it provides that a doctor's first consideration must be the well-being of his or her patient.[14]

2.19. Finally, Medicines Australia submitted that in some circumstances, medical practitioners may risk investigation by medical boards for unprofessional conduct if they accept benefits. For example, in New South Wales, the statutory definition of unsatisfactory professional conduct expressly includes:

> accepting from a person who supplies a health product (or from another person on behalf of the supplier) a benefit as inducement, consideration or reward for recommending that another person use the health product.[15]

The Pharmaceutical Benefits Scheme

2.20. The Commonwealth Pharmaceutical Benefits Scheme (the PBS) subsidises prescription medicines as a means of providing the Australian community with affordable access to necessary medication. As of May 2002, the PBS subsidised 593 generic drugs marketed as 2506 different brands.[16] It has been estimated that approximately 90% of prescriptions are for products that are listed on the PBS (or its equivalent for war veterans, the Repatriation Pharmaceutical Benefits Scheme).[17]

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[12] Elizabeth Wager, 'How to dance with porcupines: rules and guidelines on doctors' relations with drug companies' in the *British Medical Journal* Volume 326 31 May 2003, p 1196.
[13] AMA Position Statement *Doctors' Relationships with the Pharmaceutical Industry* (2002).
[14] AMA *Code of Ethics* clause 1.1, downloaded from the AMA website at www.ama.com.au on 23 October 2003.
[15] Section 36(f), *Medical Practice Act 1992*. 'Health products' include pharmaceutical products.
[16] 'About the PBS', available from www.health.gov.au/pbs.
[17] Productivity Commission *Evaluation of the Pharmaceutical Industry Investment Program* February 2003, p 3.4.

2.21. Broadly, the PBS operates as follows:

- **Prescription medicines must be listed on the PBS.**

  Applications for the listing of medicines on the Schedule are usually made by pharmaceutical manufacturers, and are assessed by the Pharmaceutical Benefits Advisory Committee (the PBAC). The PBAC is an independent body that considers the effectiveness, safety and cost of a proposed new listing in comparison to alternative therapies, and makes a recommendation to the Commonwealth Minister for Health and Ageing who is responsible for making the decision to list a drug.

- **The Commonwealth Department of Health and Ageing negotiates the retail price** for listed prescription medicines with the manufacturer, on the basis of the advice of the Pharmaceutical Benefits Pricing Authority as to the most appropriate price.

- **The Government subsidises prescription medicines.**

  Consumers are required to make a co-payment towards the cost of the drug that has been prescribed. This co-payment is a capped amount, with the Government providing the difference between the co-payment and the retail price of the drug. The level of this co-payment varies depending on the type of patient and the volume of drugs they require. Concessional patients (such as pensioners) make a lower co-payment than general patients.

  In addition, when general patients reach a certain level of expenditure on drugs they are automatically charged the same co-payment rate as a concessional patient. When concessional patients reach a certain level of expenditure, they are no longer required to make any co-payment at all.

National Prescribing Service[18]

2.22. The National Prescribing Service (NPS) is an independent, non-profit organisation that aims to promote rational prescribing practices. It is funded by the Commonwealth Government and is comprised of 31 organisations, including consumer groups, government bodies, groups representing healthcare professionals and industry bodies such as Medicines Australia.

2.23. The NPS implements a series of programs aimed at health professionals and consumers, which seek to provide them with information about the quality use of medicines. For example, recently the NPS conducted an advertising campaign encouraging consumers not to request, and doctors not to prescribe, antibiotics as a treatment for the common cold.

2.24. The NPS also provides general practitioners with the means to conduct a review of their prescribing habits, visits practices and provides for clinical audits of prescribing habits.

[18] The following information about the NPS is sourced from its website at www.nps.org.au.

3. The Code of Conduct

3.1. The 14th edition of the Code is divided into 16 sections, the key provisions of which are outlined below.

3.2. The provisions of the Code target the following activities:

- the provision of information about prescription medicines by pharmaceutical companies to healthcare professionals and to the public (including advertising);
- marketing research conducted by pharmaceutical companies;
- pharmaceutical companies' sponsorship of educational meetings, or sponsorship of the attendance of healthcare professionals at such meetings;
- other benefits offered to health care professionals by pharmaceutical companies; and
- the conduct of medical representatives.

3.3. The Code includes explanatory notes which elaborate on the provisions of the Code.

3.4. In addition, the Code is supported by Guidelines, which provide further assistance to members about the scope of the Code, including practical examples of the activities that are likely to give rise to concerns under the Code. Authorisation was not sought for the Guidelines, but they were included with the application for the information of the Commission.

3.5. The Guidelines are intended to provide guidance to both pharmaceutical companies and to the Code of Conduct Committee that is responsible for considering alleged breaches. Medicines Australia submitted that as experience is developed through the use of the Guidelines, amendments may be made to the Code's explanatory notes to clarify the operation of the provisions of the Code.

3.6. Unless otherwise indicated, the provisions outlined below are found in the Code.

The provision of information to healthcare professionals and to the public

Information generally

3.7. All information provided to health care professionals and the general public must be current, accurate and balanced. It must not mislead either directly, implicitly or by omission.[19] The Explanatory Notes record that the majority of breaches of the Code found by the Committee concern this provision.

[19] Section 1.3.

Claims about prescription medicines

3.8. Companies are responsible for ensuring that promotional and medical claims about the qualities of prescription medicines are balanced, accurate, and can be substantiated.[20] Upon reasonable request from a healthcare professional, a company must provide additional or substantiating information about its medicines.[21] Claims must be consistent with product information approved by the TGA.[22]

Promotional material

3.9. All promotional and educational material must conform to generally accepted standards of good taste[23] and must not employ unqualified superlatives.[24] Promotional material must be clearly distinguishable as such,[25] and should not make use of health care professionals' names or photographs in a way that is contrary to professional ethics.[26]

3.10. Promotional material such as advertisements, audio visual material and articles must conform to certain standards. For example, they must contain a range of production information (approved by the TGA) such as the name of the active ingredient and information about the product's PBS listing and any restrictions on the product's availability through the PBS.[27]

3.11. Promotional material on products covered by the Code that is available on the internet must be available to healthcare professionals only, and not to the general public.[28]

Media Releases[29]

3.12. Media releases must be current, accurate and balanced and the intent must be educational rather than promotional. Media articles on specific prescription products must not be initiated or encouraged by members, although members may offer to provide educational material or review copy to ensure accuracy.

Research[30]

3.13. Research carried out by members must comply with privacy legislation.

3.14. *Post-marketing surveillance studies*[31] should have scientific or medical merit, and should not be a promotional exercise. They must operate according to a formal protocol, and the TGA's Adverse Drug Reactions

[20] Section 1.1.
[21] Section 1.2.1.
[22] Medicines Australia submission, 16 January 2003, p3.
[23] Section 1.4.
[24] Section 1.5.
[25] Section 1.10.
[26] Section 1.9.
[27] Section 3.1.1.2.
[28] Section 3.9.2.
[29] Section 9.
[30] Section 8.
[31] Research intended to generate data on prescription medicines, generated from information provided by a healthcare professional about the safety of the product when used by patients. Section 8.1.

Advisory Committee (the ADRAC) must be advised of the study. Finally, any payment to healthcare professionals must be commensurate with the work involved and not based upon the number of prescriptions written.

3.15. *Product Familiarisation Programmes* must have the aim of allowing the medical profession to evaluate and become familiar with a product, and should not be the basis for a monetary or other type of reward to healthcare professionals, their families or their employees. No formal protocol is required, and the collection of data or publication of a report is not required.

3.16. The sole purpose of *market research*[32] must be to collect data about the market from healthcare professionals and not to promote medicines and/or reward healthcare professionals. Studies must be clearly identified as market research when the initial approach is made; payment must be kept to a minimum and should not exceed a level commensurate with the contribution of the healthcare professional.

Educational Meetings

3.17. Generally, members involved in educational meetings (including educational symposia, congresses and satellite meetings) must have the primary objective of enhancing medical knowledge and the quality use of medicines in Australia.[33]

3.18. **Hospitality** offered at educational meetings organised by members "must be simple and modest, and no entertainment should be provided."[34] Further, all hospitality provided by members, directly or indirectly, at educational meetings must be secondary to the educational purpose.[35]

3.19. In this respect, the *Guidelines* suggest that:

- an appropriate level of hospitality would be that which is expected in a normal business meeting (for example, open sandwiches, rolls and quiches would be appropriate for lunch but that lobster and caviar would not); and
- where the event is organised by a third party but sponsored by a member, members should examine any entertainment that will be available (for example, non-controversial entertainment such as a string quartet would be likely to be acceptable, provided that the function itself included an educational element such as a guest speaker).

3.20. Members may **sponsor** the attendance of healthcare professionals at educational meetings, or may sponsor the meetings themselves if the primary objective of the meeting is to enhance medical knowledge and the quality use of medicines in Australia. In addition, sponsorship provided must be used for activities that further that objective, and must be able "to successfully

[32] The gathering of data on the scope or dimensions of a market, including the needs of the customers in that market. Section 8.3.
[33] Preamble to Section 6.
[34] Section 6.2.2.
[35] Section 6.2.

withstand public, professional and community scrutiny and conform to professional and community standards of ethics and good taste."[36]

3.21. The choice of **venue** for educational meetings must also "be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste"[37] and must be suitable for the attainment of the primary objective mentioned above.

3.22. The *Guidelines* suggest that some venues may not be suitable (even where they have adequate conference facilities) if, in the mind of the public, they are promoted or perceived as luxury resorts that emphasis leisure and recreation.

3.23. Educational meetings of two or more days duration may "include a modest opportunity for unstructured and individual **recreational activities** at the delegate's own expense."[38]

3.24. The *Guidelines* suggest that where an educational meeting runs for two days or longer, half a day may be allocated for recreational or sporting activities (but these activities must not be arranged or paid for by the companies involved).

Trade displays

3.25. Trade displays at educational meetings must be directed only to healthcare professionals, and must be prominently labelled with the name of the sponsoring company. Product information for the products being promoted must be available, and starter packs must not be available.[39]

Other benefits provided to healthcare professionals

Competitions

3.26. Competitions may be offered by members, but entry must not be on condition that the entrant prescribes, orders or recommends a product. The competition must be based on medical knowledge or the acquisition of such, and the prize must be directly relevant to the practice of medicine or pharmacy. The prizes must be of low monetary value, or be educational.[40]

Product Starter Packs

3.27. Starter Packs containing samples of products may only be supplied on request, should only be supplied for certain reasons (such as for gaining familiarisation with products) and should not contain more than one-third of the most commonly prescribed PBS quantity of the product.[41]

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[36] Section 6.4.
[37] Section 6.6.
[38] Section 10.1
[39] Section 6.1.
[40] Section 3.7.
[41] Section 5. This quantity is the quantity most commonly prescribed by doctors, as recorded for the purposes of the PBS.

Other promotional items

3.28. Generally, promotional items must not be given nor offers made to healthcare professionals, their families or employees unless they are sanctioned by the Code as: brand name reminders (small items such as pens featuring the brand names of particular medications); competitions; involvement in educational symposia, congresses and satellite meetings; sponsorship; hospitality; or medical educational material.[42]

3.29. Brand name reminders (items of low value intended to remind healthcare professionals of the existence of a particular product) must include the names of the product's active ingredients (unless this is impossible, in which case they must be accompanied by a document containing the information) and must not contain any promotional claims.[43]

Medical Representatives

3.30. Promotional material used by and verbal statements made by medical representatives (that is, representatives of pharmaceutical companies who make presentations to healthcare professionals) must conform with the standards for promotional material found in the Code. Medical representatives should maintain a high standard of ethical conduct and professionalism, and must not use any deception nor pay any fee to gain an appointment with a healthcare professional.[44]

3.31. Medical representatives are also required to undertake a training program delivered by Deakin University, which includes a Code of Conduct module.

Enforcement of the Code

3.32. The provisions through which the Code is enforced are outlined below.

The Code of Conduct Committee[45]

3.33. The Code is administered by the Code of Conduct Committee (the Committee). The Committee has 13 full members:

- The Chairman and Deputy Chairman, one of whom must be a lawyer with TPA experience, and both of whom are appointed by the Medicines Australia Board;
- A representative nominated by the AMA;
- A representative nominated by the Royal Australian College of General Practitioners (RACGP);
- A General Practitioner nominated by the Australian Divisions of General Practice (ADGP);
- A representative nominated by a patient support group;

[42] Section 3.8.
[43] Section 3.3.3.
[44] Section 4.
[45] Section 11.

- A representative nominated by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT);
- A representative nominated by a recognised national consumer organisation (currently a representative nominated by the Australian Consumers' Association and the Consumer Health Forum);
- Three representatives of Medicines Australia (who have no conflict of interested with the product or company against which a complaint has been lodged); and
- Two Medical/Scientific Directors from Medicines Australia member companies (who have no conflict of interest).

3.34. A meeting of the Committee requires a quorum of six full members, two of which must be representatives from Medicines Australia and one of which must be a representative of ASCEPT.[46]

3.35. In addition, the Committee's hearings may also be attended by: observers from the TGA; Medicines Australia's Marketing Working Group; Medicines Australia's member companies; and an observer invited by Medicines Australia on the basis that he or she would gain an educational benefit from attending a Committee meeting.

Code of Conduct Monitoring Committee

3.36. The Committee does not have a broad investigative function; it relies on complaints received from other parties. However, the Medicines Australia has established a Code of Conduct Monitoring Committee to monitor promotional material and activities on an ongoing and random basis. This Committee which may forward potential complaints to the Code of Conduct Committee.[47]

3.37. The Code of Conduct Monitoring Committee comprises the following permanent members:

- a Chairman who must be retired or a consulting industry representative with Code of Conduct experience;
- members from the AMA and RACGP; and
- a member of the Medicines Australia National Office secretariat.

3.38. The Monitoring Committee also includes the following rotating members: a member of the relevant patient support group; a medical director and marketing director of a medical company without conflicts of interest; and a representative of the relevant college or society.

3.39. Medicines Australia submitted that the Monitoring Committee has reviewed:

> industry-sponsored meetings to determine whether invitations, supporting material and events complied with requirements of [the Code]. By far the majority of the events

[46] Section 11.2.
[47] Section 14.

> reviewed by the Monitoring Committee complied with the requirements of the Code. However, where they have been any concerns, the Committee has required the company to respond in full to these comments and provided advice on what the Committee thought was acceptable behaviour. If any behaviour is considered inconsistent with the requirements of the Code, the Monitoring Committee can forward a complaint to the Code of Conduct Committee for consideration… Medicines Australia and its members are ever vigilant to the activities occurring in the industry. [48]

Disciplinary process[49]

3.40. Initially, the company about which a complaint has been made is provided with full details of the complaint. It then has ten working days to respond to the Committee.

3.41. The Committee considers this response, and may make any further inquiry that it considers necessary or desirable. It then meets to decide whether a breach of the Code has occurred. Within ten working days of the meeting, the Committee must provide a full explanation of its decision, including the form of any sanction that is to be imposed, to the company and the complainant.

Breaches[50]

3.42. Breaches of the Code are divided into the following categories:

- A technical breach is a breach relating to the font size specified for promotional material, or inaccurate or incorrect referencing of material;
- A minor breach has no safety implications and no major effect on the medical profession's prescription of the product;
- A moderate breach has no safety implications but may affect the medical profession's prescription of the product;
- A severe breach is one that will have safety implications and/or a major effect on the medical profession's prescription of the product and/or a significant commercial impact on the relevant market. A severe breach will also be found where a member's activities have brought discredit upon or reduced confidence in the pharmaceutical industry.

Sanctions[51]

3.43. Where a breach of the Code has been established, sanctions may be imposed. These sanctions may take the following forms:

- Requiring the member to immediately discontinue or modify any practice which is determined to be a breach;
- Requiring the member to issue retraction statements, including corrective letters and advertising. The form and content of such

[48] Medicines Australia submission, 15 January 2003, p8.
[49] Section 11.
[50] Section 12.1.4.
[51] Section 12.

statements shall be subject to the approval of the Committee. Generally, this will be required where moderate or severe breaches have been found.

- The Committee may fine the member a maximum of $100 000 for each level of breach outlined at paragraph 3.42. The Committee may fine a member a maximum of $200 000 if a member commits a severe breach where the promotional activity in question had ceased before the breach came to light, or where the same or a similar breach has been committed before.

3.44. Finally, the Committee may recommend to the board of Medicines Australia that a member be suspended or expelled as a result of a breach, where the Committee believes that such a recommendation is warranted.

Appeals[52]

3.45. A member who has been found in breach of the Code and has had a sanction imposed upon it may lodge an appeal against the finding and/or the sanction. The member must provide a written submission in support of its appeal.

3.46. The Appeals Committee consists of:

- A Chairman and Deputy Chairman, appointed by Medicines Australia;
- A representative from the College and/or Society relevant to the therapeutic class of the product (eg a complaint in relation to a dermatological product would involve a representative from the Australasian College of Dermatologists);
- A representative from the target audience to which the activity of the member was directed (eg the AMA, RACGP or a consumer organisation);
- A representative from ASCEPT;
- Two representatives from Medicines Australia; and
- One Medical/Scientific Director from a Medicines Australia member.

3.47. A meeting of the Appeals Committee will require a quorum of three full members, one of which must be a Medicines Australia representative. The members must not have heard the original complaint.[53]

3.48. The appeal is not a re-hearing of the original complaint. The Appeals Committee has the power to reverse the Committee's finding and lift or alter any sanction which has been imposed, if the Appeals Committee is persuaded that the findings or sanction should be set aside or varied.[54]

[52] Section 13.
[53] Explanatory Notes 13.4.
[54] Explanatory Notes 13.1.

3.49. The member company and the complainant may provide oral submissions to the Appeals Committee.[55]

Members' Compliance Procedures

3.50. Members are responsible for ensuring than an internal compliance procedure exists which is documented and provided to relevant employees.[56]

Reporting of Code breaches[57]

3.51. Medicines Australia issues an Annual Report on the activities of the Committee to the pharmaceutical industry and healthcare professionals. A summary of Code breaches and sanctions imposed will be published in appropriate medical journals on at least a six monthly basis. Medicines Australia will, on occasion, provide information about the activities of the Committee to the general public (including media outlets) and to parties with a genuine interest.[58]

3.52. Where complaints relate to activities directed towards the general public, information about the complaints will be made available on the Medicines Australia website.

Review of the Code

3.53. Medicines Australia will review the Code (with input from interested parties) at least every three years.

Frivolous and vexatious complaints

3.54. Where a member lodges a complaint that the Committee considers to be frivolous or vexatious, the Committee may request the complainant member to show cause why the Committee should not impose upon it a fine of a maximum of $200 000 for abuse of the Code.[59]

Past complaints[60]

3.55. Table 2 demonstrates the number and source of complaints and records the proportion of those complaints that resulted in the Committee finding that a breach had been committed.

[55] Explanatory Notes 13.1.
[56] Section 15.
[57] Section 16.
[58] Section 16.2.
[59] Section 12.3.
[60] Information in this section is sourced from the Medicines Austraila Code of Conduct Annual Reports 1999 – 2000, 2000 - 2001 and 2001 – 2002.

Table 2 - Complaints heard by the Code of Conduct Committee, 1999 - 2002

Year	Number of complaints	Source of complaints			Proportion where breach found
		MA members	healthcare professionals	Other	
1999-00	44	32	10	2	64%
2000-01	37	22	10	5	46%
2001-02	49	33	11	5	57%

3.56. The overwhelming majority of breaches related to product information and promotional material (particularly with regards to the scientific validity of promotional claims). Over the three year period outlined above, only seven complaints – that is, around five per cent of complaints – were made in relation to the provision of inappropriate hospitality or other benefits to healthcare professionals. The Committee found that three of these complaints involved breaches of the Code.

3.57. Sanctions that were imposed in each of the years outlined above usually took the form of requiring the member in breach to take action to remedy the breach (eg by withdrawing the promotional material) and to ensure that the breach did not occur again, and in some cases corrective letters were required to be sent out to affected parties.

3.58. In some cases, fines of between $10 000 and $50 000 were imposed. The table below depicts the total number of instances in which sanctions were imposed and the proportion of those sanctions that involved the imposition of fines.

Table 3 - No of sanctions imposed, including no of fines imposed

Year	No of breaches	No of cases in which sanctions imposed	Proportion of sanctions that involved fines
1999 – 2000	27	26	42%
2000 – 2001	17	13	23%
2001 - 2002	28	24	29%

Non-members and the Code

3.59. Complaints against companies that are not members of Medicines Australia may be investigated in the same manner if the non-member agrees to have the complaint adjudicated by the Committee. If the non-member does not agree, Medicines Australia has the right (but not the obligation) to forward the complaint to the TGA or to the Commission.

4. Submissions

Submissions received before the draft determination

Applicant's supporting submission

4.1. Medicines Australia provided a submission in support of its applications on 16 January 2003.

Market Definition

4.2. Medicines Australia submitted that the relevant market in which to assess the Code is the market in Australia for the supply of prescription products used under medical supervision as permitted under Australian law.

Anti-Competitive Detriment

4.3. Medicines Australia submitted that the Code has little, if any, adverse effect on the state of competition in the relevant market, particularly in light of the fact that the market is highly regulated. However, Medicines Australia submitted that some sections of the Code require better industry practices than those currently required by law. Medicines Australia acknowledged that members who agree to abide by the Code therefore face competitive restraints not faced by non-members who do not agree to abide by the Code.

Public Benefits

4.4. Medicines Australia submitted that the Code gives rise to a number of public benefits, outlined below.

- Setting out and enforcing standards of conduct for the marketing of prescription products constitutes a benefit in regard to consumer protection.
- The Code complements and encourages compliance with section 52 of the TPA (which prohibits misleading and deceptive conduct) and the TG Act's prohibition of direct-to-consumer advertising.
- The Code encourages the quality use of medicines and rational prescribing practices through the regulation of promotional activities such as gifts, sponsorship, education and hospitality.

Submissions from interested parties

4.5. In assessing the applications, the Commission considered submissions from Medicines Australia and from various interested parties. The Commission maintains a Public Register from which submissions may be obtained.

Submissions supporting the applications

4.6. Submissions supporting the applications were received from the following members of Medicines Australia:

- Pfizer Pty Ltd
- Solvay Pharmaceuticals
- Wyeth Australia Pty Ltd
- Ansto Radiopharmaceuticals and Industries
- Eli Lilly Australia Pty Ltd
- Merck Sharp & Dohme
- Boehringer Ingelheim Pty Ltd
- AstraZeneca

4.7. The **Commonwealth Department of Health and Ageing** and the **TGA** strongly supported Medicines Australia's application for authorisation.

4.8. The **Victorian Department of Human Services**, the **New South Wales Department of Health** and the **Australian Medical Association** (the AMA) also supported the application.

Submissions opposing the applications

4.9. The **Consumers' Health Forum of Australia** (CHF), the **Consumers' Federation of Australia** (CFA) and the **Australian Consumers' Association** (ACA) oppose the application. Concerns raised by one or more of these organisations include that:

- pharmaceutical companies are increasingly promoting drugs directly to consumers, including through third parties;
- self-regulation of the promotion and marketing of prescription medicines is inappropriate;
- that, via the Code, the industry is judging itself in secret;
- that information about complaints considered by Medicines Australia under the Code should be publicly available;
- that public awareness of the Code needs to be improved;
- that consumer representation on the Code Committee and the Appeals Committee is inadequate;
- that the Code's sanctions are inadequate;
- better ways must be found for consumers to lodge complaints – for example, and industry-funded but independent ombudsman to progress consumer complaints;
- non-members may refuse to have a complaint adjudicated under the Code, and Medicines Australia is not obliged to refer these complaints to the TGA or the ACCC; and

- that complaints are sometimes rejected based on technicalities.

4.10. However, the ACA and CFA did acknowledge that the 14th edition of the Code contained improvements over the 13th edition including, for example, increased maximum fines for Code breaches and improved guidelines on the provision of benefits to doctors.[61]

The Applicant's response to the submissions from interested parties

4.11. On 9 April 2003, Medicines Australia provided a response to the submissions from interested parties outlined above. Medicines Australia submitted that:

- the primary focus of the Code is the industry's relationship with healthcare professionals rather than consumers;
- transparency of the Code is enhanced by the requirement that breaches directed towards members of the public are recorded on the Medicines Australia website;
- the industry is not judging itself in secret as the majority of the voting members of the Committee are non-industry members, and the principal regulator of the industry (the TGA) is an active participant;
- Medicines Australia would be delighted to work with consumer groups to improve public awareness of the Code;
- Medicines Australia will assist any potential complainant in the preparation and lodgement of a complaint;
- access to the Code is unfettered – it is easy to use and has no cost barriers;
- by supporting the Code, the TGA accepts that the industry is sufficiently mature to self-regulate;
- Medicines Australia members do not support direct-to-consumer advertising of prescription medicines and the Code supports the current prohibition of such advertising;
- past research indicates that the sanction that attracts most attention and is most efficient to communicate to health care professionals is corrective advertising or letters;
- the level of sanctions provided for by the Code is comparable to those that may be imposed under state fair trading laws and the TPA;
- the maximum fine under the 13th edition of the Code was $50 000 and this was imposed on at least two occasions;

[61] ACA submission, 25 February 2003, p2; CFA submission, 28 February 2003, p2; CHFA submission, 18 March 2003, p3.

- corrective advertising or letters themselves have financial implications for companies found in breach;
- if a non-member refuses to have a complaint dealt with under the Code, Medicines Australia would ensure that all matters that should be referred to the TGA or to the Commission are referred (although due consideration would be given to each individual case);
- whenever the Code is reviewed, Medicines Australia seeks comments from over 20 external organisations; and
- the Code of Conduct Committee is very strict in its adoption of the principles of natural justice in its consideration of complaints.

Submissions received following the draft determination

4.12. In its draft determination, the Commission proposed to grant authorisation to the applications subject to three conditions that proposed to:

- require members of Medicines Australia to provide various details about educational meetings organised or sponsored by them to Medicines Australia prior to the event, and to require Medicines Australia to make these details available to the public through its website;
- require Medicines Australia to makes its Code of Conduct Committee Annual Report available on its website; and
- require Medicines Australia to provide the Commission with a copy of its Guidelines (with any amendments marked) on an annual basis.

4.13. Following the release of the draft determination, the Commission invited interested parties to make further submissions. These submissions are outlined below and discussed in further detail, where relevant, in section 5 of this determination.

Submission from Medicines Australia

4.14. Medicines Australia contended that the proposed Condition C1 could not be accepted by its members. Medicines Australia submitted the following.

- The proposed Condition C1 would create a significant anti-competitive effect by requiring the disclosure of commercially confidential information, thereby inhibiting competition between pharmaceutical companies in relation to promotional strategies.
- The proposed Condition C1 would discourage new membership and would cause a number of existing members to leave Medicines Australia.
- Proposed Condition C1 would cover thousands of educational meetings, the disclosure of which would place an onerous

administrative burden on both member companies and Medicines Australia.

- Proposed Condition C1 would mean that a different standard of benefits and hospitality would be offered to healthcare professionals by different sections of the pharmaceutical industry (as the over-the-counter, complementary medicines and medical supplies sectors would not be subject to the proposed condition).
- The information required to be disclosed by proposed Condition C1 would be largely irrelevant, as most consumers are unaware of the name of the manufacturer of their medication and so are unlikely to be able to assess whether their medical treatment may have been influenced by the provisions of any benefits. Further, as doctors will not be linked to benefits received, it will be impossible to determine if any conflict of interest has actually arisen. Finally, the information may be misused by media or consumer groups, which could cause patients to question the value of their prescription and possibly lead them not to fill it.
- Uninvited parties (such as the media) may use the information required to be disclosed by proposed Condition C1 to attend educational meetings for ulterior purposes. This risk could deter doctors from attending.
- Proposed Condition C1 seems to be based on an unwarranted and unjustified presumption that prescribing habits are influenced inappropriately by pharmaceutical companies.
- Insufficient weight was given to the ease and relative inexpensiveness of making complaints under the Code. Further, the Code saves the TGA and the Commission from engaging in enforcement action.
- The Monitoring Committee has recently conducted a review of activities undertaken at industry-sponsored meetings with healthcare professionals between March and May 2003.
- Medicines Australia stated that proposed Conditions C2 and C3 were acceptable as they would contribute to the transparency of its operation.

Submissions from other interested parties

4.15. Submissions made by other interested parties are outlined below. Medicines Australia responded to the submissions from interested parties on 2 September 2003. Its response is also outlined below.

Bristol-Myers Squibb Australia

4.16. **Bristol-Myers Squibb Australia** (BMSA) submitted that it had significant concerns about the proposed conditions and that the submission from Medicines Australia reflected the position of BMSA in this regard. Commission staff also met with BMSA representatives, who provided factual information of a commercially sensitive nature in relation to the promotional activities (particularly educational meetings) typically engaged in by BMSA.

Government agencies

4.17. The **TGA** supported the draft determination, and considered that the public benefits arising from the Code would be augmented by the conditions proposed by the Commission.

4.18. The **Commonwealth Department of Health and Ageing** supported the draft determination. The Department noted that the proposed Condition C1 may be opposed by the pharmaceutical industry and the medical profession, but stated that it supported measures to increase the transparency of the relationship between the pharmaceutical industry and doctors in the interests of the quality use of medicines and the sustainability of the PBS.

4.19. The **Victorian Department of Human Services** supported the draft determination.

4.20. The **South Australian Department of Human Services** stated that it did not intend to challenge the Commission's proposed decision.

Australian Medical Association

4.21. The **AMA** submitted that:

- the conditions proposed by the Commission are unnecessary and do not deliver any pro-competitive benefit;
- proposed Condition C1 may expose doctors and pharmaceutical companies to public derision from those who have no real understanding of the benefits associated with attending educational meetings;
- the AMA Code of Ethics and Guidelines on the relationship between doctors and pharmaceutical companies, and the Medicines Australia Code of Conduct, already effectively regulate this area;
- AMA members take exception to the apparent inference that doctors are likely to be influenced inappropriately by the provision of hospitality;
- the imposition of a condition requiring the disclosure of details of educational meetings prior to those meetings occurring raised the possibility that lobby groups or journalists may seek to gain access to or otherwise disrupt those meetings, and that this may in turn discourage doctors from attending such meetings;
- it is reasonable for some level of hospitality to be offered to doctors who attend educational meetings in their own time;
- educational meetings are an important avenue of continuing education for doctors;
- disclosure that is intended to 'shame' pharmaceutical companies should occur only when a proven wrong has occurred; and

- while the AMA was concerned about all three conditions, if its concerns about Proposed Condition C1 were addressed, it was likely that its concerns about the other two conditions would subside.

4.22. In its response, Medicines Australia submitted that if educational meetings ever became simple marketing exercises, AMA members would not attend and would be likely to lodge complaints under the Code.

Healthy Skepticism

4.23. **Healthy Skepticism Inc** (Healthy Skepticism) supported the draft determination but submitted that the conditions proposed in the draft determination should be expanded to strengthen the Code. Healthy Skepticism also made the following contentions.

- Research indicates that gifts distort decision making (the main problem not being deliberate corruption but unintended bias) even if the gift is not wanted and the gift-giver not trusted. Both large and small gifts are capable of distorting decisions. The evidence also indicates that disclosure of conflicts of interest does not protect the public. Accordingly, all gifts should be banned.
- Although the evidence outlined above suggests that the disclosure of conflicts of interest such as that contemplated by proposed Condition C1 is unlikely to achieve much protection for the public, Healthy Skepticism regards it as a small step in the right direction that may help achieve more effective reforms later.
- Private interactions between medical representatives and doctors are pharmaceutical companies' most powerful means of influencing prescribing habits. As proposed Condition C1 focuses on hospitality pharmaceutical companies may respond by focussing more on gift-giving by medical representatives.
- The public would benefit if all promotional activities by pharmaceutical companies were banned, as the information provided by pharmaceutical companies is inevitably biased and likely to lead to distortions in the use of medications. In the meantime, proposed Condition C1 should be expanded to require disclosure of all gifts.
- Proposed Condition C2 should be expanded to specify the information the Annual Report should contain. Minutes of the Code of Conduct Committee and Appeal Committee meetings should be posted on the Medicines Australia website, and the full text of all complaints and appeals considered at those meetings should also be placed on the website. Quarterly reports from the Monitoring Committee should be published on the website, even if there was no activity in that quarter.
- The Code should prohibit advertising a product to the public using, for example, a symbol to represent the name of the product.
- Fines are not effective in reducing ongoing misleading promotion unless they match the profits to be made from the misleading promotion.

- Corrective advertising or other retractive statements are an essential part of dealing with misleading promotion and should continue until a survey of the group that has been misled demonstrates that all unjustified impressions associated with the misleading promotion have been corrected.

4.24. In its response, Medicines Australia submitted that:

- the provision of information and items such as brand name reminders does not harm patients;
- it is not appropriate to release the minutes of Code of Conduct Committee meetings for reasons of privacy (particularly before avenues of appeal have been exhausted);
- companies are not circumventing the prohibition of direct-to-consumer advertising and the appropriate course for addressing any such allegation is to forward it to the Code of Conduct Committee or to the TGA;
- the imposition of fines of up to $200 000 is not insignificant, and the threat of such fines encourages compliance with the Code;
- the ability to impose fines means that the Commission or other regulators do not need to take action on these issues at the expense of taxpayers; and
- the Code of Conduct Committee has demonstrated that it appreciates the impact and necessity of corrective advertising in appropriate cases.

Consumers Health Forum

4.25. The **CHF** supported the conditions proposed in the draft decision, but submitted that:

- the proposed conditions should extend to all healthcare professionals, not just doctors;
- the TGA is an observer on the Code of Conduct Committee, not an active participant;
- the conclusion that the Code is primarily focused upon pharmaceutical companies' relationships with health care professionals is wrong, as the TGA does not deal with complaints regarding the advertising of therapeutic goods to consumers, but instead refers them to Medicines Australia;
- the Code and Guidelines should be regularly reviewed, with the involvement of consumer groups, healthcare professionals and non-members of Medicines Australia;
- the conditions should apply to all pharmaceutical companies, not just members of Medicines Australia, as the current arrangement generates a disincentive to join Medicines Australia;
- third parties, including non-health care professionals, should not be involved in pharmaceutical companies' promotional activities;

- the CHF strongly disagrees with the conclusion that consumer representation on the Code of Conduct and Appeals Committees is sufficient, and considers that consumers should be involved in the selection of consumer representation through an open, transparent national process;
- the Committee's activities are closed, secret and unaccountable; and
- the minutes of all Code of Conduct, Appeals and Monitoring Committee meetings should be published on Medicines Australia's website at least monthly.

4.26. Medicines Australia addressed some of these concerns in earlier submissions. It further submitted that:

- the TGA is an active and vital observer on the Code of Conduct Committee, and Medicines Australia would welcome its involvement as a full member;
- the Code is reviewed every three years, and earlier if required, in a process that involves consumers, health care professionals and other key stakeholders;
- the only practical way in which non-members could be required to comply with the Code would be for the TGA to continue with its requirement that all promotion comply with the Code;[62] and
- it is not appropriate to involve consumer representatives in the drafting of the Guidelines, as they are designed for use by members not consumers.

[62] In this respect, the Commission notes that any requirement that advertising comply with the Code in order to be approved by the TGA does not extend to the provisions of the Code dealing with hospitality or other issues not related to the advertising of products.

5. Evaluation

5.1. As indicated in the Introduction to this determination, the Commission is required to assess the likely public benefits and detriment arising from the Code.

Future with-and-without test

5.2. In order to identify and measure the public benefits and anti-competitive detriment generated by the proposed arrangements, the Commission applies the 'future with-and-without' test that was first established by the Australian Competition Tribunal (the Tribunal).[63] This requires a comparison of the public benefit and public detriment that the proposed arrangements would generate in the future if the authorisation is granted with the position if the authorisation is not granted. The scenario in which authorisation is assumed not to have been granted is termed the counterfactual.

5.3. The counterfactual employed by the Commission is that, in the absence of authorisation, the Code will not come into effect.

5.4. As regards the provision of benefits to healthcare professionals, Medicines Australia submitted that "one would expect…that community expectations and concerns about business reputation would place similar constraints on the conduct of pharmaceutical companies if it were not for the [Code]."[64]

5.5. However, Medicines Australia also emphasised that "the Code will in fact reduce the possibility of inappropriate prescribing."[65] This appears to concede that, absent the Code, at least some pharmaceutical companies would promote their prescription medicines to healthcare professionals in a more aggressive manner than is permitted by the Code.[66]

5.6. Further, the Commission notes the very large costs that pharmaceutical companies incur when researching and developing new medicines.[67] These costs would seem likely to generate a strong incentive to market medicines vigorously to healthcare professionals in the absence of the Code.

5.7. The United States Food and Drug Administration announced on 20 June 2003 that:

> AstraZeneca Pharmaceuticals LP has pleaded guilty to a large-scale healthcare crime and agreed to pay $355 million to resolve the associated criminal charges and civil liabilities….

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[63] See, for example, *Re Australasian Performing Rights Association* (1999) ATPR ¶41-701.
[64] Medicines Australia submission 2 September 2003, p 9.
[65] Medicines Australia submission, 6 August 2003, p 4.
[66] This also appears to concede that at least some doctors' prescribing habits would be inappropriately influenced by more aggressive marketing. This issue is discussed further at paragraph 5.34**Error! Reference source not found.**.
[67] One estimate of the cost of developing a new drug being US$500 million (*At a Glance: Pharmaceutical Fact Sheet* downloaded from www.medicinesaustralia.com.au on 29 October 2003).

> In one of these schemes, AstraZeneca provided thousands of free samples of Zoladex to physicians knowing that they would charge their patients and insurance programs for the samples. Another illegal inducement used by the firm involved inflating the price of Zoladex reported to Medicare as the basis for reimbursement, while deeply discounting the actual price charged to the physicians.[68]

5.8. While this case involved illegal conduct and was in the United States, and while the Commission is not aware of any similar cases in Australia, it is not unreasonable to infer from it that, absent the Code, at least some pharmaceutical companies, if not many, would promote prescription medicines to healthcare professionals more agressively and particularly through the provision of benefits banned by the Code.

5.9. As regards the provision of information to healthcare professionals, in the absence of the Code, the prohibition in the TPA on misleading and deceptive conduct would still exist (see sections 52 and 53 of the TPA), and would provide a significant constraint on pharmaceutical company representations about prescription medicines.

The relevant market

5.10. The first step in assessing the conduct for which authorisation is sought is to consider the relevant market(s) in which that conduct occurs.

5.11. The Commission uses market analysis to identify and measure the public benefit and anti-competitive detriment resulting from arrangements for which authorisation has been sought. However, depending on the circumstances, the Commission may not need to define the relevant markets comprehensively as it may be apparent that a net public benefit will or will not arise regardless of the scope of the defined market.

5.12. Medicines Australia submitted that the relevant market in which to consider the conduct is the market in Australia for the supply of prescription products used under medical supervision as permitted under Australian law.

5.13. The Commission notes that it may be possible to identify regional markets or markets associated with particular classes of prescription medicines. However, the Code would apply across all such markets. Accordingly, the Commission considers that, for the purposes of this authorisation, it is not necessary to consider whether the definition of the relevant markets is narrower than that proposed by Medicines Australia. For convenience, this determination refers to the market for prescription medicines when describing the relevant market.

Characteristics of the market for prescription medicines

5.14. Markets for health services or products often exhibit imperfections to varying degrees, including with regard to information. In the market for the supply of prescription medicines, information imperfections are particularly significant.

[68] Press release, US Food and Drug Administration, 20 June 2003, *Federal Investigation Leads to Guilty Plea in Healthcare Crime*.

5.15. Clearly, consumers (patients) will not usually possess a high level of knowledge about medical conditions and potential therapies. To gain a reasonable knowledge of pharmaceutical products requires years of training and an ongoing commitment to continuing education in order to keep abreast of new developments.

5.16. This factor underlies the decision by state and territory parliaments to require that many medicines only be supplied to consumers if prescribed by a doctor (see paragraph 2.4-2.6).

5.17. The ACA also submitted that doctors themselves may not, in practice, have sufficient time to absorb the volume of scientific studies and research available on pharmaceutical products. It further submitted that doctors consequently rely heavily on information provided by pharmaceutical manufacturers, either through sales representatives or promotional material.[69]

5.18. This is not in itself necessarily bad. Consumers routinely rely on information provided by producers – that is, advertising and promotional material – when making a purchasing decision about most products (information available in the ACA's *Choice* magazine is a notable alternative). The content of this information is regulated by, in particular, section 53 of the TPA which prohibits false or misleading representations in respect of a number of matters.

5.19. In addition, under the TG Act, prescription medicines may only be supplied in Australia by pharmaceutical companies after being rigorously tested to ensure their safety, quality and efficacy (see paragraph 2.8)

5.20. Doctors are also highly trained professionals with expertise in assessing information about pharmaceutical products.

5.21. Despite these factors, there may be an argument that doctors are not likely to be reasonably well-placed to make appropriate decisions about which prescription medicines to prescribe their patients based on the information that is available to them. However, as noted below at paragraph 5.32, the sections of the Code relating to the provision of information to doctors by pharmaceutical companies largely aim to supplement the prohibition of false and misleading representations contained in the TPA. These sections do not attempt to regulate broader information imperfections between pharmaceutical companies and doctors, should any such imperfections exist.

Areas of competition between pharmaceutical companies

5.22. Broadly, two areas of competition between pharmaceutical companies can be identified.

5.23. First, pharmaceutical companies compete by developing new drugs – that is, drugs able to treat a condition that was not previously treatable or drugs that are better at treating conditions than existing drugs (because they exhibit improved efficacy or a reduction in side effects).

[69] ACA submission, 25 February 2003, p 3.

5.24. Pharmaceutical companies are generally able to obtain patents for these types of drugs, which effectively provide a pharmaceutical manufacturer with a monopoly on the patented product for a set period (usually 20 years in Australia).[70]

5.25. This form of competition can be said to be largely driven by innovation. This innovation is expensive and protracted, with the average cost of developing a new medicine being approximately $US802 million ($A1.2 billion), and the average length of time spent developing a new medicine being approximately 12 years.[71]

5.26. The quality of prescription medicines seems to be largely driven by this form of competition between pharmaceutical companies, underpinned by the requirement in the TG Act that prescription medicines to be rigorously tested before being supplied in Australia (see paragraph 2.8).

5.27. Secondly, pharmaceutical companies compete to supply drugs that are no longer subject to patent – that is, so-called 'generic' drugs. In these cases, pharmaceutical companies are essentially each making the same medicine. The quality of generic prescription drugs is also underpinned by TG Act requirements (see paragraph 2.10).

Price of prescription medicines

5.28. The retail price of around 90 per cent of prescription medicines – both new and generic – is determined by the Commonwealth Government through the PBS (see paragraphs 2.20 - 2.21).[72] As a result, decisions by doctors about which medicines to prescribe for their patients appear to have little or no effect on the price of those medicines.

Public Benefit

5.29. Broadly, the Code regulates two areas:

- the provision of information about prescription medicines to healthcare professionals and to the public by pharmaceutical companies; and
- the provision of benefits (financial and otherwise) to healthcare professionals by pharmaceutical companies.

5.30. With regard to the provision of information to the public, the Commission notes the prohibition on direct-to-consumer advertising of prescription medicines. However, Medicines Australia has a role in assessing complaints about information that is provided to the public by pharmaceutical companies but that may not constitute direct-to-consumer advertising (such as advertisements that do not directly name a prescription medicine).

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[70] Section 67, *Patents Act 1990* (Cth).
[71] Medicines Australia, 'The Pharmaceutical Industry in Australia', Briefing Paper, downloaded from www.medicinesaustralia.com.au on 11 June 2003.
[72] Productivity Commission *Evaluation of the Pharmaceutical Industry Investment Program* February 2003, p 3.4.

Regulation of the provision of information

5.31. The Commission generally recognises that codes of conduct that facilitate compliance with general legislative provisions as they apply to specific markets can generate a public benefit by helping to ensure that the benefits that potentially flow from these general provisions are achieved in practice. However, this public benefit will often be small (that is, most public benefit derives from the legislative provision itself). This benefit arises in the form cost savings, to the extent that the Code reduces the number of companies engaging in misleading and deceptive conduct, and to the extent that cost savings arise because the Code's enforcement procedures are able to address minor cases of misleading and deceptive conduct in a more efficient manner than, for example, the Commission.

5.32. Sections 52 and 53 of the TPA are two such general provisions. Medicines Australia submits that the Code gives rise to a public benefit by facilitating compliance with these provisions. The Commission accepts that a small public benefit is likely to arise from this.

Regulation of the provision of benefits to healthcare professionals

5.33. Medicines Australia contended that the Code gives rise to a public benefit through the encouragement of rational prescribing practices, including by regulating the provision of benefits to healthcare professionals.

(i) Is it possible for healthcare professionals to be influenced inappropriately by pharmaceutical companies' promotional activities?

5.34. On one hand, doctors are subject to ethical obligations requiring them to give primacy to the welfare of their patients. Guidelines produced by the AMA state that:

> [t]he practising doctor's primary obligation is towards the patient. Considerations involving the pharmaceutical industry are appropriate only insofar as they do not intrude into or distort that primary obligation.

5.35. This could be taken to indicate that the provision of benefits to doctors by pharmaceutical companies is unlikely to influence the doctor's choice of prescription medicine, as doctors can ordinarily be expected to meet their ethical obligations.

5.36. In addition, a doctor who acts negligently in his or her dealings with a patient (including in relation to the prescription of medicines) are exposed to the risk of litigation if such negligence harms the patient.

5.37. On the other hand, the fact that pharmaceutical companies are prepared to offer benefits suggests that they anticipate that they will be able to influence a doctor's choices, and, more generally, the existence of the AMA's guidelines suggests that the AMA has some concern about the actions of at least some doctors in this regard. The issue is whether this may lead to inappropriate prescribing.

5.38. Medicines Australia specifically claimed that "the Code will in fact reduce the possibility of inappropriate prescribing" [73], which clearly seems to imply that it believes that at least some pharmaceutical companies would engage in conduct that has the potential to influence doctors inappropriately and that at least some doctors would be inappropriately influenced.[74]

5.39. The prohibition on advertising to consumers suggests that the TGA has some concern that enough doctors could be influenced by their patients to choose a drug other than the one which they would choose on a purely scientific basis to warrant action on this scale.

5.40. Finally, codes regulating the promotional activities of pharmaceutical companies exist in several other countries.

5.41. The existence of these codes and guidelines does not, by itself, demonstrate that pharmaceutical companies' promotional activities inappropriately influence healthcare professionals.[75] However, it seems clear that a wider range of relevant organisations *believe* that at least some pharmaceutical companies are likely to engage in activities that would result in at least some health professionals inappropriately prescribing medicines, or these codes and guidelines would presumably not exist.

5.42. The ACA provided research studies on the influence of pharmaceutical companies' promotional activities on healthcare professionals to the Commission. The ACA noted a review published in the *Journal of the American Medical Association* which found that:

> [c]ompany-sponsored medical education events preferentially highlighted the sponsor's products; doctors who accepted funding for travel or accommodation for these symposia were more likely to prescribe the sponsor's medication. The review concluded that "the present extent of physician-industry interactions appears to affect prescribing and professional behaviour and should be further addressed at the level of policy and education".[76]

5.43. The ACA also noted an instance in Minneapolis, United States, where the only explanation for a sudden, three-fold rise in prescriptions for a particular drug appeared to be the fact that a company-sponsored education symposium had just been held.[77]

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[73] Medicines Australia submission, 6 August 2003, p 4.

[74] This aspect of Medicines Australia's submission seems inconsistent with its argument that the Commission's draft determination impugns the reputation of doctors and pharmaceutical company executives.

[75] Indeed, it would be circular to argue that the existence of the Medicines Australia Code proves that it generates a public benefit by reducing inappropriate prescribing.

[76] A Wazana, 'Physicians and the Pharmaceutical Industry: is a gift ever a gift?' *Journal of the American Medical Association* 283: 373 – 380, in ACA submission, 25 February 2003, p3.

[77] Ibid.

5.44. In addition, Healthy Skepticism submitted research studies that found that:

- even gifts of negligible value were capable of influencing doctors' behaviour;[78] and
- even measures such as limiting gift size, requiring disclosure or educating doctors about possible conflicts of interest were unlikely to be sufficient to avert the problem of bias arising as a result of benefits received from pharmaceutical companies.[79]

5.45. The Commission considers that these research studies, in conjunction with the apparent beliefs of relevant organisations outlined above, support a conclusion that the prescribing habits of at least some healthcare professionals may be inappropriately influenced by benefits provided by pharmaceutical companies.

(ii) What type of promotional benefits might inappropriately influence healthcare professionals?

5.46. The research studies cited above suggest that most, if not all, benefits provided by pharmaceutical companies are likely to inappropriately influence healthcare professionals. This issue is beyond the scope of the Commission's examination of Medicines Australia's application for authorisation as the Code does not ban the provision of all benefits to healthcare professionals.

5.47. No research has been provided to the Commission that suggests an alternative threshold at which the provision of benefits begins to inappropriately influence doctors than that suggested by the research cited above. Having said this, the Commission notes that no research has been provided that suggests that the Code is too restrictive. The only research available suggests it is not restrictive enough (although Medicines Australia would disagree).

5.48. In light of the above, on the evidence available to it, the Commission considers that, at the least, those benefits prohibited by the Code are capable of influencing the prescribing habits of healthcare professionals.

(iii) Would pharmaceutical companies ever provide benefits capable of influencing healthcare professionals?

5.49. As discussed at paragraph 5.8, the Commission considers that, absent the Code, at least some pharmaceutical companies, if not many, would promote prescription medicines to healthcare professionals more aggressively and particularly through the provision of benefits banned by the Code.

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[78] Dana Katz, Arthur L Caplan and Jon F Merz, 'All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving', *American Journal of Bioethics* 2003; 3 (3) pp 39 – 46.

[79] Jason Dana and George Lowenstien, 'A Social Science Perspective on Gifts to Physicians from Industry', *Journal of the American Medical Association* 2003; 290; pp 252 – 255.

(iv) How large is the *potential* public benefit from the Code?

5.50. The Commission has concluded that, on the evidence available to it, without the Code, some if not many pharmaceutical companies would be likely to offer benefits to healthcare professionals that are banned by the Code and that this would lead to inappropriate prescribing by at least some healthcare professionals.

5.51. However, this conclusion does not determine the potential size of the public benefit achievable by the code from reducing inappropriate prescribing. This depends on, absent the Code, how far pharmaceutical companies would actually go in promoting medicines and how much healthcare professionals would actually be inappropriately influenced. Essentially, the Commission has concluded that the Code potentially generates a public benefit, but the actual size of the public is not clear.

5.52. The Commission recognises that the research studies cited above suggest, in particular, a high level of doctor susceptibility to pharmaceutical company promotional benefits. The Commission is not necessarily rejecting these findings. However, it is conscious that issues such as these are the subject of wide debate and it is unclear whether the studies cited reflect the weight of opinion across the debate.

5.53. Having said this, given the likely consequences of inappropriate prescribing for consumers, the Commission considers it prudent, for the purposes of assessing this application, to err on the side of caution – that is, to recognise a greater potential for inappropriate prescribing than might actually be the case. The point of taking such an approach can be illustrated by considering the consequences if, for example, the Commission concluded that healthcare professionals would never by influenced by pharmaceutical company benefits. In such a situation, this part of the Code could generate no public benefit, raising the possibility that authorisation could be denied.

5.54. On these limited grounds, the Commission recognises that that the Code potentially generates a not insignificant public benefit.

5.55. This public benefit arises from a reduction in the likelihood that doctors would prescribe medicines which may not be the most appropriate choice for their patient (according to available scientific evidence).

5.56. Such prescribing may harm patients or fail to improve the medical condition from which they suffer to the extent that would be possible if a more appropriate choice had been made.

5.57. In addition, inappropriate prescribing may reduce the incentive to innovate to which pharmaceutical companies are currently subject. Generally, if pharmaceutical companies are able to influence doctors to prescribe medicines that may not be the most suitable for particular medical conditions, this reduces the incentive to continue to develop medicines that are the most suitable for those conditions. However, in this case, the reduction in the incentive to innovate is likely to be negligible given the

relatively small size of the Australian prescription medicines market, for example in comparison to the United States.

(ii) To what extent does the Code actually reduce inappropriate prescribing?

5.58. The potential benefit discussed above only *actually* be generated if the Code is effective, that is, if it is appropriately enforced and if members believe that it will be appropriately enforced. The Commission has some concerns on this point.

5.59. In particular, the Commission has some concerns with regard to the Code's restrictions on the provision of benefits to healthcare professionals. In particular, only five per cent of complaints (that is, only seven complaints) in the three years to 30 June 2002 related to these provisions of the Code. Given the broader concerns being raised about the extent of these activities by pharmaceutical companies,[80] this percentage seems very low. It is also low in absolute terms.

5.60. In light of these concerns about the practical enforcement of the Code, the Commission considers that the actual public benefit generated by the Code is small.

Anti-competitive detriment

Regulation of the provision of information

i) Effect on competition

5.61. Generally, the promotion of products is a key aspect of any company's competitive activities, as it may significantly influence the choices made by consumers. The capacity of promotional activities to significantly influence consumers' choices is acknowledged in the existence of a prohibition in the Trade Practices Act on misleading or deceptive advertising (and the Commission's vigorous enforcement of that prohibition).[81]

5.62. It is clear that pharmaceutical companies themselves recognise the value of promoting their products. The ACA submitted that direct-to-consumer advertising of prescription products is not banned in the United States or New Zealand and that this has been associated with dramatic increases in sales of new drugs (which are those most likely to be aggressively advertised).[82]

5.63. Further, the power of promotion is recognised in the TG Act's prohibition of direct-to-consumer advertising, which the ACA submitted is designed to avoid patients influencing doctors to prescribe particular pharmaceutical products they have become aware of through advertising.[83]

[80] For example, see 'The Doctor's Gravy Train', *Sunday* Program, Channel Nine, 5 August 2001.
[81] Section 52, TPA.
[82] ACA submission dated 25 February 2003, p 5.
[83] ACA submission dated 25 February 2003, p 5.

5.64. In addition, recent research cited in the Medical Journal of Australia suggests that a significant increase in market share and retail sales can be linked to advertising of a particular product in a medical journal.[84]

5.65. Overall, this supports the Commission's general view that restrictions on advertising and promotion by businesses can significantly lessen competition in a market.

5.66. However, whether this view applies in a particular market depends on the nature of the restrictions on advertising in question, as well as any relevant characteristics of the market. In this instance, it is important to consider whether the restrictions on promotion contained in the Code are likely to significantly reduce the intensity of competition between members of Medicines Australia. More directly, will these restrictions reduce the likelihood that doctors will change their prescribing habits?

5.67. The Commission considers that the provisions of the Code relating to promotional material largely operate to ensure that pharmaceutical companies' promotional material is not false or misleading (see paragraphs 3.7-3.12). As discussed at paragraph 5.3, the TPA prohibition on false and misleading representations would still exist even if the Code were not authorised. Consequently, these provisions of the Code have minimal effect on competition between pharmaceutical companies.

5.68. However, the Code also requires that all promotional and educational material must conform to generally accepted standards of good taste and recognise the professional standing of the recipient.[85] This goes beyond the TPA prohibition on false and misleading representations.

5.69. However, given that vigorous advertising is part of the culture of the pharmaceutical industry, and that Medicines Australia is controlled by the pharmaceutical industry, the Commission is satisfied that this provision would be unlikely to be used to substantially restrict normal commercial advertising by its members. As such, the provision is also unlikely to affect competition between pharmaceutical companies significantly.

ii) Public detriment

5.70. Given that the Code's provisions regulating the promotion of prescription medicines have a minimal effect on competition, the Commission considers that they are also likely to generate minimal, if any, public detriment.

Regulation of the provision of benefits to healthcare professionals

i) Effect on competition

5.71. The Code restricts the provision of benefits to healthcare professionals by pharmaceutical companies. Again, the question is whether these restrictions reduce the likelihood that doctors will choose to change their prescribing habits.

[84] 'Drug advertising: truths, half-truths and few statistics' Volume 177 MJA 16 September 2002 p 285.
[85] Section 1.4.

5.72. At paragraph 5.48, the Commission concluded that the promotional activities of at least some pharmaceutical companies, absent the Code, are likely to influence inappropriately the prescribing habits of at least some healthcare professionals. A restriction on the provision of benefits is therefore likely to constitute at least some restriction on competition in this area. The extent of this restriction is unclear, but even if it were to be significant, it would be unlikely to generate more than a minimal detriment to the public for the reasons discussed below.

ii) Public detriment

5.73. As discussed above, given that price is largely regulated through the PBS, the issue is whether the significant lessening of competition caused by the restriction on the provision of benefits to healthcare professionals detrimentally affects the quality of pharmaceuticals produced in the market. As discussed at paragraph 5.25, this largely reduces to whether the restriction in the Code affects the ability of pharmaceutical companies to develop new drugs in any significant way.

5.74. It is possible that the provision of benefits to healthcare professionals might result in them prescribing more drugs that provide pharmaceutical companies with a greater return, which could then be used to fund research and development. The provision of benefits might also result in healthcare professionals prescribing drugs where otherwise they would not – thereby also generating more revenue which might be used to fund research.

5.75. However, on a practical level, new drugs are developed for supply worldwide. Restrictions on the provision of benefits to healthcare professionals in a smaller market such as Australia would therefore seem unlikely to significantly detract from pharmaceutical companies' ability to fund research. The Commission would also need credible evidence that any foregone revenue was likely to be directed to research and development. Given these considerations, it is likely that the Code's restrictions on the provision of benefits to healthcare professionals would generate minimal public detriment.

Balance of public benefit and detriment

5.76. The Commission has concluded that the Code generates a small public benefit and minimal public detriment.

5.77. Where it is difficult to determine precisely magnitudes of public benefit and detriment that appear to be of similar size – as is the case with Medicine Australia's application – there may be some uncertainty about whether the public benefit outweighs the public detriment.

5.78. In these cases, the Commission will generally not be satisfied that the public benefit generated by the application outweighs the anti-competitive detriment. However, it may consider whether it is possible to grant authorisation subject to conditions aimed at reducing, as far as possible, any uncertainty about whether the public benefit is greater than the anti-

competitive detriment. These conditions would either seek to increase the public benefit or reduce the anti-competitive detriment sufficiently to remove any concern that authorisation was being inappropriately granted.

Conditions

5.79. In its draft determination, the Commission proposed to grant authorisation subject to three conditions. In light of concerns raised following the draft determination, the Commission has revised Condition C1 as it was proposed in the draft determination to ensure that it is practical and effective, and provides a reasonable level of transparency of industry practices.

5.80. Accordingly, the Commission **grants** authorisation subject to the following conditions.

Condition C1

The Monitoring Committee shall, each year, require each member company to provide full details of all educational meetings and symposia as defined in Sections 6, 7 and 10 of the Code held or sponsored by that company during a defined three month period. This three month period is to be chosen at random and the duration of the period is not to be communicated to member companies until the period has ended and the information is requested.

The information that each member company will be required to provide will include:

- **details of the venue at which the meeting is held;**
- **details of any hospitality or entertainment offered at the meeting;**
- **the number of attendees together with a general description of their professional status (eg group of general practitioners); and**
- **a copy of any printed material provided to attendees.**

If the Monitoring Committee is not satisfied that the conduct of the member company with regard to the meeting would withstand public or professional scrutiny (or otherwise considers that it may breach the Code of Conduct), it will refer a report in relation to the meeting, and the member company's response, to the Code of Conduct Committee as a complaint.

The Monitoring Committee shall also provide a detailed report on its compliance with this condition, as well as its other activities, to Medicines Australia for publication on the Medicines Australia website and in the Medicines Australia Annual Report. This report is to include the details set out below.

- **The number of educational meetings examined by the Monitoring Committee during the specified period.**

- **The number of those meetings that raised concerns which were brought to the attention of the member company on the grounds that the venue selected, or the hospitality or entertainment offered, was not consistent with the requirements of the Code.**

- **In each of the cases referred to above, the details of the aspects of the meeting that raised concern should be reported. For example, if the concern related to the choice of venue, the report should indicate the nature of the venue (for example, a winery or holiday resort). If the concern related to entertainment, then the report should indicate the nature of this entertainment (for example, tickets to a theatrical performance) and if it related to hospitality, the report should indicate the nature of the hospitality (for example, inappropriately lavish meals).**

The report shall also state whether a concern raised with an MA member was forwarded to the Code of Conduct committee as a complaint. For concerns that were forwarded to the Code of Conduct Committee, the report shall also state the name of the Medicines Australia member involved and the date that the complaint was referred.

5.81. The Commission considers that this condition is likely to improve the ability of the Code to regulate properly the provision of benefits to healthcare professionals, as it requires the Monitoring Committee to continue with its recently expanded role and review the general conduct of a sample of educational meetings each year. This review will also be available to the public through the Medicines Australia Annual Report and website, thereby assisting in the transparency of the Monitoring Committee's operation.

Condition C2

Medicines Australia shall make its Code of Conduct Committee Annual Report publicly available on its website. This report shall include the same level of detail as is provided in its 2002-03 report.

5.82. The Commission considers that the online publication of the Committee's report is likely to increase the efficacy of the enforcement of the Code, as public awareness of the outcomes of the Code is likely to provide an additional incentive for Medicines Australia to enforce the Code vigorously.

Condition C3

Medicines Australia is to provide the Commission with a copy of the Medicines Australia Code of Conduct Guidelines, on which any amendments are marked, on an annual basis.

5.83. Although the *Guidelines* are not part of the application for authorisation, the Commission considers that they are an integral part of the context within which the Code operates. As a result, the Commission also considers that a significant change to the *Guidelines* could constitute a material change of circumstances that may be sufficient to warrant a revocation of the

authorisation under section 91B of the TPA. Condition C3 ensures that Medicines Australia will notify the Commission of any amendments to the *Guidelines*.

5.84. Authorisation was sought for a period of six years. The Commission considers that a period of three years is likely to be sufficient for the public benefits identified by the Commission to arise, and that the Commission will then be in a position to re-consider the authorisation. Accordingly, the Commission grants authorisation for a period of three years.

Amendments to the Code

5.85. The authorisation granted is in respect of the Code as it currently stands. Any amendment to the Code during the term of the authorisation would need to be the subject of an application for minor variation of the authorisation under section 91A of the TPA, or revocation and substitution of the authorisation under section 91C of the TPA.

Authorisation not to be held out as endorsement

5.86. The Commission has a role in endorsing effective industry codes of conduct that aim to achieve best practice within an industry. The endorsement process is quite distinct from the authorisation process. The authorisation process is set out in the TPA and only indicates that a code passes a certain legal test. Authorisation does not indicate that a code is best practice and, this conditional authorisation can in no way be held out as endorsement or approval by the Commission of the Medicines Australia Code.

Other issues

Involvement of consumer groups

5.87. The ACA, CFA and CHFA were dissatisfied with the level of consumer representation on the Code Committee and Appeals Committee.[86] The Commission notes that the Code is predominantly directed at regulating the relationship between pharmaceutical companies and healthcare professionals. However, the Commission notes that some consumer issues will be considered under the Code where they relate to information provided by pharmaceutical companies to the public, or by referral from the TGA (in relation to advertising to the public that raises concerns under the Code but that may not constitute direct-to-consumer advertising). In light of this, the Commission considers that consumer groups have an interest in the outcome of the process but considers that the current level of consumer representation on the Committee is sufficient in this regard.

Legal action for misleading and deceptive conduct

5.88. Some consumer groups expressed concern that the level of fines under the Code is significantly lower than those that could be imposed by a Court should a breach of section 52 or 53 of the TPA (which prohibit misleading and deceptive conduct) be found. The Commission notes that the immunity

[86] CFA submission, 28 February 2003, p3; CHFA submission, 18 March 2003, p3; ACA submission, 25 February 2003, pp6-7.

from legal action provided by authorisation does not, and cannot, extend to sections 52 and 53 of the TPA. Accordingly, members of Medicines Australia are still liable for any breaches of section 52 or 53 and will not be able to avoid Court-imposed sanctions by paying any fine under the Code.

Self-regulation

5.89. The ACA submitted that the possibility that prescribing patterns may be affected by the provision of benefits to doctors was of such significance that it was inappropriate to allow the industry to self-regulate. However, under the TPA, the Commission is limited to considering whether the public benefit from the Code outweighs the public detriment. It is not able to consider whether government regulation might be more appropriate.

Advertising to consumers

5.90. The ACA, CFA and CHFA all expressed concerns that some pharmaceutical companies have attempted to promote their products to consumers indirectly by, for example, sponsoring advertisements advising that a new treatment for a particular condition is available and suggesting that patients seek further information from their doctors. [87] This issue relates to the TG Act's prohibition of direct-to-consumer advertising. The Commission notes that although the TGA has not expressed a view as to whether this conduct amounts to prohibited direct-to-consumer advertising, the Code of Conduct Committee has examined the issue where a complaint has been made. It is open to consumer groups to refer any complaints in this regard to either the TGA or to Medicines Australia.

[87] CFA submission, 28 February 2003, p3; CHFA submission, 18 March 2003, pp1-2; ACA submission, 25 February 2003, p5.

6. Determination

6.1. On 16 January 2003, Medicines Australia lodged amended applications for authorisation A90779 and A90780 with the Australian Competition and Consumer Commission (the Commission).

6.2. The applications were made under section 91C of the *Trade Practices Act 1974* (the TPA) to revoke clearance C23698 which authorised the 3rd edition of the Medicines Australia Code of Conduct (the Code), and substitute it with an authorisation relating to the 14th edition of the Code.

6.3. Authorisation was sought in relation to the Code to:

- make or give effect to a provision of a contract, arrangement or understanding where the provision is, or may be, an exclusionary provision within the meaning of section 45 of the TPA; and
- make or give effect to a provision of a contract, arrangement or understanding where the provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45 of the TPA.

6.4. The applications were expressed to extend to all current and future members of Medicines Australia, pursuant to subsections 88 (6) and 88 (10) of the TPA.

6.5. Medicines Australia sought authorisation for a period of six years, and requested that authorisation not be reviewed every time that the Code is amended. Instead, Medicines Australia proposed that it provide the Commission with a copy of any amendments to the Code of Conduct and that the Commission should advise Medicines Australia if it considers that any such amendments warrant review of the authorisation.

Statutory test

6.6. For the reasons outlined in section 5 of this determination, the Commission is satisfied that the substitute authorisation sought by Medicines Australia would be likely to result in a public benefit outweighing the detriment to the public constituted by any lessening of competition that would be likely to result from the substitute authorisation, **subject to the conditions outlined below**.

Conditions

6.7. The Commission therefore revokes clearance C23698 and **grants** authorisation to applications A90779 and A90780, subject to the following conditions:

Condition C1

The Monitoring Committee shall, each year, require each member company to provide full details of all educational meetings and symposia

as defined in Sections 6, 7 and 10 of the Code held or sponsored by that company during a defined three month period. This three month period is to be chosen at random and the duration of the period is not to be communicated to member companies until the period has ended and the information is requested.

The information that each member company will be required to provide will include:

- **details of the venue at which the meeting is held;**
- **details of any hospitality or entertainment offered at the meeting;**
- **the number of attendees together with a general description of their professional status (eg group of general practitioners); and**
- **a copy of any printed material provided to attendees.**

If the Monitoring Committee is not satisfied that the conduct of the member company with regard to the meeting would withstand public or professional scrutiny (or otherwise considers that it may breach the Code of Conduct), it will refer a report in relation to the meeting, and the member company's response, to the Code of Conduct Committee as a complaint.

The Monitoring Committee shall also provide a detailed report on its compliance with this condition, as well as its other activities, to Medicines Australia for publication on the Medicines Australia website and in the Medicines Australia Annual Report. This report is to include the details set out below.

- **The number of educational meetings examined by the Monitoring Committee during the specified period.**
- **The number of those meetings that raised concerns which were brought to the attention of the member company on the grounds that the venue selected, or the hospitality or entertainment offered, was not consistent with the requirements of the Code.**
- **In each of the cases referred to above, the details of the aspects of the meeting that raised concern should be reported. For example, if the concern related to the choice of venue, the report should indicate the nature of the venue (for example, a winery or holiday resort). If the concern related to entertainment, then the report should indicate the nature of this entertainment (for example, tickets to a theatrical performance) and if it related to hospitality, the report should indicate the nature of the hospitality (for example, inappropriately lavish meals).**

The report shall also state whether a concern raised with an MA member was forwarded to the Code of Conduct committee as a complaint. For concerns that were forwarded to the Code of Conduct Committee, the report shall also state the name of the Medicines Australia member involved and the date that the complaint was referred.

Condition C2

Medicines Australia shall make its Code of Conduct Committee Annual Report publicly available on its website. This report shall include the same level of detail as is provided in its 2002-03 report.

Condition C3

Medicines Australia is to provide the Commission with a copy of the Medicines Australia Code of Conduct Guidelines, on which any amendments are marked, on an annual basis.

6.8. The Commission authorises the Code for a period of three years. However, the Commission may choose to initiate revocation of the authorisation pursuant to section 91B of the TPA if it is satisfied that there exists a material change in circumstances, which may include an amendment to the Code or to the Guidelines accompanying the Code.

6.9. Further, this authorisation is in respect of the Code as it currently stands. Any amendment to the Code during the term of the authorisation would need to be the subject of an application for minor variation of the authorisation under section 91A of the TPA, or revocation and substitution of the authorisation under section 91C of the TPA.

6.10. This determination is made on 14 November 2003. If no application for review of the determination is made to the Australian Competition Tribunal, it will come into force on 6 December 2003. If an application is made to the tribunal, the determination will come into force:

- where the application is not withdrawn – on the day on which the Tribunal makes a determination on the review; or
- where the application is withdrawn – on the day on which the application is withdrawn.