Australian Competition & Consumer Commission

Draft 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: 27 June 2003

Authorisation Nos: A90779

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Table of Contents

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 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 doctors by pharmaceutical companies; and
- the regulation of the provision of benefits (financial and otherwise) to doctors by pharmaceutical companies.

The Commission's assessment

Public benefit

Medicines Australia contended that the Code gives rise to a public benefit through the encouragement of rational prescribing practices. The Commission considers that the sections of the Code regulating the provision of information to doctors about prescription medicines generate a small public benefit by supplementing the provisions in the Act prohibiting false and misleading representations.

The Commission considers that doctors' prescribing habits are likely to be influenced by the provision of benefits by pharmaceutical companies. Where this results in doctors prescribing medicines which are not the most appropriate choice for their patient (according to the available scientific evidence), it is likely to harm patients. In addition, it is likely to result in a reduction in the incentive to innovate by pharmaceutical companies.

As a result, the Commission considers that the Code has the potential to generate a public benefit. However, this benefit will only actually be generated if the Code is effectively enforced. The Commission is concerned that this may not be the case as regards the restrictions on the provision of benefits to healthcare professionals. As a result, the Commission considers that the actual public benefit generated by the Code is minimal.

Anti-competitive detriment

The Commission considers that the Code generates minimal anti-competitive detriment. The sections regulating the provision of information do little more than 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 Commission is not satisfied that the public benefit outweighs the public detriment, as is the case here, it is still possible to grant authorisation subject to condition. This is what the Commission proposes to do as regards Medicine Australia's application for authorisation.

The conditions that the Commission proposes to impose are, broadly, as follows:

- that the Code is amended to force drug companies to make public (on Medicines Australia's website) all instances where they propose to provide sponsorship, travel, accommodation and similar promotional benefits to doctors before these benefits are provided. The community scrutiny that this would facilitate is likely to ensure that benefits are not provided which might affect doctors' prescribing habits;

- 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 proposes to **grant** authorisation to the Code subject to the conditions outlined above, for three years.

The Commission will now seek further submissions from interested parties. In addition, parties who are dissatisfied with the Commission's proposed decision may request that the Commission convene a pre-determination conference pursuant to section 90A of the TPA. The Commission will then consider any further submissions received before issuing a final determination.

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, recognises that competition may not always be consistent with the most efficient outcome. It therefore 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. 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.

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[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 flowing from the conduct.

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 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.

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[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.

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

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 draft determination.

Amendments to the Code

1.19. As noted at paragraph 1.14, Medicines Australia requested the Commission to 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.

1.20. 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

1.21. 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

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]

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]

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 that which is the subject of these applications in the United States and the United Kingdom. Further, international bodies such as the World Health

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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.

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.

The Pharmaceutical Benefits Scheme

2.18. 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.[14] 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).[15]

2.19. 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

[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] 'About the PBS', available from www.health.gov.au/pbs.
[15] Productivity Commission *Evaluation of the Pharmaceutical Industry Investment Program* February 2003, p 3.4.

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[16]

2.20. 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.

2.21. 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.

2.22. 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.

[16] 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.[17] The Explanatory Notes record that the majority of breaches of the Code found by the Committee concern this provision.

[17] 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.[18] Upon reasonable request from a healthcare professional, a company must provide additional or substantiating information about its medicines.[19] Claims must be consistent with product information approved by the TGA.[20]

Promotional material

3.9. All promotional and educational material must conform to generally accepted standards of good taste[21] and must not employ unqualified superlatives.[22] Promotional material must be clearly distinguishable as such,[23] and should not make use of health care professionals' names or photographs in a way that is contrary to professional ethics.[24]

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.[25]

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.[26]

Media Releases[27]

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[28]

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

3.14. *Post-marketing surveillance studies*[29] 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

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[18] Section 1.1.
[19] Section 1.2.1.
[20] Medicines Australia submission, 16 January 2003, p3.
[21] Section 1.4.
[22] Section 1.5.
[23] Section 1.10.
[24] Section 1.9.
[25] Section 3.1.1.2.
[26] Section 3.9.2.
[27] Section 9.
[28] Section 8.
[29] 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*[30] 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.[31]

3.18. **Hospitality** offered at educational meetings organised by members "must be simple and modest, and no entertainment should be provided."[32] Further, all hospitality provided by members, directly or indirectly, at educational meetings must be secondary to the educational purpose.[33]

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

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

withstand public, professional and community scrutiny and conform to professional and community standards of ethics and good taste."[34]

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"[35] 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."[36]

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.[37]

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.[38]

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.[39]

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[34] Section 6.4.
[35] Section 6.6.
[36] Section 10.1
[37] Section 6.1.
[38] Section 3.7.
[39] 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.[40]

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.[41]

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.[42]

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[43]

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;

[40] Section 3.8.
[41] Section 3.3.3.
[42] Section 4.
[43] 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.[44]

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.[45]

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

[44] Section 11.2.
[45] 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. [46]

Disciplinary process[47]

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[48]

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[49]

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

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

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.[51]

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.[52]

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[50] Section 13.
[51] Explanatory Notes 13.4.
[52] Explanatory Notes 13.1.

3.49. The member company and the complainant may provide oral submissions to the Appeals Committee.[53]

Members' Compliance Procedures

3.50. Members are responsible for ensuring than an internal compliance procedure exists which is documented and provided to relevant employees.[54]

Reporting of Code breaches[55]

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.[56]

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.[57]

Past complaints[58]

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.

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[53] Explanatory Notes 13.1.
[54] Section 15.
[55] Section 16.
[56] Section 16.2.
[57] Section 12.3.
[58] 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, 1999-00 – 2001-02

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

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 support 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) submitted that:

- consultation on the development of the 14th edition of the Code has not included peak consumer organisations, and Medicines Australia has not sought to increase awareness of the Code amongst consumer groups;
- that pharmaceuticals are increasingly promoting drugs directly to consumers, including through third parties;[59]
- breaches of the Code are addressed by the Committee rather than an external independent body, and the Committee's decisions are not communicated to the public;
- non-members may refuse to have a complaint adjudicated by the Committee, and Medicines Australia is not obliged to refer complaints to the TGA or the ACCC;
- that complaints are sometimes rejected based on technicalities; and
- complaints are not heard in public, and the Committee has only one consumer representative.

4.10. The **Consumers' Federation of Australia** (the CFA) submitted that:

- the Code fails to deliver on a number of vital consumer protection issues;
- the lack of transparency of the complaints process is a key weakness (the CFA suggested that the decisions made and sanctions imposed by the Committee should be published on the internet);
- many members of the public are not aware of the existence of the complaints mechanism; and
- the Committee does not have adequate consumer representation.

4.11. The **Australian Consumers' Association** (the ACA) submitted that:

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

- the Code is inadequate with regard to consumer protection;
- the 14th edition of the Code is not a fundamental improvement over previous versions;
- self-regulation is neither effective nor appropriate in this area;
- the Code is not sufficient to prevent circumvention of the rules against direct-to-consumer advertising by pharmaceutical companies;
- the sanctions are inadequate, fines are rarely imposed, and it is not appropriate that conduct that would be subject to multi-million dollar fines under the TPA is subject to a maximum fine of $200 000; and
- the process by which the Code is administered fails to achieve minimum reasonable standards of fairness and transparency.

4.12. 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.[60]

The Applicant's response to the submissions from interested parties

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

- 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 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 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;
- 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;
- corrective advertising or letters themselves have financial implications for companies found in breach;

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

- companies are not permitted to be legally representing during appeal hearings; and
- whenever the Code is reviewed, Medicines Australia seeks comments from over 20 external organisations.

5. Evaluation

5.1. As indicated in the Introduction to this draft 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).[61] 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. However, 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).

5.4. Further, the Commission considers it unlikely that, in the absence of the Code, the provision of possibly significant benefits is likely to occur. At the least, pharmaceutical companies will conduct promotional activities without any restraint whatsoever (for example, the Commission considers it unlikely that without the Code, pharmaceutical companies will 'reward' doctors who issue a large number of prescriptions for a certain product)are likely to use similar strategies to those currently used and which the Code seeks to address. For example, companies may subsidise conferences (including the travel and accommodation costs of attending healthcare professionals), or provide hospitality and entertainment to doctors attending product information presentations.

The relevant market

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

5.6. The Commission may use 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 comprehensively define the relevant markets as it may be apparent that a net public benefit will or will not arise regardless of the scope of the defined market.

5.7. 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.

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[61] See, for example, *Re Australasian Performing Rights Association* (1999) ATPR ¶41-701.

5.8. The Commission notes that it may be possible to identify regional markets or markets associated with particular classes of prescription medicines. However, the Code will 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 draft determination refers to the market for prescription medicines when describing the relevant market.

Characteristics of the market for prescription medicines

Information imperfections

5.9. 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.

5.10. 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.

5.11. 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).

5.12. 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.[62]

5.13. 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.

5.14. 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)

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

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

5.16. 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 5.26, 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

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

5.18. 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).

5.19. 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[63]).

5.20. 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.[64]

5.21. 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).

5.22. 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

5.23. 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 2.18 - 2.19).[65] As a result, decisions by doctors about

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

which medicines to prescribe for their patients appear to have little or no effect on the price of those medicines.

Public Benefit

5.24. Broadly, the sphere of regulation encompassed by the Code can be divided into two categories:

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

Regulation of the provision of information

5.25. 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).

5.26. 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

5.27. 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.

5.28. On one hand, doctors are subject to ethical obligations requiring them to give primacy to the welfare of their patients. This could be taken to indicate that the provision of benefits to doctors by pharmaceutical companies is unlikely to achieve the outcome intended (ie to influence the doctor's choice of prescription medicine).

5.29. On the other hand, it seems clear that pharmaceutical companies would offer benefits to healthcare professionals absent the Code. The fact that pharmaceutical companies are prepared to offer such benefits suggests that they anticipate that they will be able to influence a doctor's choices.

5.30. The ACA noted a review published in the *Journal of the American Medical Association* which found that:

> Company-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".[66]

5.31. 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.[67]

5.32. In addition, the prohibition on advertising to consumers suggests that the TGA has some concern that doctors could be influenced by their patients to choose a drug other than the one which they would choose on a purely scientific basis. Further, the fact that the AMA has produced guidelines on the matter highlights that doctors may have a certain level of susceptibility to influence.

5.33. In light of the above, the Commission considers that doctors' prescribing habits are likely to be influenced by the provision of benefits by pharmaceutical companies. This is likely to result in doctors prescribing medicines which may not be the most appropriate choice for their patient (according to available scientific evidence). This is likely to 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.

5.34. In addition, it is likely to result in a reduction in the incentive to innovate to which pharmaceutical companies are currently subject. In other words, 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, this reduction in the incentive to innovate is likely to be small given the relatively small size of the Australian prescription medicines market eg in comparison to the United States.

5.35. As a result, the Commission considers that the Code has the potential to generate a public benefit by assisting in ensuring that doctors' prescribing practices are rational and appropriate.

5.36. However, this benefit will only *actually* be generated if, at the least, members believe that they are likely to be caught if they breach the Code. The Commission has significant concerns that this is not the case as regards 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,[68] this percentage seems very low. It is also low in absolute terms.

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[66] ACA submission, 25 February 2003, p3.
[67] Ibid.
[68] For example, see 'The Doctor's Gravy Train', *Sunday* Program, Channel Nine, 5 August 2001.

5.37. Similarly, the Code will only generate public benefits if MA members consider that the penalties for breaching the Code are sufficiently high to provide an incentive for them comply with it.

5.38. Fines may be imposed on members for breaching the Code, with the maximum fine now being $200 000.

5.39. The issue of fines as a sanction can be problematic.The need for fines to be proportional to the gravity of the breach for which they have been imposed is likely to limit the extent to which the fines available are capable of deterring members from engaging in prohibited conduct. Disproportionately large fines may simply result in companies renouncing their membership of Medicines Australia.

5.40. Corrective advertising or the provision of retractive statements are also sanctions that are available to the Committee, but these sanctions are most likely to be applied in relation to the provision of information in breach of the Code and are unlikely to be of use when dealing with breaches of the sections relating to the provision of benefits to healthcare professionals.

5.41. In light of these issues, alternative penalties take on greater significance. In particular, a potentially important deterrent to Medicines Australia members breaching the Code is the prospect of damage to their reputation by the publication of the fact that they have breached the Code. However, information about breaches contained in the Committee's Annual Report is not generally available outside the healthcare professions – in particular, it is not available to consumers except where the breach involves activities directed towards the general public.[69]

5.42. Medicines Australia submitted that complaints about activities towards the general public typically constitute around one-sixth of total complaints.[70] Consequently, the outcome of the vast majority of complaints is not available to the public. This substantially limits the efficacy of the Code.

5.43. The Commission considers that the online publication of the Committee's report may increase the efficacy of the enforcement process, as the negative publicity that is likely to be generated by the publication of the Committee's report on the Medicines Australia website is likely to be a useful deterrent.

5.44. In light of the concerns about the practical enforcement of the Code outlined above, the Commission considers that the actual public benefit generated by the Code is minimal.

Anti-competitive detriment

Regulation of the provision of information

i) Effect on competition

[69] See, for example, Medicines Australia submission, 7 April 2003, p3.
[70] Ibid.

5.45. 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).[71]

5.46. 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).[72]

5.47. 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.[73]

5.48. 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.[74]

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

5.50. 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?

5.51. 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.

5.52. However, the Code also requires that promotional activities be "able to withstand public and professional scrutiny and conform to professional and

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[71] Section 52, TPA.
[72] ACA submission dated 25 February 2003, p 5.
[73] ACA submission dated 25 February 2003, p 5.
[74] 'Drug advertising: truths, half-truths and few statistics' Volume 177 MJA 16 September 2002 p 285.

community standards of ethics and good taste".[75] This goes beyond the TPA prohibition on false and misleading representations.

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

ii) Public detriment

5.54. 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

5.55. The Code restrict 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.

5.56. At paragraph 5.33, the Commission concluded that the provisions of benefits to doctors was likely to influence prescribing patterns. A restriction on the provision of benefits is therefore likely to be a significant restriction on competition in this area.

ii) Public detriment

5.57. 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 5.20, this largely reduces to whether the restriction in the Code affects the ability of pharmaceutical companies to develop new drugs in any significant way.

5.58. 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.

5.59. 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

[75] For example, section 6.6.

unlikely to significantly detract from pharmaceutical companies' ability to fund research. Further, the Commission has raised questions about the extent to which the Code is enforced. In light of this, tthe Commission would also need credible evidence that any foregone revenue was likely to be directed to research and development. Consequently, 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

5.60. The Commission has concluded that the Code generates minimal public benefit and detriment.

5.61. 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.

5.62. 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. This is what the Commission proposes to do as regards Medicine Australia's application for authorisation.

Conditions

5.63. The Commission proposes to **grant** authorisation subject to the following conditions.

Condition C1

The Code shall be amended to require members to provide Medicines Australia with the following information at least one month before the relevant educational meeting occurs:

- **the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and general details of any hospitality and entertainment associated with any educational meeting which a member proposes to subsidise by contributing funds or goods or services to the organising body (or bodies);**

- **the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality and entertainment associated with any educational meeting in relation to which a**

member proposes to provide funds or goods or services to the organising body (or bodies) in return for allowing the member to promote its products or itself in any way at the meeting or at any event (including entertainment) associated with the meeting;

- **all instances where a member proposes to provide funding or goods or services to a body where there is a reasonable prospect that the funding or goods and services or funding saved by the body by not having to purchase the goods and services will be used to subsidise an educational meeting. Where it is reasonable to expect that the funding or goods and services or funding saved by not having to purchase the goods or services will be used to subsidise a specific educational meeting, the member shall provide the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality and entertainment associated with that meeting;**

- **the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality to be provided in relation to any educational meeting proposed to be organised by a member;**

- **general details of any proposed opportunities for unstructured individual entertainment during educational meetings organised by a member; and**

- **the number of persons attending an educational meeting (whether organised by the member or not) whose attendance a member proposes to subsidise, partially or wholly, in any way (for example, travel and accommodation costs); the proportion of these persons who are medical or healthcare practitioners; the medical specialties in which these medical practitioners practice; and the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality and entertainment associated with the educational meeting.**

This information (including the name of the relevant Medicines Australia member) shall be accessible by the public through Medicines Australia's website.

If any of the information listed above changes during the month preceding the relevant education meeting, Medicines Australia must be provided with the amended information within 3 working days.

Except in exceptional circumstances (for example, where there are significant technical difficulties relating to Medicines Australia's website generally), Medicines Australia shall place (original or amended) information on its website within 5 working days of receiving it.

Educational meetings include conferences, symposiums, satellite meetings, seminars and any other type of meeting (with one exception) where one objective is to disseminate information about medical, pharmaceutical or similar matters. It does not include meetings solely between medical representatives of Medicines Australia members and some or all of the healthcare professionals working within a single practice or healthcare facility.

The Code shall be amended to provide that any failure by Medicines Australia members to provide the information listed above within the required timeframes is a severe breach of the Code.

5.64. 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.

Condition C2

Medicines Australia shall make its Code of Conduct Committee Annual Report publicly available on its website.

5.65. The Commission considers that the imposition of this condition addresses concerns about the transparency of the complaints process.

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.

5.66. 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*.

5.67. 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 proposes to grant authorisation for a period of three years.

Amendments to the Code

5.68. The authorisation that is proposed to be granted is in respect of the Code as it stands at the time that authorisation is granted. As a result, 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.

Other issues

Involvement of consumer groups

5.69. The ACA, CFA and CHFA were dissatisfied with the level of consumer representation on the Code Committee and Appeals Committee.[76] The Commission notes that the Code is predominantly directed at regulating the relationship between pharmaceutical companies and healthcare professionals. The Commission accepts, however, that consumer groups have an interest in the outcome of the process and considers that the current level of consumer representation on the Committee is sufficient in this regard.

Misleading and deceptive conduct

5.70. With regard to the concern expressed by some consumer groups that the level of fines is significantly lower than those that could be imposed by a Court should a breach of section 52 or 53 of the TPA (prohibiting misleading and deceptive conduct) be found, the Commission notes that authorisation does not, and cannot, extend to Part V of the TPA. Accordingly, members of Medicines Australia are still liable for any breaches of section 52 or 53 of the TPA and will not be able to avoid Court imposed sanctions by paying any fine under the Code.

Self-regulation

5.71. 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

5.72. 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. [77] However, this issue is not directly regulated by the Code and in fact appears to relate to the TG Act's prohibition of direct-to-consumer advertising.

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

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

- **the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and general details of any hospitality and entertainment associated with any educational meeting which a member proposes to subsidise by contributing funds or goods or services to the organising body (or bodies);**

- **the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality and entertainment associated with any educational meeting in relation to which a member proposes to provide funds or goods or services to the organising body (or bodies) in return for allowing the member to promote its products or itself in any way at the meeting or at any event (including entertainment) associated with the meeting;**

- **all instances where a member proposes to provide funding or goods or services to a body where there is a reasonable prospect that the funding or goods and services or funding saved by the body by not having to purchase the goods and services will be used to subsidise an educational meeting. Where it is reasonable to expect that the funding or goods and services or funding saved by not having to purchase the goods or services will be used to subsidise a specific educational meeting, the member shall provide the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality and entertainment associated with that meeting;**

- **the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality to be provided in relation to any educational meeting proposed to be organised by a member;**

- **general details of any proposed opportunities for unstructured individual entertainment during educational meetings organised by a member; and**

- **the number of persons attending an educational meeting (whether organised by the member or not) whose attendance a member proposes to subsidise, partially or wholly, in any way (for example, travel and accommodation costs); the proportion of these persons who are medical or healthcare practitioners; the medical specialties in which these medical practitioners practice; and the name, date, venue, duration, subject matter, general description of likely attendees (for example, members of particular medical specialty or specialties) and details of any hospitality and entertainment associated with the educational meeting.**

This information (including the name of the relevant Medicines Australia member) shall be accessible by the public through Medicines Australia's website.

If any of the information listed above changes during the month preceding the relevant education meeting, Medicines Australia must be provided with the amended information within 3 working days.

Except in exceptional circumstances (for example, where there are significant technical difficulties relating to Medicines Australia's website generally), Medicines Australia shall place (original or amended) information on its website within 5 working days of receiving it.

Educational meetings include conferences, symposiums, satellite meetings, seminars and any other type of meeting (with one exception) where one objective is to disseminate information about medical, pharmaceutical or similar matters. It does not include meetings solely between medical representatives of Medicines Australia members and some or all of the healthcare professionals working within a single practice or healthcare facility.

The Code shall be amended to provide that any failure by Medicines Australia members to provide the information listed above within the required timeframes is a severe breach of the Code.

Condition C2

Medicines Australia shall make its Code of Conduct Committee Annual Report publicly available on its website.

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 proposes to authorise 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, for example, an amendment to the Code or the Guidelines accompanying the Code amounts to a material change in circumstances.

6.9. Further, the authorisation that is proposed to be granted is in respect of the Code as it stands at the time that authorisation is granted. As a result, 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.

Further submissions

6.10. The Commission will now seek further submissions from interested parties. In addition, the applicant or any interested party may request that the Commission hold a pre-determination conference pursuant to section 90A of the TPA.