Australian Competition & Consumer Commission

Determination

Applications for Revocation and Substitution

lodged by

Medicines Australia Inc

in respect of

Medicines Australia Inc

Code of Conduct 15th Edition

Date: 26 July 2006

Authorisation Nos:	A90994 A90995 A90996	**Commissioners:** Samuel Sylvan King
Public Register No:	C2005/1917	Martin McNeill Smith Willett

Executive Summary

The ACCC **grants** authorisation, subject to a condition, to Edition 15 of the Medicines Australia Code of Conduct for three years.

The Applications

On 30 November 2005, Medicines Australia lodged an application for revocation of authorisations A90779 and A90780 and their substitution with authorisations A90994, A90995 and A90996 (the current applications).

Medicines Australia is the national association representing the prescription medicines industry in Australia. It is seeking authorisation for Edition 15 of its Code of Conduct (the Code). Compliance with the Code is a requirement of membership of Medicines Australia. The Therapeutic Goods Administration also requires that promotional material for products on the Australian Register of Therapeutic Goods complies with the Code.[1]

The Code

The Code seeks to regulate certain activities of pharmaceutical companies. These can be divided into three broad categories:

- the regulation of the provision of information about prescription medicines to health care professionals and the public by pharmaceutical companies
- the regulation of the provision of benefits (financial and otherwise) to health care professionals by pharmaceutical companies and
- the regulation of members' conduct in other regards, such as their supply of starter packs of prescription medicines.

The ACCC's assessment

The ACCC notes that in assessing the Code, it must compare the public benefit and detriment that are likely to result from the arrangements compared to the counterfactual, that is, the 'future without' the authorisation in place. The ACCC considers that if authorisation were not granted, the most likely counterfactual would be that the Code would not come into effect, and the activities of pharmaceutical companies would only be governed by existing legislation.

Public benefit

The ACCC considers that the Code could result in a public benefit through:

- encouraging compliance with the legislative prohibitions on misleading and deceptive conduct and advertising to consumers
- encouraging rational prescribing practices through regulating pharmaceutical companies activities in providing information and benefits to healthcare professionals and

[1] Medicines Australia submission, 30 November 2005, p2.

- increasing public safety through regulating members' supply, storage and handling of starter packs.

However, the ACCC continues to have real concerns about whether the Code is effectively enforced. The ACCC also doubts whether the code can effectively regulate company behaviour without an appropriate level of transparency. It therefore considers that the extent of the public benefit that will *actually* result from the Code is uncertain.

Public detriment

The ACCC is also of the view that the Code is likely to result in minimal public detriment. Subject to one amendment (relating to the promotion of medicine delivery devices), the ACCC considers that the Code is unlikely to significantly affect member companies' ability to compete with one another, and hence is unlikely to result in significant anti-competitive detriment. It also considers that the Code is likely to result in minimal public detriment arising other than through its effect on competition.

Condition

The ACCC considers that it is difficult to precisely determine the potential (but not certain) public benefit arising from the code. It therefore considers that there is some uncertainty about whether the Code will result in a net public benefit. To ensure that the proposed arrangements satisfy the public benefit test, the ACCC grants authorisation subject to a condition requiring the publication of details of educational events held over the year. This condition is designed to improve transparency in pharmaceutical companies' provision of benefits to healthcare professionals. The ACCC considers it will increase confidence in the work of the Monitoring Committee and provide an assurance that the Code of Conduct is effectively enforced.

The ACCC notes that a number of interested parties expressed concern with the Code and recommended improvements. While the ACCC notes these concerns, its role in assessing applications for authorisation is to consider the arrangements before it. It is not to craft an 'ideal' code.

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List of Abbreviations

ACA	Australian Consumers' Association
ACCC	Australian Competition and Consumer Commission
ADGP	Australian Divisions of General Practice
ADRAC	Adverse Drug Reactions Advisory Committee
AMA	Australian Medical Association
ANF	Australian Nursing Federation
ANZTPA	Australia New Zealand Therapeutic Products Authority
ARR	Absolute Risk Reduction
ARTG	Australian Register of Therapeutic Goods
ASCEPT	Australian Society of Clinical and Experimental Pharmacologists and Toxicologists
ASMI	Australian Self-Medication Industry
CHC	Complementary Healthcare Council of Australia
CHF	Consumers' Health Forum of Australia
The Galbally Review	National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation
MDD	Medicine Delivery Device
NCCTG	National Co-ordinating Council on Therapeutic Goods
NNT	Numbers Needed to Treat
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PFP	Product Familiarisation Program
QUM	Quality Use of Medicines
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TG Act	*Therapeutic Goods Act 1989* (Cth)
TGA	Therapeutic Goods Administration
TPA	*Trade Practices Act 1974* (Cth)

1. Introduction

1.1 The Australian Competition and Consumer Commission (the ACCC) is the independent Australian Government 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, resulting in a greater choice for consumers in price, quality and service.

1.2 The TPA, however, allows the ACCC 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 ACCC for what is known as an 'authorisation.'

1.3 Broadly, the ACCC may 'authorise' businesses to engage in anti-competitive conduct where it is satisfied that the public benefit from the conduct outweighs any public detriment.

1.4 The ACCC conducts a comprehensive public consultation process before making a decision to grant or deny authorisation.

1.5 Upon receiving an application for authorisation, the ACCC invites interested parties to lodge submissions outlining whether they support the application or not, and their reasons for this.

1.6 The TPA requires that the ACCC then issue a draft determination in writing proposing to either grant the application (in whole, in part or subject to conditions) or deny the application. In preparing a draft determination, the ACCC will take into account any submissions received from interested parties.

1.7 Once a draft determination is released, the applicant or any interested party may request that the ACCC hold a conference. A conference provides interested parties with the opportunity to put oral submissions to the ACCC in response to the draft determination. The ACCC will also invite interested parties to lodge written submissions on the draft.

1.8 The ACCC 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. Should the public benefit outweigh the public detriment, the ACCC may grant authorisation. If not, authorisation may be denied. However, in some cases it may still be possible to grant authorisation where conditions can be imposed which sufficiently increase the public benefit or reduce the public detriment.

1.9 Under section 91C of the TPA, the ACCC may revoke an existing authorisation and grant another authorisation in substitution for the one revoked, at the request of the person to whom the authorisation was granted, or another person on behalf of such a person. The ACCC must consider the substitute authorisation in the same manner as the standard authorisation process (outlined at paragraphs 1.3 – 1.8).

Medicines Australia

1.10 Medicines Australia is the national association representing the prescription medicines industry in Australia. It states that its members represent more than 90 percent of the prescription market and are engaged in the research, development, manufacture, marketing, sale and export of prescription medicines. Medicines Australia promotes the interests of the industry by encouraging a favourable investment environment, working on behalf of its members in an advocacy and consultative capacity with government and non-government organisations in Australia and overseas.[1]

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.[2]

The Applications

1.12 On 30 November 2005, Medicines Australia lodged an application for revocation of authorisations A90779 and A90780 and their substitution with authorisations A90994, A90995 and A90996 (the current applications).

1.13 Authorisations A90779 and A90780 (the previous authorisations) were themselves a revocation and substitution of clearance C23698, granted in 1977 in respect of the 4th edition of the Code.

1.14 The ACCC issued a determination granting the previous authorisations on 14 November 2003, subject to three conditions.

1.15 In lodging the current applications Medicines Australia has sought substitute authorisations under sections 88(8) and 91C, as appropriate, to:

- make or give effect to a contract, arrangement or understanding where a provision of the contract, arrangement or understanding is, or may be, an exclusionary provision within the meaning of section 45 of the TPA (A90994)

- make or give effect to a provision of a contract, arrangement or understanding, a provision of which has or may have the effect, of substantially lessening competition within the meaning of section 45 of the TPA (A90995) and

- engage in conduct that constitutes or may constitute the practice of exclusive dealing (A90996).

1.16 Medicines Australia is seeking authorisation for a period of five years.

1.17 A copy of the Code is available from the ACCC's website. Key provisions are outlined in Chapter 3 of this draft determination.

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[1] Information in this paragraph was sourced from the Medicines Australia website at www.medicinesaustralia.com.au , accessed 7 March 2006.
[2] Medicines Australia 30 November 2005, p2.

Draft determination and interim authorisation

1.18 On 26 April 2006, the ACCC issued a draft determination proposing to grant authorisation, subject to one condition, for three years.

1.19 At the time of issuing its draft determination the ACCC also granted interim authorisation until the date the ACCC's final determination comes into effect, or if circumstances warrant revocation or amendment of interim authorisation at an earlier stage, until such date as interim authorisation is revoked or amended.

Chronology of the applications

1.20 A chronology of the Commission's assessment of the applications in relation to the 15th edition of the Code is at Table 1 below.

Table 1: Chronology of the ACCC's assessment

Date	Action
30 November 2005	Medicines Australia lodged applications for revocation of authorisations A90779 and A90780 and their substitution with authorisations A90994-96 in relation to the 15th edition of the Code. Medicines Australia also sought interim authorisation in respect of the applications.
5 December 2005	The ACCC sought submissions from interested parties on the applications and the request for interim authorisation.
9 January 2006	Medicines Australia provided an initial response to interested parties' submissions on its request for interim authorisation.
24 January 2006	Medicines Australia provided an additional response to interested parties' submissions.
25 January 2006	The ACCC denied Medicines Australia's request for interim authorisation, but noted that it would reconsider the request at the draft determination stage.
31 January 2006	The ACCC requested further information from Medicines Australia.
8 March 2006	Medicines Australia provided a further response to interested parties' submissions, and further information requested by the ACCC.
15 March 2006	Medicines Australia provided further information as requested by the ACCC.
7 April 2006	Medicines Australia provided further information as requested by the ACCC.
26 April 2006	ACCC issued draft determination.
4 May 2006	Medicines Australia provided comments on the draft determination
23 May 2006	Due date for interested parties who wished to provide written submissions on the draft determination.

7 June 2006	ACCC wrote to Medicines Australia outlining a proposed reporting regime for condition C1
8 June 2006	Medicines Australia provided a further response to interested parties' submissions
14 June 2006	Meeting with Medicines Australia representatives
28 June 2006	Medicines Australia provided comments on the proposed reporting regime for condition C1
6 July 2006	Meeting with Medicines Australia representatives
13 July 2006	Medicines Australia provided further comments on the proposed reporting regime for condition C1
21 July 2006	ACCC wrote to Medicines Australia regarding likely reporting requirements
25 July 2006	Medicines Australia reply to ACCC letter of 21 July 2006
26 July 2006	ACCC issued final determination

2. The Prescription Medicine Industry

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 can only be obtained on the instructions of a medical practitioner.

2.2 According to Medicines Australia, the Australian pharmaceutical industry comprises 1.3 per cent of the world pharmaceutical market, with a turnover of $7.8 billion. The industry, broadly defined, employs 36 000 people across at least 300 firms and institutions, including manufacturing, research and wholesaling. It employs approximately 15 000.[1]

2.3 Medicines Australia has 39 full and nine affiliate member companies. It states that its members represent over 90 per cent of the Australian prescription medicine market.[2]

2.4 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 (ASMI)[3] represents this sector).

The regulation of therapeutic goods

State and Territory regulation

2.5 Each state and territory has its own laws that determine where consumers can buy a particular drug or poison, and how it is to be packaged and labelled. However, State and Territory Governments classify the vast majority of drugs and poisons in accordance with the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) to achieve a uniform national approach to the scheduling of substances and uniform labelling and packaging requirements. The SUSDP is administered by a committee of Commonwealth, state and territory government representatives known as the National Drugs and Poisons Scheduling Committee.[4]

2.6 For example, in New South Wales, a Poisons List proclaimed under the *Poisons and Therapeutic Goods Act 1966* (NSW) 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).[5]

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[1] Medicines Australia website, *Industry*, http://www.medicinesaustralia.com.au/pages/page4.asp (accessed 22 February 2006).
[2] Medicines Australia website, *Our Role*, http://www.medicinesaustralia.com.au/pages/page26.asp (accessed 22 February 2006).
[3] See www.asmi.com.au.
[4] This committee is established under Part 5B of the *Therapeutic Goods Act 1989* (Cth).
[5] NSW Health Pharmaceutical Services Branch *Guide to Poisons and Therapeutic Goods Legislation for Medical Practitioners and Dentists* (updated January 2006), available from www.nsw.health.gov.au.

The Therapeutic Goods Act

2.7 The *Therapeutic Goods Act 1989* (the TG Act) and the associated Regulations and Orders set out the regulatory framework for the manufacture, promotion and supply of medicines and medical devices in Australia.

2.8 Medicines must be *listed* or *registered* on the Australian Register of Therapeutic Goods (ARTG) before they can be sold in Australia. [6]

2.9 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.

2.10 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).

2.11 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.

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

The Therapeutic Goods Administration

2.13 The Therapeutic Goods Administration (the TGA) is currently responsible for administering the TG Act. However, it is anticipated that, in the near future, it (and its New Zealand counterpart, the NZ Medicines and Medical Devices Safety Authority) will be replaced by the Australia New Zealand Therapeutic Products Authority (the ANZTPA). The ANZTPA will assume responsibility for regulating therapeutic products including prescription and over-the-counter medicines, complementary medicines, medical devices and blood products in both countries.

2.14 The start date for the ANZTPA is expected to be after the second half of 2007.[7]

Promoting prescription medicines

2.15 The TG Act effectively prohibits manufacturers from directly promoting prescription medicines to the general public.[8] The ACCC understands that this

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

[7] 'Joint Australia and New Zealand Therapeutic Products Authority planned for next year', Meeting Outcomes Statement, 11 May 2006, http://www.anztpa.org/media/060511tpimc.htm (accessed 16 May 2006).

[8] 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 relates to a 'designated therapeutic good' and has been approved by the Secretary of the Department of Health and Ageing pursuant to regulation 5G of the Therapeutic Goods Regulations 1990. 'Designated therapeutic

prohibition will remain after the ANZTPA starts up, even though direct-to-consumer advertising is permitted in New Zealand.[9]

2.16 The TG Act does allow pharmaceutical manufacturers to promote prescription medicines to healthcare professionals. However, the TGA, through its marketing approval letter, requires that promotional material for prescription medicines registered or listed on the ARTG to comply with the requirements of the Code.[10] This requirement exists regardless of whether or not the company is a member of Medicines Australia.

2.17 In addition to the regulation provided by the Code, the marketing of prescription medicines is also regulated through the prohibitions on misleading and deceptive conduct contained in the TPA.

2.18 Most non-prescription medicines[11] and medical devices[12] may be marketed directly to consumers provided the advertisements comply with the Therapeutic Goods Advertising Code. Certain forms of advertising of non-prescription medicines (including broadcast and print media) must first be approved by the ASMI or the Complementary Healthcare Council of Australia (CHC).[13]

The Pharmaceutical Benefits Scheme

2.19 The Australian Government's Pharmaceutical Benefits Scheme (the PBS) subsidises prescription medicines as a means of providing the Australian community with affordable access to necessary medication. Around 80 per cent of prescriptions dispensed in Australia are for products that are listed on the PBS (or its equivalent for war veterans, the Repatriation Pharmaceutical Benefits Scheme).[14]

2.20 The Pharmaceutical Benefits Advisory Committee (PBAC) recommends which medicines should be listed on the PBS. In making this recommendation, it is required to consider the effectiveness and cost of a proposed medicine, including by comparing the effectiveness and cost of that therapy with that of alternative therapies.[15] The PBAC's membership includes doctors, other health professionals and a consumer representative.[16]

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goods' are goods other than those included in Schedules 3 (unless included in Appendix H), 4 and 8 to the Poisons Standard. This effectively prohibits direct-to-consumer advertising.

[9] Trans Tasman Agency to Regulate Therapeutic Products, *Description of the joint regulatory scheme for the advertising of therapeutic products*, December 2005, p8.

[10] Medicines Australia 30 November 2005, p2.

[11] Except for certain goods contained in Schedule 3 of the SUSDP (pharmacist only medicines).

[12] Defined in s 41BD of the TG Act.

[13] *Regulation of advertising of therapeutic goods in Australia*, TGA website, http://www.tga.gov.au/docs/html/advreg.htm, accessed 3 March 2006.

[14] *About the PBS*, Department of Health and Ageing website, http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-aboutus.htm-copy2, accessed 22 February 2006.

[15] Section 101, *National Health Act 1953* (Cth).

[16] Listing Medicines on the PBS, Department of Health and Ageing website, http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-list_on_pbac.htm, accessed 27 March 2006.

3. The Code of Conduct

3.1 Edition 15 of the Code is divided into 16 sections and two appendices. The key provisions are outlined below. Where a provision is new or has been amended since Edition 14, this is noted in the footnotes.

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)
- the conduct of company representatives
- the size, labelling, storage and distribution of product Starter Packs
- marketing research conducted by pharmaceutical companies
- the provision of benefits provided by pharmaceutical companies to healthcare professionals, including through their involvement in educational meetings and through sponsorship
- other benefits offered to health care professionals by pharmaceutical companies.

3.3 The Code includes explanatory notes which elaborate on the provisions of the Code. It is also supported by Guidelines, which are designed to be read in conjunction with the Code. Authorisation was not sought for the Guidelines, although a copy was provided to the ACCC. 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.

3.4 Unless otherwise indicated, the provisions outlined below are found in the Code. Terms which are underlined (eg starter pack) are defined in the Code's glossary.

Provision of information about prescription medicines

Nature and availability of information and claims

3.5 The onus is on companies, their employees and advisors to ensure that the content of all promotional and medical claims is balanced, accurate, correct and fully supported.[1]

3.6 All information, claims and graphical representations provided to healthcare professionals or the general public must be current and not be misleading.[2] Promotional material must be clearly distinguishable as such,[3] and conform to generally accepted standards of good taste.[4]

[1] Section 1.1.
[2] Section 1.3.
[3] Section 1.10.
[4] Section 1.4.

3.7 Products that have not been approved for registration by the TGA must not be promoted.[5]

Product information

3.8 Certain types of promotional material must include or be accompanied by product information, abridged product information or minimum product information.[6] There are specified requirements for each category of information,[7] but all must facilitate easy reading,[8] conform to minimum typeface sizes[9] and contain specific information.[10]

Promotional material

3.9 All promotional material that is not a brand name reminder must include a clear and prominent statement drawing the reader's attention to any PBS listing, and restrictions or non-availability through the PBS.[11]

3.10 There are provisions setting out the specific requirements for:[12]

- Journal advertising (including primary, secondary and short advertisements)
- Reference manual advertising
- Printed promotional material, whether handed directly to a healthcare professional or transmitted by other means
- mailings
- audiovisual promotional material
- computer promotional material (eg promotional material such as software programs used by company representatives during interchanges with healthcare professionals)
- the internet and
- restricted access television advertising

3.11 Company commissioned articles (also known as advertorials) must be clearly identified as such. They must conform to the provisions in section 1 of the Code. Where they contain promotional claims, the article must comply with the requirements for a primary advertisement (or a secondary advertisement if a primary advertisement appears elsewhere in the publication).[13]

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[5] Section 1.3.1.
[6] Section 2.
[7] Section s 2.1 – 2.4.
[8] Explanatory notes, section 2.
[9] Sections 2.1.1, 2.2.1, 2.3.1.
[10] Sections 2.1.2-3, 2.2.2-2.2.3, 2.3.2.
[11] Section 3.
[12] See sections 3.1, 3.2, 3.3 (amended), 3.4, 3.6, 3.7, 3.8, 3.10.
[13] Section 3.1.4 (amended).

Advertising in electronic prescribing software packages[14]

3.12 An advertisement in an electronic prescribing software package must comply with certain requirements, depending on whether it is a primary or short advertisement. A company cannot negotiate or accept any offer from a software manufacturer that results in the presentation of its own product over a competitor's.

3.13 In addition, companies must ensure that no advertisements are placed with clinical tools or patient education materials that may be used for consultation or discussion with a patient.[15]

Trade displays at educational meetings etc[16]

3.14 Trade displays at educational symposia, congresses and satellite meetings must meet certain requirements. These include that product information must be available at the stand, and starter packs must not be available for collection from unattended stands.

Provision of benefits to healthcare professionals

3.15 Benefits must not be offered to healthcare professionals to influence them in their prescribing or dispensing of pharmaceutical products.[17]

3.16 There is a blanket prohibition on companies providing items or services to employees or family members of healthcare professionals.[18] A similar prohibition applies to items or services provided to healthcare professionals unless they are sanctioned by the Code, such as:

- Brand name reminders[19] (items designed to remind healthcare professionals of the existence of a product) must include certain information about the product. They should be of token value (less than $20[20]), and only be relevant to the working environment of a healthcare professional (eg mugs, pens, boxes of tissues). Items that are more likely to be used in the home or for recreational activities (eg beach towels) are unacceptable.[21]

- Prizes in competitions which meet certain criteria, including that they are designed to increase medical knowledge, and have prizes of low monetary value and which are directly relevant to the practice of medicine.[22] The Guidelines recommend the maximum values for a prize as $500 for an individual prize (or $5,000 if an educational item), with the total value of

[14] Section 3.9.
[15] Section 3.9.1 (new).
[16] Section 6.1.
[17] Section 10.
[18] Section 3.11.
[19] Section 3.12.
[20] Guidelines, p 19.
[21] Explanatory note, section 3.12. The requirement that they be relevant to the working environment is new.
[22] Section 3.13.

the prize pool for competitions associated with a particular product limited to $50,000 per calendar year.[23]

- Sponsorship of activities involving healthcare professionals (see 3.21 below).

- Hospitality (see 3.17 below)

- Medical educational material[24]

Hospitality[25]

3.17 Any hospitality provided by companies to healthcare professionals must be secondary to the educational purpose of the meeting. The venue and location at which hospitality is provided must be conducive to education and learning and not chosen for its leisure or recreational facilities.[26]

3.18 Meals provided at educational meetings should not be extravagant or exceed standards which would meet professional and community scrutiny.[27]

3.19 No entertainment should be provided,[28] although an exception to this is that educational meetings of two or more day's duration may include a modest opportunity (no more than half a day[29]) for unstructured and individual recreational activities at the delegate's own expense.[30]

Travel[31]

3.20 Companies may subsidise healthcare professionals' travel and accommodation costs to attend educational meetings etc. provided that the meeting is directly related to the healthcare professional's area of expertise. Companies must not subsidise or pay for family members' travel costs.

Sponsorship[32]

3.21 This must meet certain requirements, including that companies must develop guidelines on how they select the healthcare professionals they sponsor.

3.22 There are also specific requirements for companies sponsoring a healthcare professional to provide support for medical practice activities.[33] These are activities undertaken within a medical practice which are sponsored by a pharmaceutical company. Examples may include a diabetes nurse educator, a

[23] Guidelines, p20-21.
[24] Section 10.4.
[25] Section 6.2 (in respect of involvement in educational symposia, congresses etc) and 10.2 (more generally).
[26] Section 10.2.
[27] Section 6.2.2.
[28] Sections 6.2.2, 10.1.
[29] Explanatory note, section 10.1
[30] Section 10.1.
[31] Sections 6.8 (in respect of involvement in educational symposia etc) and 10.3 (generally).
[32] Section 7.
[33] Section 7.1.5 (new).

practice nurse who conducts ambulatory blood pressure monitoring, or a nurse or other qualified health professional who reviews patient medical records and advises doctors on quality use of medicines, clinical monitoring or follow up.[34]

Consultants and advisory boards[35]

3.23 Companies may seek the services of suitably qualified and experienced healthcare professionals to provide advice and guidance on a range of matters. Such professionals can be offered remuneration and reimbursement for reasonable travel, accommodation and meal expenses incurred.

3.24 All relationships between companies and consultants and advisory board members must meet certain criteria, including:

- A legitimate need for the services must have been identified in advance of requesting them. A document summarising the purpose, objectives, justification and size/number of the advisory boards must be prepared and available for scrutiny should a complaint be lodged.[36] There must also be a written contractual agreement outlining the nature and duration of the services to be provided.

- The number of healthcare professionals retained should not be greater than the number reasonably necessary to achieve the identified purpose. The Guidelines recommend 8–12 would be appropriate.[37] The formulation of multiple advisory boards for a single product must be justifiable.

- Meetings must be held in Australia and conform with the venue requirements in section 6, except in certain circumstances.

- Interactions must not include entertainment, nor should companies subsidise the costs of family or companions of consultant or advisory board members.

Relationship with health consumer organisations[38]

3.25 Companies may enter into relationships with health consumer organisations. When entering into such a relationship, they should consider the principles set out in *Working Together – A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies*.

Company representatives[39]

3.26 Company representatives should ensure that their visits do not cause inconvenience to healthcare professionals. They must not use any deception to obtain an appointment, or pay a fee to gain access to a healthcare professional,

[34] Medicines Australia, 8 March 2006, p15.
[35] Section 10.6 (new)
[36] Explanatory note, section 10.6.1
[37] Guidelines, p41
[38] Section 9.9 (new).
[39] Section 4.

although the provision of a meal (which complies with the requirements of section 10) would not be a breach.[40]

Education of company representatives[41]

3.27 All company representatives are required to have completed or be currently undertaking an endorsed Medicines Australia program for representatives (the endorsed program). All representatives entering the Australian prescription pharmaceutical industry for the first time must enrol in the Code of Conduct component of the endorsed program within the first six months of employment, and must complete the full program within two years.

3.28 This requirement also applies to any person who is directly involved in the development, review and approval of promotional materials and educational material for the general public, or has direct interaction with healthcare professionals.[42] The Guidelines state that this requirement does not apply to third party contractors (such as advertising agencies) although they are also encouraged to undertake the Code of Conduct component.[43]

Research[44]

3.29 These provisions apply whether the research is carried out directly by a company or by an organisation acting under its direction. Companies must ensure that privacy legislation is complied with.

3.30 These provisions do not apply to evaluations being carried out under the approval of a human research ethics committee in a hospital or clinical trials of products approved for registration.

Post marketing surveillance (PMS) studies[45]

3.31 PMS studies are defined as research intended to generate data on safety parameters of a product that has been approved for registration. They should have scientific or medical merit and objectivity and not be designed or conducted as a promotional exercise.

3.32 PMS studies must have a formal protocol, a requirement for data collection and generation of a report. Companies intending to undertake a PMS study must advise ADRAC[46] of their intention.

3.33 No starter packs or free trade packs should be distributed as part of the study, and any payment to the medical profession must be commensurate with the work involved and not based on the number of prescriptions written.

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[40] Explanatory note, section 4.11.
[41] Sections 4.12-4.14.
[42] Section 4.14 (new).
[43] Guidelines, p26.
[44] Section 8.
[45] Section 8.1.
[46] The Adverse Drug Reactions Advisory Committee of the Australian Drug Evaluation Committee.

Market research[47]

3.34 The Guidelines state that this section is primarily directed at research conducted with healthcare professionals, but recognises that market research may also be undertaken with members of the general public on occasion.[48]

3.35 The sole purpose of market research must be to collect data and not a means to promote or reward healthcare professionals. Promotion should not be represented as market research or research of any type.

3.36 Any payment (whether cash or voucher in lieu of cash) must be kept to a minimum and should not exceed a level commensurate with the work involved. If a voucher is provided, it must be valid only to obtain an item that is directly relevant to the practice of medicine or pharmacy. A donation to a registered charity in lieu of cash payment is acceptable if the amount remains commensurate with the work undertaken.[49]

Product starter packs[50]

Supply

3.37 A starter pack is defined as a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists.[51]

3.38 Starter packs can only be supplied by representatives employed by the holder of a manufacturer or wholesale dealer's licence. They can only be supplied to authorised healthcare professionals at their request, and only if he/she has legal authority to prescribe the product.[52]

3.39 The maximum quantity supplied must be at the healthcare professional's discretion and should reflect his/her needs until the next visit by the company representative. The company representative must not supply starter packs without a signed request from an authorised person.

3.40 Leaving starter packs with a receptionist for the attention of a healthcare professional without a signed request is a breach of the Code.

Size, labelling, storage, records to be kept etc

3.41 The size of starter packs should not exceed 1/3 of the PBS primary quantity for each strength of a product. For non-PBS products, starter packs should be no larger than 1/3 of the smallest trade pack.

3.42 Labelling of all starter packs must comply with the current Therapeutic Goods Order on labelling.

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[47] Section 8.2.
[48] Guidelines, p34
[49] Explanatory note, section 8.2.2.
[50] Section 5.
[51] Glossary.
[52] Code of Conduct Guidelines (Guidelines), p27.

3.43 Representatives must take adequate precautions to ensure the security of starter packs in their possession. The Code sets out the way they must be transported and stored, including when they are in a vehicle and when they are sent by mail.

3.44 On request, companies must promptly accept the return of starter packs. They must be disposed of in an environmentally sound manner according to the requirements in each state and territory.

3.45 Company representatives must keep records of every sample received or supplied. Companies must keep all records of the request, supply, return and disposal of starter packs for at least three years in a way that they are available for inspection by the appropriate authorities.

Relationship with the general public

3.46 Companies cannot promote prescription products to the general public (including on the internet[53]), but may provide them with educational material.

Medicine delivery devices

3.47 Promotion of a medicine delivery device to the general public is permitted in restricted circumstances, being:[54]

- when it is used for the administration of a prescription medicine, including Schedule 3 medicines that are predominately prescribed by a medical practitioner
- it is distributed independently from the active ingredient
- can be used to administer products from more than one company
- is not branded with the name of particular medicine and
- is listed with the TGA as a device.

Media Statements[55]

3.48 A media release to the lay media will be allowed if the product has been registered for use in Australia and the medical profession has been supplied with the appropriate information. The media release may include the product's brand name, the Australian approved name and must indicate any PBS listings. It must also be accompanied by a copy of the current consumer medicine information. The media release must not include any material that could be considered promotional or comparative with other products.

3.49 Companies are always responsible for all material prepared for them by the agencies they engage.

[53] Section 9.6
[54] Explanatory note, section 9.4 (amended).
[55] Sections 9.2-9.4

3.50 Companies should not attempt to encourage the publication of general media articles with the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.

Product Familiarisation Programs (PFPs)[56]

3.51 Product Familiarisation Programs (PFPs) are defined as programs run by a company with the aim of allowing the medical profession to evaluate and become familiar with a product. Under a PFP, a company makes starter packs available to doctors for up to 10 patients to allow them to prescribe the product without cost to the patient whilst gaining an understanding from their own experience of the efficacy and side effects of the new medicine.[57]

3.52 Companies should develop a rationale for each PFP which describes the clinical rationale for the program, the total number of patients to be enrolled and the duration that the medicine will be provided to each patient, based on a clinical assessment.

3.53 Companies should not offer any monetary or any other type of reward to healthcare professionals, their families and/or employees for taking part in PFPs.

3.54 The company will provide an information document for the healthcare professional to give to the patient which explains that the medication will be provided under the PFP for a fixed period, after which it may only be available on a private prescription if it is not reimbursed by the PBS.[58]

3.55 No individual patient data may be collected, although aggregated data on a healthcare professional's experience with the product may be.[59]

Patient Support Programs[60]

3.56 Companies may arrange or become involved in Patient Support Programs, which are programs run with the aim of improving compliance by patients (eg by reminding them to take their medicine) and positive health outcomes. They usually involve providing educational materials for consumers which are provided by the healthcare professional who prescribes the medicine.[61]

Administration of the Code[62]

3.57 The administration of the Code is supervised by the Code of Conduct Committee (the Code Committee), responsible to the Medicines Australia board.

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[56] Section 5.2.
[57] Medicines Australia 8 March 2006, p13.
[58] Section 5.2.4 (new).
[59] Explanatory note, section 5.2.7
[60] Section 9.8.
[61] Medicines Australia 8 March 2006, p15.
[62] Section 11.

Membership of the Code Committee

3.58 The following are members of the Code Committee:

Full membership	• Chairman (lawyer with trade practices experience selected from a panel of five) • One representative from each of the AMA, RACGP, ADGP, ASCEPT and the TGA • A specialist nominated by the Royal Australasian College of Physicians (RACP) • A consumer representative nominated by the CHF • Three Medicines Australia company Association Representatives • Two Medicines Australia member company Medical/Scientific Directors
Observers (no voting rights)	• Maximum of two employees of Medicines Australia member companies • One observer nominated by Medicines Australia

3.59 The Explanatory Notes set out the procedures by which the members are appointed. There is a process set out for ensuring that members of the Code Committee hearing a complaint do not have a conflict of interest.[63]

Referral of complaints

3.60 Complaints about advertisements that may breach the Therapeutic Product Acts or Rules can be referred to the Joint Therapeutics Agency of Australia and New Zealand's Central Complaints Panel.[64] Similarly, Medicines Australia may refer complaints about members who are also members of the Australian Self-Medication Industry (ASMI) to that association for consideration under its code.[65]

Complaint handling procedure

3.61 The Code sets out the procedure for dealing with an alleged breach of the Code by members. If a complaint is received about a non-member, it can either be dealt with under the Code (if the non-member agrees), or Medicines Australia can (but is not obliged to) forward the complaint to the TGA or the ACCC (if it relates to a possible breach of the TPA).[66]

3.62 Appendix 1 sets out guidelines to try and resolve complaints prior to a formal complaint being lodged with Medicines Australia.

3.63 Where a complainant is external to the industry, Medicines Australia may provide assistance, including providing access to an independent facilitator to assist them in submitting their complaint. However, it first encourages the

[63] Section 11.3 (new).
[64] Section 11.6 (new).
[65] Section 11.7.
[66] Section 11.5.

complainant to contact the company that is the subject of the complaint (the subject company).

3.64 Medicines Australia will not to accept anonymous complaints. If an individual or healthcare professional wishes have his/her identity protected, the Medicines Australia Secretariat will work with that person to ensure that his/her concerns are addressed.

3.65 Where a complaint is made by another company (whether or not a member), the complainant company must seek to resolve the complaint through inter-company dialogue before Medicines Australia will accept the complaint. The procedures for engaging in inter-company dialogue are set out in Appendix 1. The only exception to this requirement is when there is an allegation of a repeat breach.[67]

3.66 The main stages of the complaint handling procedure are:

- The complaint is received, and acknowledged in writing. The information that must be included with the complaint is set out in Appendix 1.

- The subject company is invited to comment on the complaint. It should provide certain information, the requirements of which is set out in Appendix 1.

- The subject company and complainant then provide the information necessary to fully investigate the complaint. This is provided to the Code Committee, along with any explanation provided by the subject company. The Code Committee can also make any further inquiries if necessary or desirable. It then makes a determination on whether or not there has been a breach of the Code.

- If the Code Committee finds that the company breached the Code, the subject company will be notified within two working days of what section it has been found to breach and the sanction that has been imposed. Within 10 working days of the meeting, the CEO will provide the subject company and the complainant with copies of the extracts of the minutes, including a full explanation of the decision and the form of any sanction to be imposed.

- If the Committee does not find a breach, the parties will be informed of this and supplied with the minutes within 10 working days.

- The full reasons for the decision will be supplied to the subject company and the complainant within 10 working days.

3.67 All findings and/or sanctions shall remain confidential and not be released to any third parties until after the subject company and the complainant have exhausted all appeals procedures and the outcome of any appeal is known.

[67] New section.

3.68 If the Code Committee requires a company to cease or withdraw a promotional activity, the company must comply with the ruling at once pending any appeal against the decision of the Code Committee pursuant to the Rules. The promotional activity in question cannot be reactivated before the appeals process has been concluded.

3.69 The Code Committee may refer questions on the interpretation of the Code to the Medicines Australia Board for determination.

Frivolous and vexatious complaints[68]

3.70 Where a company 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.

Sanctions[69]

3.71 The Code Committee can impose any of a range of sanctions for a breach, including that the subject company:

- take immediate action to discontinue or modify any practice constituting a breach of the Code
- issue retraction statements, including corrective letters and advertising (this is generally required for moderate or severe breaches). If corrective action is not taken within 30 days, the Code Committee can impose a $50,000 fine.[70]
- pay a fine as determined by the Code Committee. Broadly, this can be up to $100,000, or $200,000 for a repeat breach.

3.72 The Code Committee can also recommend that the Medicines Australia Board suspends or expels a member.

Appeals[71]

3.73 The subject company can appeal the Code Committee's decision that there was a breach, and/or the sanction imposed. The complainant can also appeal the decision.

3.74 When a subject company or an industry complainant lodges an appeal, they must lodge a bond of $20,000 with Medicines Australia. This requirement does not apply to non-industry complainants. The bond is used to defray the costs of the Code and Appeals Committee meetings and contribute to Code education programs.

[68] Section 12.3.
[69] Section 12.
[70] Section 12.1.2 (new).
[71] Section 13.

3.75 An administration charge of $6,000 will automatically be deducted from this. The Appeals Committee then has the discretion to refund all, part or none of the remaining $14,000 if the findings/sanction are changed/lifted.

3.76 The following are members of the Appeals Committee:

- Chairman (lawyer with trade practices experience selected from a panel)
- One representative from the College and/or Society from the therapeutic class of the product subject to appeal, the target audience to which the activity was directed (eg AMA, RACGP, ADGP)
- A representative of ASCEPT (must not have a conflict of interest with the subject product/company or have chaired the Code Committee at which the original complaint was heard)
- A consumer representative nominated by the Consumers' Health Forum of Australia (CHF)[72]
- Two Medicines Australia company Association Representatives
- One Medicines Australia member company Medical/Scientific Director

3.77 The Chair and the members from the industry and college/society must not have sat on the Code Committee that heard the original complaint.[73]

3.78 The Appeals Committee has the power to affirm, set aside or vary the findings and/or any sanction imposed by the Code Committee if it is persuaded that the Code Committee's findings involved an error.

3.79 The Code sets out the procedure that will be followed when an appeal is lodged. Broadly, this allows both parties to prepare written submissions and also make oral submissions before the Appeals Committee.

3.80 The Appeals Committee has the discretion to receive new evidence, but otherwise shall determine the appeal on the evidence before the Code Committee and that provided by the parties' submissions. It may refer questions on the interpretation of the Code to the Medicines Australia Board for determination.

3.81 There is a process set out for ensuring that members of the Appeals Committee hearing a complaint do not have a conflict of interest.[74]

Monitoring[75]

3.82 The Medicines Australia Monitoring Committee (Monitoring Committee) will monitor selected promotional material and activities of member companies on a regular basis. It will review different therapeutic classes[76] and types of promotional material each year. Medicines Australia states that it intends that the Monitoring Committee will each year undertake as a minimum:

[72] Section 13.2 (new addition to membership).
[73] Explanatory note, section 13.2.
[74] Section 13.3 (new).
[75] Section 14.
[76] See Explanatory note, section 14.1 for the list of therapeutic classes.

- the review of one type of promotional material in three different therapeutic classes and

- a review of three different promotional activities covered by the Code across all therapeutic classes, which would include the review of company sponsored educational meetings and symposia.[77]

3.83 Member companies will be required to submit copies of the selected type of promotional material (eg printed advertisements, audio-visual material) used over the past three months for the product under review.

3.84 If the Monitoring Committee considers a breach of the Code may have occurred, it may (after contacting the subject company seeking an explanation) either provide advice on compliance with the Code or refer the matter to the Code Committee as a complaint.

3.85 The Monitoring Committee will contribute a report to the Medicines Australia Code of Conduct annual report. This will include the therapeutic categories and type of promotional activities reviewed, the number of items reviewed, the number and type of breaches detected and the number of Code complaints generated.

3.86 The following are members of the Monitoring Committee:

Permanent members	• Chairman – consultant with industry experience in marketing and knowledge of the Code (selected from a panel of three) • One representative from each of RACGP and the AMA • A consumer representative nominated by the CHF[78]
Rotating members	• One representative from the college and/or society from the therapeutic class being reviewed • One Medicines Australia member company Medical Director and one Medicines Australia member company Marketing Director, neither of which have a conflict of interest in the therapeutic class
Advisors	• Medicines Australia Code Secretary • Medicines Australia officer responsible for scientific and technical affairs

3.87 There is a process set out for ensuring that members of the Monitoring Committee hearing a complaint do not have a conflict of interest.[79]

3.88 The Code provides that the operations of the Monitoring Committee will be reviewed on a regular basis.[80]

[77] Medicines Australia, 4 May 2006, p2.
[78] New addition to membership.
[79] Section 14.3 (new).
[80] Section 14.6.

Enforcement of the Code[81]

Reporting of breaches

3.89 Medicines Australia issues an annual report on the activities of the Code, Appeals and Monitoring Committees. It contains information such as the complaints received and the decisions made by the Code and Appeals Committees, and the time taken to deal with complaints.[82] Under Edition 15, Medicines Australia will also publish on its website a quarterly report on the outcomes of all complaints finalised during the reporting period.[83]

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

Statistics

3.91 Table 2 sets out the number and source of complaints, and records the proportion of those complaints that resulted in the Committee finding that a breach from July 2002 – June 2005.[84]

Table 2: Complaints heard by the Code of Conduct Committee, 2002 – 2005

Year	No of complaints	Source of complaint				breach/ partial breach found
		MA member	healthcare professional	TGA	Other*	
Jul-Dec 2005	15	5	7	0	3	40%
2004-05	51	30	11	7	3	70.8%♦
2003-04	36	22	6	6	8	52.8%
2002-03	48	28	11	5	13	65.2%

** includes non-member companies, consumers and others.*

♦ does not include three complaints that have been withheld until the next reporting period.

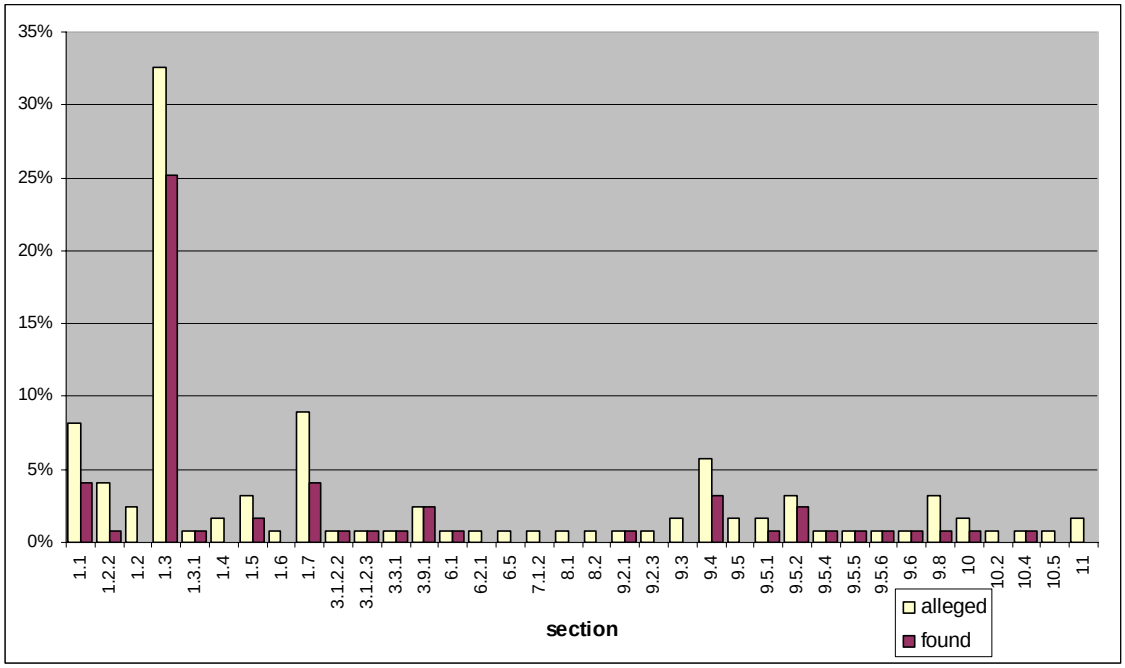
[81] The data in this section are sourced from the Medicines Australia Code of Conduct *Annual Reports 2002-03, 2003-04, 2004-05* and *Code Outcomes, July – December 2005*, all downloaded from Medicines Australia's website: http://www.medicinesaustralia.com.au.

[82] Section 16.1.

[83] Section 16.2 (amended– previously published six-monthly).

[84] Edition 14 of the Code came into effect on 1 January 2003, so some of the complaints in the 2002-03 columns relate to Edition 13.

Figure 1: Complaints made, and breaches found, by section of the Code, 2004-05.



3.92 Figure 1 above set outs the complaints made and breaches found by section for 2004-05. The most commonly complained about sections both in 2004-05 and for the whole period of 2002-05 were those relating to promotional material (particularly sections 1.1, 1.3 and 1.7) and the prohibitions on marketing prescription medicines to the general public (particularly section 9.4).

3.93 By contrast, only ten complaints (approximately 7 per cent of those received) related to the provision of inappropriate benefits to healthcare professionals. Out of these, only two breaches were found.

Sanctions

3.94 Table 3 sets out the number of sanctions imposed. The most common sanctions imposed were requiring the subject company to remedy the breach by withdrawing the material, and ensure it did not appear in its current form again. In some cases companies were also required to send corrective letters to affected parties.

Table 3: No of sanctions imposed, including fines

Year	No of breaches	Sanction imposed				
		Withdraw material	Corrective advertising	Corrective letter	Other	Fine imposed
Jul-Dec 2005	12♣	3	0	3	1	2
2004-05	55	26	0	7	2	20
2003-04	31	17	1	4	0	9
2002-03	53	31	4	2	0	16

♣ *Some of the sanctions applied to multiple breaches.*

3.95 In a number of cases, the Committee also imposed a fine for the breach. Table 4 sets out the number and level of fines imposed in each year.

Table 4: Level of fines imposed

Year	Level of fine imposed					
	up to $25,000	$25,000-$49,999	$50,000-$74,999	$75,000-$99,999	$100,000-$149,999	$150,000-$200,000
Jul-Dec 2005	2	0	0	0	0	0
2004-05	13	4	2	0	1	0
2003-04	6	3	0	0	0	0
2002-03	12	1	2	1	0	0

3.96 In a number of cases, the subject company or the complainant appealed the Code Committee's decision. Table 5 below sets out the decisions of the Appeals Committee for each year.

Table 5: Appeals lodged and outcomes

Year	No. lodged	Outcome		
		Appeal not upheld: breach confirmed	Appeal partly upheld: partial breach	Appeal upheld: no breach
Jul-Dec 2005	2	2	0	0
2004-05	11	7	3	1
2003-04	7	5	2	0
2002-03	9	4	4	1

4. Submissions

4.1 Medicines Australia provided a submission in support of its applications on 30 November 2005. It also provided a number of additional submissions before and following the draft determination.

4.2 The ACCC also sought submissions from a number of interested parties. The following parties provided submissions prior to the draft determination:

- Professor Richard Day, University of NSW
- Therapeutic Goods Administration
- Healthy Skepticism Inc
- Dr Ken Harvey, La Trobe University
- Australian Consumers' Association
- Novo Nordisk Pharmaceuticals Pty Ltd
- Consumers' Health Forum of Australia (CHF)
- Australian Medical Association Ltd (AMA)
- Queensland Health
- Victorian Department of Human Services
- ACT Health
- Pfizer Australia Pty Ltd
- Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Tasmanian Department of Health and Human Services
- Wyeth Australia Pty Ltd
- NSW Health
- Australian Government Department of Health and Ageing
- Merck, Sharp & Dohme (Australia) Pty Ltd
- WA Department of Health
- Doctors Reform Society
- Sanofi-aventis
- South Australian Department of Health and
- Australian Nursing Federation.

4.3 In addition, the following parties also provided submissions following the draft determination:

- Therapeutic Goods Administration (TGA)
- Australian Government Department of Health and Ageing
- Australian Consumers' Association (ACA)
- Dr Ken Harvey, La Trobe University
- WA Department of Health

- Healthy Skepticism Inc and
- Australian Nursing Federation (ANF)
- Australian Medical Association Ltd (AMA)

4.4 The views of Medicines Australia and interested parties are outlined in the ACCC's evaluation of the arrangements in Chapter 6 of this determination.

4.5 Copies of public submissions are available on the ACCC's website.

5. Statutory provisions

5.1 Under section 91C of the TPA, the ACCC may grant an application to revoke an existing authorisation and grant a substitute authorisation at the request of the party to whom the authorisation has been granted, or another person on behalf of such a party. The ACCC may also institute an application for revocation and substitution in certain circumstances.

5.2 In order for the ACCC to grant an application to revoke an existing authorisation and grant a substitute authorisation, the ACCC must consider the substitute authorisation in the same manner as the standard authorisation process.

The statutory tests

5.3 In assessing an application made under section 91C of the TPA, the relevant tests Medicines Australia must satisfy for the substitute authorisation to be granted are outlined in sections 90(6), 90(7) and 90(8) of the TPA.

5.4 Under section 90(6) of the TPA, the ACCC may grant authorisation in respect of a proposed contract, arrangement or understanding that may have the purpose or effect of substantially lessening competition if it is satisfied that:

- the contract, arrangement or understanding would result, or be likely to result, in a benefit to the public and
- that benefit would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if the proposed contract or arrangement were made and the provision concerned were given effect to.

5.5 Under section 90(7) of the TPA, the ACCC may grant authorisation in respect of a contract, arrangement or understanding that may have the purpose or effect of substantially lessening competition if it is satisfied that:

- the contract, arrangement or understanding would be likely to result in a benefit to the public and
- that benefit would outweigh the detriment to the public constituted by any lessening of competition that would be likely to result from the contract arrangement or understanding.

5.6 Section 90(8) provides that the ACCC shall not make a determination granting authorisation under subsection 88(1) or 88(8) in respect of a provision of a proposed contract, arrangement or understanding that is or may be an exclusionary provision unless it is satisfied in all circumstances that the provision has resulted, or is likely to result in such a benefit to the public that the contract, arrangement or understanding should be allowed to be given effect to.

Application of the tests

5.7 There is some variation in the language particularly between the tests in sections 90(6) and 90(7) and that in section 90(8) of the TPA.

5.8 The Australian Competition Tribunal (the Tribunal) has found that the tests are not precisely the same.[1] In particular the Tribunal considered that the test under section 90(6) was limited to a consideration of those detriments arising from a lessening of competition but that the test under section 90(8) was not so limited.

5.9 However, the Tribunal has previously stated that with respect to the test under section 90(6):

> [the] fact that the only public detriment to be taken into account is lessening of competition does not mean that other detriments are not to be weighed in the balance when a judgment is being made. Something relied upon as a benefit may have a beneficial, and also a detrimental, effect on society. Such detrimental effect as it has must be considered in order to determine the extent of its beneficial effect.[2]

5.10 Consequently, when applying either test, the ACCC can take all public detriment likely to result from the relevant conduct into account either by looking at the detriment side of the equation or when assessing the extent of the benefits.

5.11 Given the similarity in wording between sections 90(6) and 90(7), the ACCC considers the approach described above in relation to section 90(6) is also applicable to section 90(7).

Definition of public benefit and public detriment

5.12 Public benefit is not defined by the TPA. However, the Tribunal has stated that the term should be given its widest possible meaning. In particular, it includes:

> …anything of value to the community generally, any contribution to the aims pursued by society including as one of its principle elements … the achievement of the economic goals of efficiency and progress.[3]

5.13 Similarly, public detriment is not defined by the TPA but the Tribunal has given the concept a wide ambit. It has stated that the detriment to the public includes:

> …any impairment to the community generally, any harm or damage to the aims pursued by the society including as one of its principal elements the achievement of the goal of economic efficiency.[4]

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[1] *Australian Association of Pathology Practices Incorporated* [2004] ACompT 4; 7 April 2004.
[2] Re Association of Consulting Engineers, Australia (1981) ATPR 40-2-2 at 42788. See also: *Media Council case* (1978) ATPR 40-058 at 17606; and *Application of Southern Cross Beverages Pty. Ltd., Cadbury Schweppes Pty. Ltd. and Amatil Ltd. for review* (1981) ATPR 40-200 at 42,763, 42766.
[3] *Re 7-Eleven Stores; Australian Association of Convenience Stores Incorporated and Queensland Newsagents Federation* (1994) ATPR ¶ 41-357 at 42677. The Tribunal recently followed this in *Qantas Airways Limited* [2004] ACompT9.
[4] ibid., 42683.

Future with-and-without test

5.14 The ACCC uses the 'future-with-and-without-test' established by the Australian Competition Tribunal to identify and measure the public benefit and anti-competitive detriment generated by the arrangements for which authorisation is sought.[5]

5.15 Under this test, the ACCC compares the public benefits and detriments generated by the arrangements in the future if the authorisation is granted with those generated if the authorisation is not granted. This requires the ACCC to make a reasonable forecast about how the relevant markets will react if authorisation is not granted. This forecast is often referred to as the counterfactual.

5.16 Under this test, the ACCC compares the public benefit and detriments generated by arrangements in the future if the authorisation is granted with those generated if the authorisation is not granted. This requires the ACCC to predict how the relevant markets will react if authorisation is not granted. This prediction is often referred to as the counterfactual.

Term of authorisation

5.17 Section 91(1) of the TPA allows the ACCC to grant authorisation for a specific period of time.

Future parties

5.18 Section 88(10) of the TPA provides that an authorisation may be expressed so as to apply to or in relation to another person who becomes a party to the proposed arrangements in the future.

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

6. Evaluation

6.1 Under the TPA, the ACCC is required to assess the likely public benefits and detriment arising from the Code.

6.2 In undertaking this assessment, the ACCC notes that when considering an application for revocation and substitution, it is required to consider the application as a whole. It cannot just compare the amendments to the previously authorised conduct.

General issues

Adequacy of self-regulation

6.3 Prior to the draft determination, some interested parties commented that self-regulation of the industry is not appropriate.[1] Following the draft determination, the ACA commented that:[2]

> In a letter sent to the Minister for Health … the ACA argued the focus of regulating the promotion of pharmaceutical products needs to shift to more direct regulation, as occurs in a range of other sectors of the economy. This should occur through legislation enforced by the appropriate regulator. Failing this preferred option, there should be a requirement that industry develop an effective Code of Conduct that meets certain policy objectives established by legislation.

6.4 As stated in the draft determination, the ACCC considers that the issue of whether self-regulation of the pharmaceutical industry in this respect is a matter for government policy, and well beyond the scope of the authorisation.

6.5 When considering an application for authorisation, the ACCC is required under the TPA to assess what the likely benefits and detriments of the arrangements before it. If it is not satisfied that the arrangements are likely to result in a net public benefit, it may impose conditions. However, its role is not designing a better code, nor considering whether other regulatory arrangements may be more or less appropriate.

Market definition

6.6 The first step in assessing the public benefits and detriments of the conduct for which authorisation is sought is to consider the relevant markets(s) in which the conduct occurs.

6.7 Defining the markets affected by arrangements proposed for authorisation assists in assessing the public benefit and public detriment from the arrangements. However, depending on the circumstances, the ACCC 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 this definition.

[1] See, eg ACA 20 January 2006, p6, Dr Ken Harvey, 24 January 2006, pp2-3.
[2] ACA 22 May 2006, p2.

6.8 Medicines Australia submitted that the relevant market is the market in Australia for the supply of prescription products used under medical supervision as permitted under Australian law.[3]

6.9 It noted that the ACCC used this definition when considering the previous authorisations, and submitted that there has been no change in the dynamics of the relevant market such that the ACCC should reach a different view in relation to market definition for Edition 15.[4]

6.10 None of the submissions from interested parties commented on what market definition was appropriate.

6.11 As the ACCC found in the previous determination,[5] 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 ACCC considers that it is not necessary to consider whether the definition of the relevant markets is narrower than that proposed by Medicines Australia.

6.12 Based on the information before it, the ACCC considers that for the purposes of this authorisation, the relevant market is the market for supply of prescription products used under medical supervision as permitted under Australian law. For convenience, this determination refers to this market as the market for prescription products.

Characteristics of the market for prescription medicines

Regulation

6.13 The market for prescription medicines in Australia is regulated by both Commonwealth and state/territory legislation (as discussed at paragraphs 2.5 – 2.19). This affects several elements of the market, including:

- *Price*: as discussed at 2.19, the retail price of approximately 80 per cent of prescription medicines (both branded and generic) is determined by the Australian Government through the PBS. As a result, decisions by doctors about which medicines to prescribe for their patients are unlikely to have an effect on the price consumers pay for those medications.

- *Product selection*: consumers cannot purchase prescription medicines directly. They must first consult a medical practitioner whose role is to determine what the most appropriate medicine may be for that person. Hence they are likely to have a limited role in choosing which particular product they purchase.

6.14 The ACCC understands that the rationale behind requiring consumers to first obtain a prescription reflects that consumers themselves will not usually possess

[3] Medicines Australia 30 November 2005, p13.
[4] Ibid.
[5] Applications for revocation and substitution A90997, A90780, lodged by Medicines Australia, ACCC final determination 14 November 2003.

a high level of knowledge about medical conditions and potential remedies. Therefore, they are required to consult a person with knowledge and expertise (a medical practitioner) to increase the likelihood that they will be prescribed an appropriate medicine for their condition.

6.15 It its previous determination,[6] the ACCC found it was possible that medical practitioners may also not possess perfect information on the range of remedies available. This is because, in practice, they may not have sufficient time to absorb the volume of scientific studies and research available on pharmaceutical products. Therefore, they may rely heavily on information provided by pharmaceutical manufacturers.

6.16 However, the ACCC noted three factors that may act to reduce the possibility of any such information imperfections resulting in sub-optimal prescribing:

- under the TG Act, prescription medicines may only be supplied in Australia after being rigorously tested to ensure their safety, quality and efficacy
- medical practitioners are highly trained professionals with expertise in assessing information about pharmaceutical products and
- sections 52 and 53 of the TPA (and certain provisions of the TG Act) prevent pharmaceutical companies from engaging in misleading or deceptive conduct when promoting or providing information on medicines to medical practitioners.

Areas of competition between pharmaceutical companies

6.17 Also as discussed in the previous determination,[7] the ACCC considers that there are two areas of competition between pharmaceutical companies:

- The development of new drugs, being drugs able to treat a condition that was not previously treatable or drugs that are better at treating conditions than existing drugs (either due to increased efficacy or reduced side-effects). Pharmaceutical companies are generally able to obtain patents for these types of drugs.
- The supply of drugs that are no longer subject to patent ('generic drugs'). In these cases pharmaceutical companies are essentially each making the same medicine. The quality of generic prescription drugs is also underpinned by the TG Act (see paragraph 2.11).

Future with-and-without test

6.18 As discussed at 5.14 - 5.16, in order to apply the 'future-with-and-without-test', the ACCC must determine the counterfactual, that is, the way relevant markets will react if authorisation is not granted.

[6] Paragraphs 5.17 – 5.21.
[7] Paragraphs 5.22 – 5.27.

6.19 Neither Medicines Australia nor any interested party commented on what the most appropriate counterfactual should be.

6.20 Based on the evidence before it, the ACCC considers that the most likely scenario is that if the ACCC does not grant authorisation, Edition 15 of the Code will not come into effect. The ACCC considers it is unlikely that Medicines Australia and its member companies would choose to enforce the Code without immunity from legal action under the TPA.

6.21 If the ACCC were to deny authorisation, Edition 14 of the Code would continue to regulate the conduct of pharmaceutical companies until the previous authorisations expire on 31 December 2006. Following this date, the most likely scenario is pharmaceutical companies' conduct would be regulated only by existing legislation (eg the TG Act and the TPA).

6.22 It is possible that in the absence of Medicines Australia's Code, governments may pass legislation regulating the conduct of pharmaceutical companies in respect of the matters currently covered by the Code. However, there is no indication that this is likely.

6.23 Indeed, it appears there is a general move away from legislative regulation of the pharmaceutical sector. For example, the Secretary of the Department of Health and Ageing has delegated the responsibility under the TG Act for approving non-prescription product advertising to the CHC and ASMI through co-regulatory arrangements (see 2.18). In addition, the expansion of the provisions of the Code governing starter packs (see 3.37 – 3.45) is a result of a decision to repeal state/territory legislation. Instead, their supply, storage and handling will now be regulated by the Code.

6.24 As such, in conducting its analysis, the ACCC will employ the counterfactual that in the absence of authorisation, Edition 15 of the Code will not come into effect. Instead, once the current authorisations expire, the conduct of pharmaceutical companies in respect of the matters covered by the Code would be governed by existing legislation only.

Public benefit

6.25 The ACCC considers that the Code regulates three main categories of pharmaceutical companies' conduct, being broadly:

- their provision of information about prescription medicines to healthcare professionals and the general public
- their provision of benefits (financial and otherwise) to healthcare professionals and
- their conduct in other regards, such as the supply, storage and handling of starter packs.

6.26 Some of the elements of the Code that Medicines Australia claims will result in a public benefit, some interested parties consider will result in a public

detriment. The ACCC has characterised these as detriments that may offset the claimed benefits, and will discuss them in this section.

6.27 The ACCC notes that a number of interested parties raised concerns that the Code is ineffectively enforced, and hence the claimed public benefits are unlikely to flow. The issue of the Code's effectiveness is discussed at 6.107 – 6.1589.

Regulation of the provision of information

6.28 Medicines Australia claims a range of public benefits will result from the sections of the Code that regulate the provision of information. These include:

- reducing misleading and deceptive conduct
- enhancing compliance with the TG Act's prohibition on direct-to-consumer advertising
- encouraging rational prescribing practices and
- benefits resulting from the provision of information more generally.

Reduction in misleading conduct

6.29 Medicines Australia submitted that the Code provides a 'substantial' public benefit through the setting out and enforcement of standards of conduct for the marketing of prescription products. In particular, it:[8]

> … complements and encourages compliance with the prohibition on misleading and deceptive conduct in the TPA and the prohibition on advertising in the TG Act by setting out in detail the types of claims … which will be considered to be in breach of the Code and by setting out details of the level of supporting information which should accompany claims.

6.30 A number of interested parties supported Medicines Australia's claims.[9] They emphasised that some of the amendments to Edition 15 are likely to enhance the public benefit in this respect, such as:

- the improvements to the regulation of advertisements and promotional claims directed at healthcare professionals[10] and
- the enhanced requirements for the conduct and knowledge of company representatives, requiring them to possess certain medical and technical knowledge, and requiring employees in particular roles to complete certain training.[11]

6.31 However, other interested parties do not consider that the Code results in a public benefit in this respect. For example, the ACA commented that the Code

[8] Medicines Australia 30 November 2005, p14.
[9] See, eg, TGA 5 December 2005, p1; Merck, Sharp & Dohme 18 January 2006, p1; Wyeth 13 January 2006, p1; Pfizer 5 January 2006, p1; Professor Ric Day 28 November 2005, p1.
[10] See, eg Pfizer 5 January 2006, p1; ASCEPT 9 January 2006, p1; Wyeth 13 January 2006, p1.
[11] See, eg Pfizer 5 January 2006, p1.

does not consider the evidence used in advertisements (eg by requiring companies to publish Absolute Risk Reductions (ARR) or Numbers Needed to Treat (NNT) statistics). It argued that 'companies are therefore more likely to be able to make misleading or false claims and for those claims to be undetected.'[12] Similarly, Healthy Skepticism proposed that the Code should:[13]

- provide a positive list of the types of information that health professionals need, which should be included in all types of promotion
- list promotional techniques that are unhelpful for health professionals and thus should not be used and
- include a clause requiring that promotion not omit, or disclose only in fine print, information that is relevant to good prescribing decisions.

6.32 Medicines Australia responded to the ACA's comments by outlining why it would be inappropriate to require ARR and NNT statistics in advertising by pharmaceutical companies.[14] It also commented that Healthy Skepticism's first proposal was 'too prescriptive for inclusion in a voluntary industry code', while it considered the other proposals were already addressed by the Code.[15]

ACCC view

6.33 The ACCC notes that the majority of complaints received by the Code Committee relate to companies' provision of information, both to healthcare professionals and the general public (see 3.91 – 3.93).

6.34 In its previous determination,[16] the ACCC found that codes which facilitate compliance with general legislative provisions can generate a public benefit by helping to ensure that the benefits that potentially flow from these general provisions are achieved in practice. It found that the Code was likely to give rise to a small public benefit by facilitating compliance with the general prohibitions on misleading and deceptive conduct contained in the TPA.

6.35 For similar reasons, the ACCC considers that a small public benefit could arise from Edition 15 of the Code.

6.36 Some of the amendments contained in Edition 15 impose additional requirements on the provision of information by companies. The ACCC considers these may increase the likely public benefit by reducing the probability that companies will engage in misleading or deceptive conduct. They include:

[12] Australian Consumers' Association (ACA) 20 January 2006, p5.
[13] Healthy Skepticism submission to Medicines Australia Review of the Code of Conduct May 2005, paragraphs 17 – 20.
[14] Medicines Australia 8 March 2006, p10.
[15] Medicines Australia 7 April 2006, pp2-3.
[16] Paragraphs 5.31 – 5.32.

- the requirement that company commissioned articles which contain promotional claims comply with the requirements for a primary or secondary advertisement[17]

- the additional requirements in respect of printed promotional material[18] and

- the requirement that any company employees directly involved in the development, review and approval of promotional/educational materials or who have direct interaction with healthcare professionals undertake the Code of Conduct component of the Medicines Australia education program within 12 months of commencing employment.[19]

6.37 The ACCC is aware that a number of interested parties consider that the Code does not go far enough in regulating the provision of information by companies. However, the authorisation process set out in the TPA requires the ACCC to assess the benefit and detriment of the Code as drafted by Medicines Australia, and not to design an 'ideal' code. When assessed against a counterfactual or 'future without', where the Code does not exist and the only regulation is provided by existing legislation, the ACCC considers that some public benefit could result.

Advertising to consumers

6.38 Medicines Australia stated that the Code results in a public benefit by encouraging compliance with the prohibition on direct-to-consumer advertising contained in the TG Act.[20]

6.39 A number of interested parties agreed with these claims, making comments similar to those outlined at 6.30.

6.40 However, some interested parties were not convinced the Code encourages compliance in this respect. The AMA commented that it has:[21]

> previously expressed concerns about the lack of distinction between education of consumers versus promotion to consumers, and the capacity of the Code to deter breaches by pharmaceutical companies.

6.41 CHF stated that it has previously raised concerns about companies' advertising that referred consumers to condition-related websites without clear acknowledgement they were run by industry.[22]

6.42 The ANF stated:[23]

> Despite evidence that direct-to-consumer advertising leads to increases in sales of prescription drugs, and patient pressure to prescribe advertised medicines, even when the therapeutic benefits are questionable, pharmaceutical companies in Australia get around the

[17] Section 3.1.4.5.
[18] Section 3.3.
[19] Section 4.14.
[20] Medicines Australia 30 November 2005, p14.
[21] AMA 19 December 2005, p1.
[22] CHF 19 December 2005, p1.
[23] ANF 3 February 2006, p2.

> ban by support programs and campaigns targeting a specific condition or disease, and directing the public to phone lines or websites for help.

6.43 Further, some parties claimed that some pharmaceutical companies currently advertise directly to consumers in spite of the prohibition. For example, the ACA noted that 'direct to consumer advertising is illegal; yet still occurs in less obvious ways which the Code does not adequately address.'[24] It also gave examples of what it considered to be companies advertising to consumers, including through:[25]

> masquerading advertising as education campaigns … stories in the media which are presented as 'medical breakthroughs' … sponsoring high profile support groups … subsidising academics to provide their 'expert' opinions about particular drugs or by sponsoring prizes for journalist awards.

ACCC view

6.44 The ACCC notes that the prohibition on direct-to-consumer advertising is incorporated into the TG Act. It therefore considers that if the Code encourages compliance with this legislative prohibition, it could result in a public benefit.

6.45 The ACCC acknowledges the comments about the methods some pharmaceutical companies use to promote their products without directly advertising them. It appears that the Code does not necessarily regulate this kind of activity. However, the ACCC again notes that its role is to assess the arrangements before it. It cannot craft an 'ideal' code.

Advertising in electronic prescribing software

6.46 For some interested parties, an area of particular concern was advertising in the electronic prescribing software used by GPs.[26] Section 3.9.1 of Edition 15 requires companies to ensure that no advertisements are placed with clinical tools or patient education material which may be used by a prescriber for consultation or discussion with a patient. Edition 14 of the Code permitted such advertising.[27]

6.47 Medicines Australia stated that this section was included both because of submissions received through the Code review process,[28] and due to a complaint in the form of an article published in the *Medical Journal of Australia* (the MJA article).[29]

6.48 A number of interested parties supported the amendment, stating that it will 'assist companies to ensure that they meet their obligations not to advertise prescription medicines to consumers.'[30] Similarly, the AMA noted that it is: [31]

[24] ACA 20 January 2006, p3.
[25] Ibid, pp3-4.
[26] See AMA 19 December 2005, p1; ACA pp5-6, Dr Ken Harvey 14 December 2005 p1 and 24 January 2006 pp2-3, ANF 3 February 2006, p1.
[27] Medicines Australia 9 January 2006, p3 (see section 3.10 of Edition 14).
[28] Medicines Australia 30 November 2005, p4.
[29] Harvey, KJ, Vitry AI, Roughead E, et al. 'Pharmaceutical advertising in prescribing software: an analysis.' *Medical Journal of Australia*, 183(2): 75-79.
[30] ASCEPT 9 January 2006, p1.

> opposed to the use of advertising and promotional material in prescribing software because of its potential to interfere with the doctor-patient relationship during consultations.

6.49 However, other interested parties[32] expressed doubt that the amendment would be effective, particularly in light of the MJA article's findings. For example, Dr Ken Harvey (one of the authors of the MJA article) commented that:[33]

> Drug advertisements occur in many places where they are visible to patients apart from those functions now prohibited by the 15th Edition of the Code … I predict that this cosmetic prohibition (and Medical Director's elimination of advertisements that occur while the 'script was printing) will do little or nothing to reduce the volume of prescription drug advertisements visible to patients.

6.50 Following the draft determination, the ACA stated:[34]

> The Code has significant gaps and does not adequately regulate all forms of advertising, for example, advertisements appearing in prescribing software.

6.51 The ACCC understands that the MJA article assessed the advertisements appearing in Medical Director (version 2.81) and found advertisements were appearing in a range of areas that would be viewed by patients during consultations. The authors also considered there were other breaches of the Code, including generic names and misleading claims.

6.52 These issues were investigated by the Code Committee (complaint 801).[35] On request from Medicines Australia, the Monitoring Committee also reviewed all advertisements for prescription medicines in version 2.83 of Medical Director. It then provided advice to companies whose advertisements were found to not comply with the Code. Medicines Australia stated that all of the companies accepted the Monitoring Committee's assessment and undertook to withdraw the non-compliant advertisements.[36]

6.53 In addition, Medicines Australia understands that:[37]

> Medical Director, a major supplier of prescribing software, has removed large format advertisements from the screen displayed whilst a document is printing, which was complained of particularly by doctors and their representative bodies – the AMA and RACGP.

6.54 More generally, Medicines Australia considers that:[38]

> … the fundamental issue is whether advertisements in prescribing software in views other than the clinical tools and patient educational materials should be considered as advertising to consumers or healthcare professionals. … If there is a part of the software that is intended for use directly with patients, Medicines Australia agrees that there should be no advertisements for prescription medicines.

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[31] AMA 19 December 2005, p1.
[32] ACA 20 January 2006, Dr Ken Harvey 24 January 2006, p1.
[33] Dr Ken Harvey 24 January 2006, p1.
[34] ACA 22 May 2006, p1.
[35] A copy of the Committees' findings is at Attachment 1 of Medicines Australia's submission, 8 March 2006.
[36] Medicines Australia 8 March 2006, p3.
[37] Medicines Australia 9 January 2006, p4.
[38] Medicines Australia 8 March 2006, p1.

6.55 However, it also considers:[39]

> that it is legitimate to include advertisements directed to healthcare professionals in media that are primarily intended for healthcare professionals. An analogy is advertisements in print media such as medical journals or other professional print publications which may also be coincidentally observed by a patient during a consultation if the doctor has the journal in the consultation room. It must be kept in mind that any advertisement for prescription medicines in prescribing software is not intended for, or directed to, a patient. … Edition 15 of the Code is designed to prevent the viewing of promotional material through avenues which are intended to be used directly with patients.

6.56 In its draft determination, the ACCC found only a limited public benefit resulting from these sections of the Code. It expressed concern that the way the sections were drafted may not ensure full compliance with the prohibition on advertising to consumers.

6.57 It also commented that the restriction on advertising displayed in Medical Director is self-imposed, and not as a result of the Code. As such, if this restriction resulted in a public benefit through increasing compliance with the legislative prohibition, it could not be attributed to the Code.

6.58 Medicines Australia responded to these comments by stating:[40]

> … that restriction on advertising displayed by Medical Director is directly attributable to the amendments included in … Edition 15 … MA would therefore be grateful if the Commission could acknowledge in the Final Determination that this is a benefit directly attributable to the Code.

ACCC view

6.59 The ACCC remains of the view that only a limited public benefit could to result from this section of the Code. It remains concerned that the current wording of section 3.9.1 only prohibits advertising 'with clinical tools or patient education materials which may be used by a prescriber for consultation or discussion with a patient'.

6.60 This does not appear to prevent advertising in other functions of software packages which may be seen by a patient even though they are not 'clinical tools or patient education materials'. As such, the ACCC considers that the section may not ensure full compliance with the legislative prohibition on advertising to consumers.

6.61 One example of such a function is the screen displayed while a prescription is printing. The ACCC does not consider that the current wording of the section prohibits the display of such advertisements. Therefore, it considers that the restriction on advertising in this section imposed by Medical Director is self-imposed and any benefit resulting from it cannot be attributed to the Code.

[39] Ibid, p2.
[40] Medicines Australia, 23 May 2006, p2.

Encouragement of rational prescribing practices

6.62 Medicines Australia also claimed that a public benefit would result by encouraging 'the quality use of medicines and rational prescribing practices, through the regulation of promotional activity including advertisements'.[41]

6.63 A number of interested parties supported these claims, making comments similar to those outlined at 6.30.

6.64 However, other interested parties considered that the Code was inadequate in this respect, and the resulting public detriment would offset any claimed benefit. For example, the ACA stated that 'false advertising claims can negatively impact on consumers' health.'

6.65 In addition, several interested parties[42] felt that the Code has a negative impact on the viability of the PBS, both through:

- 'leakage' (described as where 'established drugs are used for indications for which the original sponsor had not sought marketing approval'[43]) and
- encouraging the use of brand name rather than generic drugs,[44] including through illegible generic names in electronic prescribing software.[45]

6.66 For example, Dr Harvey stated:[46]

> The end result is a code which encourages inappropriate demand and prescribing of heavily promoted drugs that is often not in accord with cost-effective best-practice. This is one reason why the cost of the Pharmaceutical Benefits Scheme has increased exponentially over the last decade (at about 11% per annum, twice the increase of medical or hospital services). In response, the government has recently introduced large increases in co-payments and safety-nets (transferring more of the costs of the PBS from government to consumers) which have inevitably resulted in consumer detriment; poorer consumers are now forgoing necessary medicines to the detriment of their health.

6.67 Medicines Australia responded to these concerns by noting that the Code (both Editions 14 and 15) 'includes specific requirements for companies to clearly communicate to healthcare professionals the PBS listing restrictions for a medicine.' It also commented that:[47]

> These requirements were introduced as part of the PBS Quality Enhancement Program which is a measure … aimed at supporting the quality prescribing of medicines listed on the PBS … The QEP has been evaluated each year since its introduction by an independent consultant … Healthcare Management Solutions (HMA). Medicines Australia has been informed by HMA that these evaluations have demonstrated a net saving to Government

[41] Medicines Australia 30 November 2005, p14.
[42] See, eg, ACA 20 January 2006, Dr Ken Harvey 24 January 2006, p2; Doctors Reform Society 20 January 2006, Healthy Skepticism submission to Medicines Australia Review of the Code of Conduct May 2005, paragraph 3; ANF 3 February 2006, p1.
[43] ACA 15 December 2005, p1.
[44] See, eg ACA 20 January 2006, p7, Ken Harvey 24 January 2006, p2, Doctors Reform Society 20 January 2006, p2.
[45] Ken Harvey 24 January 2006, p2.
[46] Ibid (footnotes omitted).
[47] Medicines Australia 9 January 2006, p6.

> expenditure … directly linked to companies' compliance with the Code requirements to communicate to healthcare professionals the PBS listing restrictions for a medicine.

6.68 In respect of concerns about generic names, Medicines Australia noted that the Code (both this and previous editions) requires that the Australian Approved Name (the generic name) 'of the active ingredient(s) must be included in all forms of promotional materials.'[48]

ACCC view

6.69 In its previous determination,[49] the ACCC considered whether a public benefit was likely to flow from the Code reducing inappropriate prescribing by doctors. In that determination, it only considered this issue in the context of the Code's regulation of the provision of benefits.

6.70 However, the submissions received from interested parties in respect of the current applications discuss the issue in respect of the promotion of prescription medicines more generally, not just via the provision of benefits.

6.71 The ACCC considers that both the provision of benefits (discussed at 6.80 – 6.100) and the promotion of prescription medicines raise similar issues. The main question appears to be whether the Code is likely to result in a public benefit by reducing the level of inappropriate prescribing by healthcare professionals attributable to inappropriate influence by pharmaceutical companies.

6.72 The ACCC notes that globally, pharmaceutical companies spend significant sums on promotion of their products, with some commentators estimating that they spend 2-3 times more on promotion of products than on research and development.[50] It appears that this is also the situation in Australia. The ACA has estimated that expenditure on promotion is approximately $1 billion per year.[51] The ACCC considers this is a significant amount, even for an industry with an estimated turnover of nearly $8 billion (see paragraph 2.2).

6.73 These figures include both over-the-counter and prescription only products. The ACCC has not been provided with estimates of expenditure on prescription products only. However, it considers that this level of spending indicates that pharmaceutical companies clearly believe that promotion of their products will increase sales.

6.74 Therefore, the ACCC considers it is likely that, absent the Code, pharmaceutical companies would market their products more aggressively to healthcare professionals.

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[48] Medicines Australia 8 March 2006, p6.
[49] Paragraphs 5.33 – 5.60.
[50] TA Ruff and H Haikal-Mukhtar 'Doctors, drugs, information and ethics: a never-ending story' *Medical Journal of Austr*alia (2005) vol 187, pp73-77, citing M Angell, 'Excess in the Pharmaceutical Industry', *Canadian Medial Association Journal* (2004) vol 171, pp 1451-1453.
[51] ACA, 'Drug Advertising', (June 2004) <http://www.choice.com.au/viewArticle.aspx?id=104325&catId=100231&tid=100008&p=1 >, accessed 31 January 2006.

6.75 Any such promotion would still be required to comply with the prohibitions on misleading and deceptive conduct in the TPA. However, the Code requires companies to include some additional information in promotional materials (as set out in section 3 of the Code) over that required by legislation. Companies would not be required to include that information in promotional materials in the 'future without', where the Code does not exist.

6.76 The absence of this information may be unlikely to demonstrate a breach of the misleading or deceptive conduct provisions of the TPA. However, it could increase the level of inappropriate prescribing by, for example, increasing the probability that a healthcare professional may be unaware of certain characteristics of the product which mean it is not the most appropriate choice for that patient.

6.77 Therefore, the ACCC considers that some public benefit may result from these provisions of the Code.

Provision of information more generally

6.78 Medicines Australia claims that it and its members 'make extensive efforts to responsibly provide healthcare professionals with information about medicines, which will improve the health of Australians.' It submits that these activities meet certain needs of healthcare professionals, including 'continuing education responsibilities … and the need to be informed of new and developing technologies in the treatment of diseases and conditions.'[52]

6.79 The ACCC does not dispute that the provision of balanced and impartial information on pharmaceutical products may be a public benefit. However, the ACCC considers that the benefit arising from the Code is likely to be nominal. This is because companies are likely to provide this information regardless of the existence of the Code, as it may provide them with a competitive advantage. Further, even in the absence of the Code, the possibility of legal action under the TPA is likely to provide an incentive for companies to ensure that any information they provide is not misleading or deceptive.

Regulation of the provision of benefits to healthcare professionals

6.80 The second broad area of pharmaceutical companies' conduct regulated by the Code is the provision of benefits to healthcare professionals.

6.81 Medicines Australia submitted that in this respect, the Code:[53]

> … encourages the quality use of medicines and rational prescribing practices, through the regulation of promotional activity including advertisements, gifts and other incentives to medical practitioners

6.82 Of those interested parties that supported the applications, only a few specifically dealt with this point. One was the AMA, who considers the Code is

[52] Medicines Australia 30 November 2005, p18.
[53] Ibid, p14.

effective in regulating the provision of benefits to healthcare professionals, particularly in light of the amendments to Edition 15.[54]

6.83 However other interested parties consider that the Code will not result in a public benefit in this respect, as it will not be effective in regulating companies' provision of benefits, whether to individual healthcare professionals or organisations.[55]

6.84 For example, the ACA referred to a recent article[56] and noted:[57]

> … data confirms that there is a high level of interaction between the pharmaceutical industry and medical organisations in Australia. This participation is common and takes many forms as the industry provides support for a wide range of activities including for: education, research, conferences, equipment and journal publications.

ACCC view

6.85 In its previous determination,[58] the ACCC noted that doctors were subject to an ethical obligation requiring them to give primacy to the welfare of their patients. It also noted that the AMA had produced guidelines on doctors' interaction with pharmaceutical companies.[59] These broadly provide that a 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.

6.86 However, the ACCC also noted that pharmaceutical companies were prepared to offer benefits, which indicated that they considered they would be able to influence a doctor's choices. In addition, it noted that a range of organisations – including the AMA, the TGA, Medicines Australia and other similar overseas bodies – believed that at least some pharmaceutical companies were likely to engage in conduct that would result in at least some health professionals inappropriately prescribing medicines.

6.87 It therefore considered that a public benefit was likely to result from reducing inappropriate prescribing. It noted that this arose from reducing the likelihood that doctors would prescribe medicines that may not be the most appropriate choice for their patient (according to scientific evidence). However, it expressed doubt that the Code was actually effective at regulating companies' conduct. It therefore found that the actual public benefit generated by the Code in this regard was small.

6.88 The ACCC notes that Edition 15 of the Code has a broader scope, regulating the provision of some types of benefits which have not previously been covered, for example, medical practice activities (see 3.22).

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[54] See, eg AMA 19 December 2005, p1.
[55] ACA 20 January 2006, pp4-5; Doctors Reform Society 20 January 2006, p1; ANF 3 February 2006, p1.
[56] Kerridge, I, Maguire, J, et al 'Cooperative Partnerships of Conflict of Interest? A National Survey of Interaction Between the Pharmaceutical Industry and Medical Organisations' *Internal Medicine Journal* (2005), v 35, pp206-210.
[57] ACA 20 January 2006, p4 (footnotes omitted).
[58] Paragraphs 5.34-5.41.
[59] AMA Position Statement *Doctors' Relationships with the Pharmaceutical Industry* (2002), see paragraph 2.16 of the previous determination.

6.89 However, it also notes that since the previous determination, there has not been a change in the perception that the provision of benefits by pharmaceutical companies may inappropriately influence healthcare professionals' prescribing. Indeed, it appears that this view is becoming more prevalent.

6.90 For example, there have been recent reports that some US states are considering introducing legislation requiring reporting of, or placing restriction on, the provision of benefits to healthcare professionals.[60] Similarly, as noted by the ACA, there is an increasing acknowledgement of the potential for pharmaceutical companies to influence medical organisations, as well as individuals.

6.91 In a recent study undertaken by Consumers International into Drug Promotion and the Pharmaceutical Industry in Europe, they found that the

> "lack of commitment to adhere to internationally accepted standards of ethical corporate behaviour at the company level raises serious doubts about the strength of industry self-regulation in ensuring high rates of implementation when it comes to corporate social responsibility codes."[61]

6.92 The report also notes that

> "Pharmaceutical companies offer health professionals a variety of incentives to promote their drugs, rather than putting consumer health and safety first… Often payments or other favours to healthcare professionals to induce them to prescribe specific drugs are disguised in some way. For example, doctors may be paid for consulting services, to attend meetings, and to provide their opinion, while the intent of the meeting may be to promote a drug. Fully sponsored continuing medical education courses or other professional events may be organised at holiday resorts or include expensive social events."[62]

6.93 The ACCC also notes in May 2006 the Royal Australasian College of Physicians updated its *Guidelines for ethical relationships between physicians and industry.* Among other things, these:

- recommend that physicians reject gifts, including items of small value[63]
- note that while accepting hospitality in connection with a professional educational meeting may be acceptable, 'it is current practice for doctors to reject pharmaceutical company entertainment invitations, and this response is appropriate and expected'[64] and
- recommend that in respect of pharmaceutical companies' support of meetings and other educational activities, physicians exercise 'great care' before accepting travel sponsorship or gifts.[65]

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[60] See, eg, States want info about drugmakers' gifts to doctors', *USA Today* <http://www.usatoday.com/money/industries/health/2006-02-16-doctor-gifts-usat_x.htm>, accessed 10 March 2006.
[61] Consumers International, *Branding the Cure*. June 2006, 26
[62] Ibid, 27-8
[63] RACP, *Guidelines for ethical relationships between physicians and industry* pp23-4.
[64] Ibid, p24.
[65] Ibid, p27.

6.94 Further, the ACCC again notes that as discussed at 6.72 – 6.73, the amount pharmaceutical companies spend on promotion indicates that they believe it will be effective.

6.95 In light of this information, the ACCC considers that to the extent the Code prevents the provision of benefits that are likely to inappropriately influence healthcare professionals – and thus reduce the level of inappropriate prescribing that may otherwise occur – it could result in some public benefit. However, the ACCC still doubts whether the code can effectively regulate company behaviour without an appropriate level of transparency.

Activities of the Monitoring Committee

6.96 In the previous determination, the ACCC imposed a condition (C1) requiring the Monitoring Committee to monitor members' provision of benefits to healthcare professionals. The aim of the condition was to improve the ability of the Code to properly regulate the provision of benefits to healthcare professionals, and to improve transparency by allowing public access to the report. The condition required companies to provide certain details of all educational meetings and symposia held or sponsored by that company during a defined three month period. The Monitoring Committee was then required to:

- refer a complaint to the Code Committee about any meeting if it was not satisfied that it would withstand public or professional scrutiny (or otherwise breached the Code) and

- provide a report to Medicines Australia for publication in its Annual Report setting out the number of meetings it had examined, the number of these that had raised concerns and were brought to the attention of the member company (including details of the aspect that raised concern), and whether any of these were forwarded to the Code Committee as a complaint.

6.97 In its submission accompanying the current applications, Medicines Australia requested that the ACCC not impose this condition due to both its 'limited benefit' and its impact on the regular activities of the Monitoring Committee. It stated that complying with this condition took up a significant proportion of the Monitoring Committee's meetings in 2004 and 2005, and resulted in it being unable to fulfil its primary function of reviewing promotional material. It also commented:[66]

> By far the majority of materials reviewed … complied with the requirements of the Code. In those cases where there was a potential breach of the Code, member companies were advised to clarify the materials they produced so that healthcare professionals would be able to decide whether or not to attend based on the educational content of the meeting. No complaints needed to be referred to the Code of Conduct Committee.

6.98 In response to a request, Medicines Australia also supplied the ACCC with copies of the Monitoring Committee reports.[67] These have been placed on the ACCC's public register.

[66] Medicines Australia 30 November 2005, p17.
[67] Medicines Australia 15 March 2006, Appendix B.

6.99 The reports set out the number of meetings examined each year (2003-04, 2004-05, 2005-06). The Committee found that compliance was high in all three years. It also provided an outline of the issues that had been raised with members and made general recommendations about how companies should conduct educational meetings. The ACCC notes that some of these recommendations are now incorporated into Edition 15 of the Code.

6.100 However, the reports do not provide some of the details that the ACCC requested be included, such as the number of meetings that raised concerns, nor what aspects of the meetings were of concern. As such, it is difficult for the ACCC to determine how effective the Code is at regulating the provision of benefits to healthcare professionals, and hence the likely extent of any public benefit. The ACCC has reconsidered this issue following the release of its draft determination. The ACCC has formed the view that in order to be satisfied of the codes effectiveness in that regard, there needs to be greater disclosure of the details of each event. This issue is discussed further at paragraphs 6.146 – 6.152.

Regulation of members' conduct in other regards

Starter packs

6.101 Section 5 of the Code regulates the distribution, storage and the information to be included with clinical samples (starter packs) of medicines (see paragraphs 3.37 – 3.45).

6.102 Medicines Australia stated that this section has been revised and expanded as a result of the *National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review). Recommendation 12 was that the states and territories repeal their legislation relating to the supply of samples of medicines and poisons, and that Medicines Australia amend its Code to include these standards.[68] This recommendation was accepted by the Australian Health Ministers' Council Working Party in its response to the Galbally Review.[69]

6.103 Medicines Australia stated that state and territory legislation relating to starter packs will be repealed by 1 July 2006.[70] It considers that there is no detriment between the Code provisions and these legislative provisions existing together until the legislation is repealed.[71]

6.104 A number of state/territory health departments commented on this section. They generally support these amendments as they appear to improve accountability and standards around possession and handling of starter packs.[72]

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[68] Medicines Australia 30 November 2005, p6.
[69] Australian Health Ministers' Advisory Council Working Party *Response to the Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review)* (April 2003), p33.
[70] Medicines Australia 30 November 2005, p6.
[71] Medicines Australia 9 January 2006, p2.
[72] See, eg Queensland Health 20 December 2005, p1; Tasmanian Department of Health and Human Services 12 January 2006, p1; WA Department of Health 18 January 2006, P1; NSW Health 16 January

6.105 Some state/territory health departments noted that the National Coordinating Committee on Therapeutic Goods (NCCTG) had not yet endorsed these provisions. However, on 15 March 2006 Medicines Australia provided a copy of a letter from the TGA stating that NCCTG members supported the Code in its revised form. Medicines Australia has since informed the ACCC that the following amendments were adopted by the Medicines Australia members on 20 June; as recommended by the NCCTG[73]:

- the words 'or by authorised company representatives (including agents working under a contract to, but not directly employed by, the holder of a manufacturer's licence or wholesale dealer's licence) have been added at the end of section 5.1.1;
- the word 'lockable' is replaced with the word 'locked' in the second sentence of section 5.1.10 and
- the words 'and can be used to administer products from more than one company' have been deleted from the Explanatory Note in section 9.4 and from the definition of Medicine Delivery Device in the Glossary.

6.106 The ACCC considers that section 5 of the Code is likely to result in some public benefit, particularly assuming that the anticipated repeal of state/territory legislation goes ahead. It notes that the Galbally review found repealing the current legislation (which varied across jurisdictions) and placing the provisions in the Medicines Australia Code would result in benefit to the community through:[74]

> reduced hospital and medical costs from medical misadventure, poisoning or diversion. There may also be some benefits to rural communities through improved access.

Effectiveness of the Code

6.107 The extent to which the benefits discussed above will flow will be determined by whether the Code is actually effective in regulating the conduct of pharmaceutical companies. If the Code is not effective, companies are unlikely to comply with it, and hence the public benefit is likely to be minimal.

6.108 In its previous determination,[75] the ACCC considered whether Medicines Australia's Code was effective only in regulating companies' provision of benefits to healthcare professionals. It expressed concern about the practical enforcement of the Code, and found that the actual public benefit generated by the Code was small.

2006, p1; ACT Health 4 January 2006, p1; Victorian Department of Human Services 29 December 2005, p1.

[73] Medicines Australia, *E-mail to ACCC*, 10 June 2006.

[74] Galbally review, p99.

[75] Paragraphs 5.58-5.60.

6.109 In its submission supporting the current applications, Medicines Australia outlined a number of amendments to Edition 15 designed to improve its general effectiveness.[76]

6.110 A number of interested parties supported these amendments, and felt that the Code was effective in regulating the conduct of pharmaceutical companies.[77] For example, Wyeth noted that:[78]

> the Code has proven to be vitally important to the prescription medicines industry in the efficient and effective regulating of marketing medicines.

6.111 However, some interested parties consider that the Code is ineffective in regulating the conduct of pharmaceutical companies.

6.112 In addition to the general comments about the Code discussed above, other examples include the Doctors Reform Society's comments that 'the Code is written in suitably vague terms such that it can be interpreted in favour of the industry very easily,'[79] although this was disputed by Medicines Australia.[80]

6.113 A number of interested parties also considered that the Code was ineffective due to flaws in its administration, including that:

- the complaints process is too onerous (particularly for consumers) and not transparent[81]
- the sanctions imposed by the Code committees are not significant, and hence do not deter companies from breaching[82]
- there is a lack of transparency surrounding the Code processes[83]
- the committees that enforce the Code are not independent[84]
- the monitoring undertaken by the Monitoring Committee is ineffective[85] and
- the processes for reviewing the Code are inadequate.[86]

[76] Medicines Australia 30 November 2005, pp3-13.
[77] See, eg, Pfizer 5 January 2006, p1; TGA 5 December 2005, p1, NSW Health 16 January 2006, Australian Government Department of Health and Ageing 17 January 2006, p1; CHF 19 December 2005, p2.
[78] Wyeth, 13 January 2006, p1.
[79] Doctors Reform Society 20 January 2006, p1.
[80] Medicines Australia 8 March 2006, p13.
[81] Doctors Reform Society 20 January 2006, p1; ACA 20 January 2006, p2.
[82] See, eg Ken Harvey 14 December p1 and 24 January 2006 p2; ACA 20 January 2006 p4; ANF 3 February 2006 p1.
[83] ACA 20 January 2006, pp2-3.
[84] See, eg Healthy Skepticism submission to Medicines Australia Review of the Code of Conduct May 2005, paragraph 21; ANF 3 February 2006 p1; Doctors Reform Society 20 January 2006, p1.
[85] ACA 20 January 2006, p2.
[86] See, eg, ACA 22 May 2006, p1.

Accessibility of complaints mechanism

6.114 Several interested parties raised concerns about the complaints mechanism being inaccessible, particularly for individuals wishing to make complaints about companies' conduct. As the Doctors Reform Society commented:[87]

> The requirement that a complaint must be registered with the Committee means that many health professionals and members of the public who have concerns do not bother with complaints because it is too onerous a task … Once a complaint has been lodged, the Appeals mechanism steps in and the complainant then has to take on the power of a multinational company, write further submissions, find time to be involved in hearings etc.

6.115 The ACA noted that no complaints had been made by consumers during 2004/05 and commented that the Code was 'not consumer friendly, most consumers are unaware of its existence.'[88] Following the draft determination, the ACA recommended that the ACCC impose a condition 'simplifying the complaints process so that consumers can become more involved.'[89]

6.116 Medicines Australia responded to these comments by recognising that it is often 'intimidating or daunting for consumers to prepare and submit complaints'[90] and that it has put in place a number of mechanisms to assist non-industry complainants to participate in the complaints process. It proposes to extend these under Edition 15, including by appointing a panel of independent facilitators to assist non-industry complainants at Medicines Australia's expense. It also notes that non-industry complainants are not required to prepare extensive complaint documentation or argument, either initially or in an appeal, but that they are able to participate in the process to whatever extent they wish.[91]

6.117 Following the draft determination, Medicines Australia stated that it 'considers that the complaints process is sufficiently accessible to consumers.'[92] It stated it has:[93]

> … recently launched a revised website which includes a pro forma complaint submission form. Further materials are in the process of being prepared that will include information directed to members of the general public about how to lodge a complaint, and how complaints are considered by the Code of Conduct and Appeals Committees. When Edition 15 of the Code comes into effect, additional information will be included in relation to the new provisions of the Code providing access to an independent facilitator.

6.118 It also stated that it has recently published a brochure for consumers. A copy of this is available on the ACCC's public register.[94]

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[87] Doctors Reform Society 20 January 2006, p1.
[88] ACA 20 January 2006, p2.
[89] ACA 22 May 2006, p2.
[90] Medicines Australia 8 March 2006, p10.
[91] Medicines Australia 8 March 2006, p11.
[92] Medicines Australia 8 June 2006, p4.
[93] Medicines Australia 23 May 2006, p2-3.
[94] Medicines Australia 8 June 2006, p4.

Sanctions

6.119 A major area of concern for some interested parties was that the sanctions imposed by the Code Committee are inadequate,[95] with the maximum possible fine for a breach being $200,000, 'insignificant for an industry which has an annual turnover of $14.5 billion.'[96] The ACA described the penalties specified in the Code as 'wholly inadequate'[97] and also noted that companies could continue to engage in the conduct while the complaint was being resolved, giving them 'ample time' to promote their new drugs.[98]

6.120 The ACA and Dr Ken Harvey felt that further evidence of the sanctions' inadequacy was:[99]

> the fact that many pharmaceutical companies repeatedly breach the Code, probably because the fines imposed are minuscule in relationship to the money gained from promotional excess (and Code breaches).

6.121 Dr Harvey also suggested some amendments to the Code in this respect:[100]

- requiring fines, publicity and corrective advertising for all proven breaches of the Code, including illegible generic names and missing information required by the Code and
- doubling the fine each time a company has an additional Code breach within the Code authorisation period (all companies have fines set to base levels when a new Code is authorised).

6.122 Healthy Skepticism proposed that:[101]

> In cases where misleading claims could lead to serious adverse health consequences, as judged by a panel independent of industry, correctional statements should commence within one week of the complaint being received.

6.123 It also recommended that the ACCC should impose a condition that:[102]

> If a promotional item or event is found to be misleading then a corrective statement should always be required.

6.124 Medicines Australia responded to these comments by noting that 'fines are only one aspect of sanctions that can be imposed if a company is found to have breached the Code.'[103]

6.125 It stated that the sanction of 'most concern to companies and most efficient to communicate to health care professionals is corrective advertising or letters'.

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[95] ACA 20 January 2006, p3; Dr Ken Harvey 24 January 2006, p2; ANF 3 February 2006, p1.
[96] ACA 20 January 2006, p3. See also ANF 3 February 2006, p1.
[97] ACA 22 May 2006, p1.
[98] ACA 20 January 2006, p3.
[99] Dr Ken Harvey, 14 December 2005, p1. See also ACA 20 January 2006, p3.
[100] Dr Ken Harvey, 24 January 2006, p3.
[101] Healthy Skepticism submission to Medicines Australia Review of the Code of Conduct May 2005, paragraph 28.
[102] Healthy Skepticism, 23 May 2006, p1.
[103] Medicines Australia 8 June 2006, p3.

The Code Committee was likely to require this type of sanction 'both to ensure any incorrect messages are corrected and to increase compliance with the provisions of the Code.'[104] It also stated that the Committee 'pays particular attention to ensure that corrective communications are not an opportunity for further promotion of any product.'[105]

6.126 It also noted that if a company is found in breach of the Code, it must cease the activity as soon as it receives the Committee minutes. It cannot recommence the activity unless and until the appeal has been heard and upheld.[106]

6.127 Further, it commented that:[107]

> The effect on companies and the cost of corrective advertising are comparable with penalties and sanctions imposed under State fair trading laws and the TPA for misleading conduct and other Part V breaches.

6.128 With respect to repeat breaches, Medicines Australia noted that companies who have breached the Code on more than one occasion are 'typically the larger pharmaceutical companies which have a wider range of products'[108] It also noted that 'higher sanctions up to a maximum fine of $200,000 apply for breach repetitions … and repeat of a previous breach.' However, it considers that it:[109]

> would be a denial of natural justice and an exhibition of prejudice to impose a very heavy sanction for a relatively minor matter simply because other complaints had been submitted against a particular company without assessing the full circumstances.

6.129 As discussed at paragraphs 3.71 – 3.72, under Edition 15 (and Edition 14), the Code Committee can impose fines of up to $100,000, or $200,000 for a severe breach or repeat breach. Edition 15 also allows for the Code Committee to impose a $50,000 fine if required corrective action is not taken within 30 days. It is also possible for the Committee to recommend a member be expelled or suspended, although there does not appear to be any evidence of this occurring in recent years.

Transparency

6.130 A number of interested parties raised concerns about the transparency of the complaints process.[110] In particular, the ACA noted that Medicines Australia will not release information before the relevant company is contacted, and that there is no provision for what will happen if the company refuses to allow the information to be released.[111]

6.131 Healthy Skepticism proposed that the full minutes of decisions by the Code and Appeals Committees be publicised by placing them on the website of the body administering the Code and the ACCC, and via media releases to health

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[104] Medicines Australia 8 March 2006, p6.
[105] Medicines Australia 7 April 2006, p1.
[106] Medicines Australia 8 March 2006, pp6-7.
[107] See, eg, Medicines Australia 8 June 2006, p3.
[108] Medicines Australia 9 January 2006, p5.
[109] Medicines Australia 8 March 2006, pp3-4.
[110] See, eg Doctors Reform Society 20 January 2006, p1; ANF 3 February 2006, p2.
[111] ACA 20 January 2006, p2.

professionals and the general public within specified timeframes.[112] Following the draft determination, it also proposed that the ACCC impose a condition that:[113]

> The Monitoring Committee should be required to publish a list of all promotional material and events that it has examined and its determinations about those materials and events.

6.132 Medicines Australia commented that the:[114]

> amendments … in relation to public reporting of Code breaches 'should diminish the Commission's previous concerns about the practical enforcement of the Code. As a result, the public benefit generated by these provisions is greater than the public benefit generated by the provisions of Edition 14.

6.133 It responded to interested parties' concerns by noting:[115]

- In addition to the information contained in its Annual Report, Medicines Australia currently publishes information about finalised complaints every six months on its website. This information will be published quarterly under Edition 15.

- Complaints about activities directed to consumers are published as soon as the complaint is finalised. It also noted that under Edition 15 a company cannot refuse to have information relating to complaints published.

- It commented that the timeframes suggested by Healthy Skepticism are 'impractical and could not reasonably be met.'[116]

- It considered Healthy Skepticism's proposed condition was not 'necessary or appropriate.' It also stated that if this were adopted, it would 'result in inefficiency and delay in the monitoring process.'[117]

Independence

6.134 Some interested parties expressed the concern that the committees dealing with breaches of the Code are not sufficiently independent of Medicines Australia.[118] Following the draft determination, Healthy Skepticism proposed that:[119]

> The Code of Conduct Committee should include a majority of people with expertise at evaluating pharmaceutical promotion who have no competing interests during the past five years involving any pharmaceutical company. There should be at least one person with expertise in each of the following fields: clinical pharmacology, informal logic, ethics, marketing, advertising, public relations and the psychology of influence.

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[112] Healthy Skepticism submission to Medicines Australia Review of the Code of Conduct May 2005, paragraphs 25-6.
[113] Healthy Skepticism 23 May 2006, p1.
[114] Medicines Australia 30 November 2005, p15.
[115] Medicines Australia 8 March 2006, pp5-6.
[116] Medicines Australia 7 April 2006 p3.
[117] Medicines Australia 8 June 2006, p4.
[118] See, eg ANF 3 February 2006, p1; Doctors Reform Society 20 January 2006, p1; ACA 20 January 2006, p7.
[119] Healthy Skepticism 23 May 2006, p1.

6.135 Medicines Australia responded that the majority of the Code of Conduct Committee's membership is independent of the pharmaceutical industry. It stated:[120]

> Therefore it is unreasonable to claim that the process is unbalanced or weighted in favour of particular companies or the industry broadly.

Monitoring

6.136 The ACA commented that the 'Monitoring Committee is ineffective in monitoring the advertisements of pharmaceutical companies', primarily due to a lack of clarity on monitoring procedures.[121]

6.137 Medicines Australia responded by outlining the process the Monitoring Committee uses to review companies' promotional material.[122] Following the draft determination, it also clarified the Monitoring Committee's activities (see paragraph 3.82) and stated:[123]

> It is certainly not Medicines Australia's intention to reduce the Committee's role. Rather the amendment … included in Edition 15 is intended to reflect the greater breadth of activities to be reviewed each year.

Processes for reviewing the Code

6.138 Prior to the draft determination, CHF had commented on the need for consumer organisations to be able to provide input about the Code (see paragraph 6.231).

6.139 Following the draft determination, the ACA commented:[124]

> There are no adequate measures … to consult the public, consumer organisations or others on required changes to the Code or to review and improve the Code.

6.140 Medicines Australia responded that it:[125]

> … undertook extensive and comprehensive consultations with internal and external organisations during the development of Edition 15 of the Code. … MA also submits that through the authorisation process it has submitted the Code to further comprehensive review and has demonstrated its willingness to respond to valid comments made during this process.

ACCC view

Accessibility

6.141 The ACCC understands that the vast majority of complaints made under the Code are made by other pharmaceutical companies (see Table 2, page 22). It considers it is difficult to determine whether the lack of complaints by others (particularly consumers) is due to a lack of awareness of the Code's existence, or difficulties with accessing the complaints mechanism.

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[120] Medicines Australia 8 June 2006, p2.
[121] ACA 20 January 2006, p2.
[122] Medicines Australia 8 March 2006, p5.
[123] Medicines Australia, 4 May 2006, p2.
[124] ACA 22 May 2006, p1.
[125] Medicines Australia 8 June 2006, p3.

6.142 The ACCC considers that some of the amendments included in Edition 15 (such as the provision of independent facilitators) may improve accessibility for non-industry complainants. Further, any increase in the information available to the general public on the complaints process may improve accessibility. The ACCC notes Medicines Australia's advice that further changes are to be implemented to improve the complaints process (see 6.118). However, it is difficult to determine that these changes have actually had an effect until they have been operating for a period of time.

Sanctions

6.143 The ACCC notes that the data in Table 3 (page 23) indicate it is far more likely for the Code Committee to require a company to take corrective action (including withdrawing the material) than it is to impose a fine. Further, Table 4 (page 24) shows that nearly all of the fines that are imposed are at the lower end of the range.

6.144 It is aware of Medicines Australia's contention that in many cases, the cost and 'negative publicity' associated with withdrawing or correcting material found to be in breach is likely to be a stronger incentive for companies to comply than a pecuniary penalty. However, the ACCC is concerned that the Code and Appeals Committees do not appear to impose heavy sanctions in any circumstances. It considers that this raises some doubt about the effectiveness of the Code.

6.145 The ACCC is also concerned that the Code Annual Reports indicate that some companies have been found to breach the Code multiple times. Even taking into account Medicines Australia's explanation that these companies tend to be those with a greater product range, it is still concerned that they are regularly breaching the Code, and that the penalties imposed by the Code Committee do not appear to reflect this.

Transparency

6.146 The ACCC considers that the Code Annual Reports currently set out adequate detail on the complaints heard by the Code committees. It notes that it was a condition of the previous authorisation that these reports were published on Medicines Australia's website, and welcomes this being incorporated into Edition 15 of the Code.

6.147 However, the ACCC remains concerned about the general level of transparency surrounding the activities of pharmaceutical companies.

6.148 In particular, it remains concerned about whether the Code is effective in regulating a key area for potential public benefit, namely the provision of benefits to healthcare professionals. The ACCC notes that the level of complaints received about this continues to be low (see 3.93). This may be due to a high level of compliance by member companies. However, it could also be due to a low level of awareness of what benefits companies are providing to healthcare professionals.

6.149 The ACCC considers that it is difficult to determine the level of compliance in the absence of published information on the details of meetings. Without this information, it is difficult for outside groups to access information on what activities companies are engaging in, or to understand the standards applied by the Monitoring Committee when assessing whether companies are complying with the Code. This is particularly relevant as many of the standards are subjective (eg whether meals provided are 'extravagant or exceed standards which would meet professional and community scrutiny').[126]

6.150 The ACCC is therefore imposing a condition, discussed at 6.200 – 6.228.

Monitoring

6.151 The ACCC acknowledges the continuing role of the Monitoring Committee in encouraging compliance with the Code, particularly through reviewing companies' promotional material. The small presence of those outside the industry is of concern and adds to the ACCC's concerns regarding transparency outlined at 6.147 - 6.151.

6.152 The ACCC notes that unlike Edition 14, Edition 15 does not specify the amount or subject-matter of the material that the Monitoring Committee will review each year. However, as outlined at paragraph 3.82, Medicines Australia has stated that as a minimum, it will review:

- one type of promotional material in three different therapeutic classes and
- three different promotional activities across all therapeutic classes.

6.153 This appears to be less than was required by Edition 14, which required the Monitoring Committee to review 'specific types of promotional material' for seven therapeutic classes each year.[127] However, the ACCC also considers it may be more useful for the Monitoring Committee to assess a wider *variety* of promotional activities than similar promotional activities over different therapeutic classes. It particularly encourages the Monitoring Committee to review 'non-traditional' promotional activities, such as company websites.

Process for reviewing the Code

6.154 The ACCC is aware that section 11.4 of the Code requires that it be reviewed every three years. It considers that a key way of ensuring the Code is effective is to provide opportunities for as many stakeholders as possible to give feedback on its operation. This issue is discussed further at 6.230 – 6.234 below.

General comments

6.155 The ACCC is of the view that the Code's effectiveness in actually modifying the conduct of pharmaceutical companies remains somewhat unclear. Hence it is difficult to determine the extent of any public benefit.

[126] See sections 6.2.2 and 10.2.
[127] See Appendix 3, Edition 14.

6.156 It notes that some of the amendments in Edition 15 may improve its effectiveness, such as:

- the provision of an independent facilitator to assist non-industry complainants
- the TGA member now having voting rights and
- the new procedures managing the potential conflict of interest for committee members.

6.157 As discussed earlier, under the authorisation process, the ACCC must compare the Code with a situation in which the Code does not exist at all. While some interested parties have made suggestions for ways the Code could be improved, the ACCC's role is to assess the Code as drafted. It cannot craft an 'ideal' code.

6.158 Overall the ACCC continues to have real concerns about whether the Code is actually effective in modifying companies' conduct without the condition. As such, the ACCC has apprehension about the uncertain nature of possible benefits.

6.159 The ACCC notes that the Code does not cover certain activities of pharmaceutical companies. It is particularly concerned that the Code does not appear to regulate certain forms of promotion, including indirect promotion to consumers (see paragraph 6.45). The ACCC is of the view that the Code would be more effective if it regulated *all* activities of pharmaceutical companies which may result in promotion of their products.

Anti-competitive detriment

Regulation of provision of information

6.160 In its previous determination, the ACCC concluded that the provisions of the Code regulating the provision of information were unlikely to significantly affect competition between pharmaceutical companies. Consequently the ACCC found they were likely to generate minimal, if any, public detriment.[128]

6.161 Medicines Australia submits that these conclusions 'should apply equally to the relevant provisions of Edition 15.'[129]

6.162 With the exception of promotion of Medicine Delivery Devices (see 6.163) few interested parties explicitly commented on whether the Code was likely to affect competition. Of those that did, most considered that any detriment would be minimal.[130] For example, Pfizer stated:[131]

> We do not consider that the new edition of the Code will cause any detriment to the general public or that it will have a substantial impact on competition between pharmaceutical

[128] Paragraphs 5.61 – 5.69.
[129] Medicines Australia 30 November 2005, p14.
[130] See, eg, AMA 19 December 2005, p2, Merck, Sharpe & Dohme 18 January 2006, p1.
[131] Pfizer 5 January 2006, p2.

> companies. In our view, the new Code still allows pharmaceutical companies to effectively compete with each other – it simply requires them to do so in accordance with the high standards of conduct that are contained in and promoted by the Code.

Medicine Delivery Devices

6.163 Novo Nordisk expressed concern with the explanatory note to section 9.4. This stipulates that the only Medicine Delivery Devices (MDDs) which can be promoted to the general public are those that 'can be used to administer products from more than one company' (see paragraph 3.47). It made the following points:

- The proposed amendment differs from the guidelines provided in the Therapeutic Goods Advertising Code (TGAC) for medical devices.[132] It has not been able to identify any TGAC requirement for medical devices to be able to administer medicines from more than one company.[133]
- A number of insulin delivery devices registered/listed on the ARTG can be used for the administration of more than one medicine from one supplier. Under Edition 15, promotion of these devices would no longer be allowed.[134]
- The proposed amendment may inadvertently provide a competitive advantage for insulin and device suppliers whose products can be used for the administration of medicines from more than one company.[135]

6.164 However, Sanofi-aventis supported the proposed amendment to section 9.4 and accompanying explanatory note. It considered that:[136]

> promotion of insulin devices that can only be used with a limited range of prescription insulin's (sic) that are only provided by a single sponsor amounts to promotion of that insulin.

6.165 The ACCC notes that this explanatory note has been expanded from Edition 14, which simply stated that 'promotion of an insulin delivery device is permitted.'[137]

6.166 A MDD is defined in the glossary as being:

> any device used for the administration of a prescribed medicine, including Schedule 3 medicines that are predominantly prescribed by a medical practitioner that is distributed independently from the active ingredient and can be used to administer products from more than one product [sic]. The device will be listed with the TGA as a device.

6.167 In its submission of 8 March 2006, Medicines Australia stated that it had sought advice from the TGA on this matter. It noted that the TGA had advised it that the inclusion of the words 'and can be used to administer products from more

[132] Novo Nordisk 15 December 2005, p3.
[133] Ibid, p5.
[134] Ibid, p3.
[135] Ibid.
[136] Sanofi-aventis 23 January 2006, p1.
[137] Explanatory note, section 9.4 of Edition 14.

than one company' imposed too restrictive an interpretation of the TGAC. It also stated:[138]

> Medicines Australia therefore intends to propose to its members that the Explanatory Note to Section 9.4 is amended by deletion of those words.

ACCC view

6.168 As noted in the previous determination,[139] the ACCC considers that generally, promotion of products is a key aspect of a company's competitive activities, as it may significantly influence consumers' choices. However, whether the restrictions imposed in a particular case will actually reduce competition depends on the nature of the restrictions on advertising in question, as well as any relevant characteristics of the market.

6.169 The ACCC found that the sections of Edition 14 regulating the provision of information were likely to result in a minimal effect on competition, and that their primary function was to ensure that pharmaceutical companies' promotional material is not false or misleading. As the legislative prohibitions on false or misleading representations would still exist even if the Code was not authorised, the ACCC considered that the Code was likely to have a minimal effect on competition between pharmaceutical companies.

6.170 However, the Code also goes beyond the legislative prohibition. It requires all promotional and educational material to conform to generally accepted standards of good taste, and to recognise the professional standing of the recipient. Despite this, the ACCC found it was unlikely to significantly affect competition between pharmaceutical companies. This was because vigorous advertising was part of the culture of the pharmaceutical industry, and as Medicines Australia is controlled by the pharmaceutical industry, the provision was unlikely to be used to substantially restrict normal commercial advertising by its members.

6.171 For similar reasons, the ACCC considers that the sections of Edition 15 regulating the provision of information are unlikely to significantly affect competition. While there have been some amendments to these provisions – particularly in the additional information companies are required to include in advertisements (see paragraphs 3.5 – 3.14) – it does not consider that these are likely to have a significant impact on competition.

6.172 The only possible exception to this conclusion relates to the advertising of MDDs. The ACCC notes that direct-to-consumer advertising of MDDs is permitted under the TG Act, although it must comply with the TGAC.

6.173 The ACCC notes that Medicines Australia has stated it intends to amend the Explanatory Note. Accordingly, the ACCC has assessed the explanatory note as if it reads:

> Promotion of a medicine delivery device to the general public is permitted in restricted circumstances. A medicine delivery device which is used for the administration of a

[138] Medicines Australia 8 March 2006, p13.
[139] Paragraphs 5.61 – 5.69.

> prescription medicine, including Schedule 3 medicines that are predominantly prescribed by a medical practitioner, that is distributed independently from the active ingredient, is permitted as long as the medical device is not branded with the name of a particular medicine. The device must be listed with the TGA as a device.

6.174 Without this proposed amendment, the ACCC considers that the provision would go beyond the requirements of the TG Act and the TGAC. However, with this amendment, the ACCC considers that this section is unlikely to raise competition concerns.

Regulation of provision of benefits to healthcare professionals

6.175 In its previous determination,[140] the ACCC found that without the Code, the promotional activities of at least some pharmaceutical companies may inappropriately influence the prescribing habits of at least some healthcare professionals. It noted that a restriction on the provision of benefits was therefore likely to constitute at least some restriction on competition in this area.

6.176 In respect of the current applications, Medicines Australia commented that the Code:[141]

> encourages good practices … which are over and above the legal requirements faced by suppliers of prescription pharmaceutical products. This means that members and non-members that submit to the Code face competitive constraints.

6.177 In its previous determination, the ACCC considered that the main effect of a significant lessening of competition would be to reduce the degree to which healthcare professionals would otherwise prescribe pharmaceutical companies' products. This could detrimentally affect the quality of pharmaceuticals produced in the market by reducing pharmaceutical companies' returns, and hence their available funds for research and development.

6.178 However, the ACCC found that even if the restriction on competition was significant, in practical terms it would be unlikely to generate more than a minimal detriment to the public. This is because pharmaceutical companies develop new drugs for supply worldwide, and it was unlikely that restrictions on the provision of benefits to healthcare professionals in a smaller market such as Australia would significantly detract from companies' ability to fund research. The ACCC also noted it would need credible evidence that any foregone revenue was likely to be directed to research and development.

6.179 Medicines Australia submits that the ACCC's conclusions 'in relation to the minimal public detriment … should apply equally to the relevant provisions of Edition 15.'[142]

6.180 No interested party considered that these provisions of the Code were likely to result in a lessening of competition.

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[140] Paragraphs 5.71 – 5.75.
[141] Medicines Australia 30 November 2005, p14.
[142] Ibid.

ACCC view

6.181 Consistent with the reasons outlined in its previous determination, the ACCC considers that the anti-competitive detriment resulting from the sections of the Code regulating the provision of benefits to healthcare professionals is likely to be minimal.

Regulation of members' conduct in other regards

Starter packs

6.182 The ACCC considers it is possible that section 5 of the Code could result in some lessening of competition between pharmaceutical companies, primarily by placing some constraints on one method they may use to promote their products.[143]

6.183 However, the ACCC considers that this detriment is likely to be minimal, particularly as the provisions do not prohibit the supply of starter packs altogether.

Other public detriment

6.184 Some interested parties considered that the Code may result in public detriment that was not related to any anti-competitive effects.

Conduct of company representatives

6.185 The ACA expressed particular concern about the Code's limited regulation of the conduct of pharmaceutical company representatives, who 'have more influence on prescribing practices that all other promotional modalities.'[144] It considers that:[145]

> Even though medical practitioners voice concern about the quality of information pharmaceutical representatives provide, they remain reliant on them for much of their information. … these conflicts of interest can be potentially extremely dangerous because human lives are at stake.

6.186 Medicines Australia responded by noting that:[146]

> It is a fundamental tenet of the Code … that all promotion must be balanced, accurate, correct and fully supplemented by the TGA approved Product Information.

6.187 Following the draft determination, the ACA proposed that the ACCC impose a condition to make 'information about the training program which pharmaceutical company representatives undergo more transparent'. It commented that 'members of the public who are not enrolled are currently unable to obtain any information about the course.'[147]

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[143] As noted by the Galbally review, p98.
[144] ACA 20 January 2006, p4.
[145] Ibid.
[146] Medicines Australia 8 March 2006, p8.
[147] ACA, 22 May 2006, p2.

6.188 Medicines Australia responded that the ACA's claims were incorrect, as a course outline is available from the MA website, and from the University of Queensland website.[148]

6.189 The ACCC notes the ACA's concerns. However, in the absence of these sections of the Code, the ACCC considers it unlikely that company representatives would be required to undertake any such training. Therefore, while it is not clear that the Code is entirely effective in regulating the conduct of company representatives, it considers it is difficult to find that it results in a public detriment in this regard.

Product Familiarisation Programs

6.190 The SA Department of Health provided a submission discussing some concerns about Product Familiarisation Programs (PFPs). It noted that the South Australian Therapeutics Advisory Group is currently considering a state-wide policy relating to PFPs, and set out a number of areas that are not currently covered by the Code, but may be covered by the policy.[149]

6.191 Medicines Australia noted these concerns, but stated:[150]

> The industry has been criticised in the past for supplying large numbers of doctors and patients with medicines at no cost in order to gain market share or to exert influence on advisory committees such as the PBAC when considering an application for listing on the PBS.

6.192 Medicines Australia also submitted that some of the issues raised by the SA Department of Health would be more appropriately dealt with by hospital policies and procedures.

6.193 The ACCC notes the concerns raised by the SA Department of Health, and particularly the potential for some detriment to the public to result from PFPs being used inappropriately. However, the ACCC considers that without the Code, there would be minimal regulation of PFPs. As such, compared to the counterfactual, it finds it unlikely that the Code will result in a public detriment in this respect.

6.194 The ACCC also notes that the Code does not prevent hospitals or other bodies implementing procedures to govern how pharmaceutical companies interact with their staff and/or patients.

Balance of benefit and detriment

6.195 Before it can grant authorisation it must be satisfied that the Code is likely to result in a net public benefit. The ACCC questions the potential for public benefit resulting from the code as it is unsure whether the code is effective in changing the behaviour of pharmaceutical companies.

6.196 The ACCC considers that the Code could result in some public benefit through:

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[148] Medicines Australia 8 June 2006, p4.
[149] SA Department of Health 24 January 2006, pp1-2.
[150] Medicines Australia 8 March 2006, p14.

- enhancing compliance with the legislative prohibitions on misleading or deceptive conduct

- enhancing compliance with the legislative prohibition on direct-to-consumer advertising and

- encouraging rational prescribing practices.

6.197 However, the ACCC remains concerned about the Code's effectiveness in regulating the conduct of pharmaceutical companies. It therefore considers that the extent of the public benefit that will actually result from the Code is uncertain, particularly with respect to its regulation of the provision of benefits to healthcare professionals which is an area which the ACCC has identified as a key area of possible public benefit.

6.198 The ACCC also considers that the Code is likely to result in minimal public detriment, particularly as its effect on competition between pharmaceutical companies is likely to be negligible.

Condition

6.199 The ACCC considers it is difficult to precisely determine the potential (but not certain) public benefits arising from the code. It therefore considers that there is some uncertainty about whether the public benefit outweighs the public detriment. In cases such as this, the ACCC may consider whether it is possible to grant authorisation subject to conditions. Conditions can be aimed at reducing the anti-competitive detriment or increasing the public benefit, to ensure that the public benefit outweighs the public detriment of the proposed arrangement.

6.200 In this case, the ACCC continues to be particularly concerned about the level of transparency surrounding pharmaceutical companies' activities in the provision of benefits to healthcare professionals.

6.201 In the draft determination, the ACCC proposed a condition (C1) which required member companies to provide information on all company-supported educational events for a randomly chosen month each year. The Monitoring Committee was then to assess this information, and also publish certain information as part of the Code of Conduct Annual Report.

6.202 Following the release of the draft determination, Medicines Australia provided an outline of how it proposed to comply with this condition.[151] The ACCC was concerned that this proposal would not provide adequate detail to ensure an appropriate level of transparency. It therefore proposed a different reporting regime, which required more detail of each event to be published.[152]

6.203 Medicines Australia initially expressed a number of concerns with this proposal. It stated that 'there is no factual basis for the Commission's proposal'

[151] Medicines Australia, 4 May 2006.
[152] ACCC letter to Medicines Australia, 7 June 2006

as the Monitoring committee has never found it necessary to refer an issue to the Code Committee as a complaint.[153]

6.204 It considered that imposing the condition seemed to be based on an 'unwarranted and unjustified presumption by the Commission that the prescribing habits of doctors are influenced inappropriately by pharmaceutical companies' which it feels 'impugn[s] the reputation of the medical profession as a whole' and is 'by implication, an apparently baseless denigration of the character of MA industry executives.'[154]

6.205 Medicines Australia also considered that the proposed condition would have an anti-competitive effect by:[155]

- Requiring competitors to disclose commercially confidential information about their marketing strategies and about the 'nature and scale of investment by MA member companies (as opposed to non-member companies) in medical community education programs'.

- Placing members at a disadvantage because the activities of non-members will not be reported at all. It also considers that requiring publication of such detailed information may deter some companies from being members, 'which would significantly undermine the purpose and benefits afforded by the Code.'

- Standardising the benefits provided by member companies, and therefore reducing 'legitimate competitive activity' resulting in 'an overall decrease in the educational benefits provided to medical professionals and a corresponding decrease in the public benefit flowing from the better education of health professionals'.

6.206 It also considered that it would place an unduly onerous administrative burden on both the Monitoring Committee and member companies. It stated that even with the reporting period reduced to one month, the 'monitoring Committee is likely to review some 700 educational events and symposia'.[156] It also made a number of comments about the potential for certain criteria to be difficult to interpret.[157]

6.207 Medicines Australia also stated that the amended condition:

- Has 'no discernible benefit to consumers or healthcare professionals' as it does not provide information that will enable a consumer to determine whether his/her doctor has prescribed a certain drug due to the inappropriate influence of a pharmaceutical company. Further, 'healthcare professionals and their governing bodies such as the RACGP and AMA must, and MA submits, so, take responsibility for deciding which benefits … should be accepted by prescribers without giving rise to potential conflict of interest

[153] Medicines Australia, 28 June 2006, p4.
[154] Ibid, pp4-5.
[155] Ibid, pp5-6.
[156] Ibid, p6.
[157] Ibid, p7.

which have the capacity to compromise the treatment decisions made by the healthcare professional.

- Has the potential to be misinterpreted or misused 'by elements of the media or consumer groups … and could cause patients to question the value of their medicines, ultimately discouraging them from filling a prescription or from taking their medicines altogether.'[158] It stated:[159]

  > The level of detail that the Commission proposes companies should provide will expose both healthcare professionals and pharmaceutical companies to public criticism by those who lack understanding as to the genuine educational benefits of the meetings.

- May deter doctors from attending 'legitimate and valuable educational events', as companies will be required to disclose to attendees in advance of every meeting that details of the proposed meeting may be disclosed to the 'Monitoring Committee and ultimately in the public domain'. It also stated that in fields where there are a small number of practising specialists, 'it would be relatively easy to deduce that a particular doctor had attended a meeting'.[160] It feels that dissuading doctors may:[161]

  > deprive them of an important source of education and information, as well as depriving the medical profession of genuine opportunities for networking and gaining vital professional accreditation points. Ultimately, this could lead to a less informed healthcare profession.

6.208 Finally, Medicines Australia considered that it may impact on venue providers through:[162]

- encouraging companies to select certain venues, as their publishing 'a list of venues that have not raised a complaint … may be interpreted as a "positive" list

- having 'perverse effects on the market, such as the exertion of pressure to select one venue over another solely on the basis of cost rather than its suitability as a location to provide eduction'

- adversely affecting competition between venue providers through increasing transparency of the costs they charge.

6.209 The AMA highlighted concerns regarding the 'intrusive' nature of the proposed condition.

> "The AMA is concerned that the level of detail of reporting that is required in this condition is unjustified in relation to the demonstrated public benefit, and that it is likely to deter pharmaceutical companies from providing educational services, and may also discourage doctors from attending them."[163]

[158] Ibid, p8.
[159] Ibid.
[160] Ibid, p9.
[161] Ibid.
[162] Ibid, p9.
[163] AMA, 6 July 2006

6.210 The ACCC strongly disagreed with these submissions from Medicines Australia in response to the ACCC's proposed reporting requirements.

6.211 To grant authorisation, the ACCC must be satisfied that the public benefits that arise from the proposed arrangements outweigh the public detriments. Where conditions are required to satisfy the ACCC that this will occur, it is appropriate for the ACCC to impose conditions accordingly.

6.212 The ACCC remains of the view that improving transparency of the functions sponsored by pharmaceutical companies is important, particularly given the concerns raised by interested parties (see 6.83 – 6.84). It considers that this will increase confidence in the work of the Monitoring Committee and provide an assurance that the Code of Conduct is effectively enforced.

6.213 As discussed at 6.148 – 6.150, the level of complaints received about the provision of benefits to healthcare professionals continues to be low. This could indicate either that the Code is not being effectively enforced, or that there is a high level of compliance. The ACCC considers that, if the latter is correct, requiring companies to publish details of educational meetings is a useful tool to demonstrate this and strengthen confidence in the Code. Alternatively, if the former is correct, the condition should assist in enhancing enforcement.

6.214 Medicines Australia initially considered that the imposition of the condition somehow impugns the reputation of the medical profession and MA executives. These arguments fly in the face of the purpose of the code and the benefits Medicines Australia says it delivers. By their own admission, the code is said to regulate the behaviour of pharmaceutical companies to avoid inappropriate hospitality and/or sponsorship.

6.215 The ACCC notes a harbour cruise function that was held in late 2005. Whilst a complaint was lodged by another pharmaceutical company, the ACCC notes that in the Committee's findings no invitation to the event was supplied to the monitoring committee. This raises serious concerns about the committee's reliance on invitations to such events being supplied by the pharmaceutical companies. If a complaint had not been made by a competitor, the event would never have been scrutinised by the Committee.

6.216 The intention behind the reporting condition as described at 6.213 above does no more than support the intent of the code itself; it intends to ensure appropriate practices and to enhance confidence in the code.

6.217 As for Medicines Australia's initial concerns that there is no evidence that matters of concern arise, the ACCC accepts that it may reflect the position that there are few instances of concern. However, the ACCC is not confident that current review practices are sufficient to pick up all instances of inappropriate hospitality.

6.218 Discussions with Medicines Australia and the contents of its annual report make it clear that in reviewing invitations, the Committee has a focus of form over substance. In two recent findings on complaints lodged by competitor

pharmaceutical companies regarding the venue chosen for educational meetings, the Committee focused on the prominence of the restaurant name on the invitation rather than appropriateness of hospitality provided.

> "BMS stated that the venue on the invitation was Bondi Icebergs Function Room whereas it is the Icebergs Dining Room and Bar that has received recognition for fine dining…Members considered that while it may be possible for a casual reader to assume that the meeting was to be held at the restaurant, there was no emphasis on the venue in the design of the invitation."[164]

> "The Committee considered that the invitation did not emphasise the venue for the meeting, but the Committee did encourage Biogen to provide greater detail in future invitations about the duration of the educational component at a meeting." [165]

6.219 The ACCC considers that the condition is necessary for it to be satisfied that the benefits from the Code are realised.

6.220 The ACCC notes Medicines Australia's initial comments that the reporting proposed by the ACCC was highly resource-intensive for the Monitoring Committee. However, the ACCC considers that requiring public reporting of companies' provision of benefits to healthcare professionals is likely to be the only way for those outside the industry to determine the extent to which companies are complying with the Code in this respect.

6.221 The ACCC considers that much of the tabulation of information will be undertaken by member companies. This is likely to further reduce the reporting burden on the Monitoring Committee.

6.222 The ACCC notes that the administrative burden placed on member companies is unlikely to be significant as it is likely that member companies compile information of this nature in order to evaluate their educational activities throughout the year.

6.223 In reviewing the condition following the release of the draft determination, the ACCC has increased the monitoring and reporting period. Whilst the ACCC acknowledges that this will involve the tabulation and review of more data, the ACCC believes that the increase in administrative burden will be minimal, as the form the data will be presented in will be much easier to compile and review. The ACCC considers the reporting and monitoring periods included in this determination important to ensure a necessary level of transparency.

6.224 The ACCC notes Medicines Australia's initial arguments, supported to some extent by the AMA, that the reporting proposed by the ACCC would somehow deter medical practitioners from attending legitimate educative functions. The ACCC rejected these arguments outright. The reporting does not identify individuals. The argument that public scrutiny would jeopardise attendance at legitimate educative events is not accepted by the ACCC.

6.225 The ACCC wrote to Medicines Australia on 21 July 2006 advising it that the ACCC was likely to impose reporting requirements similar to those set out in

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[164] Medicines Australia, *2005 Code of Conduct Annual Report*, 32-3
[165] Medicines Australia, *Report July – December 2005, Complaints finalised.* 10

the table attached to the ACCC's letter of 7 June 2006[166] and to extend the period of Medicines Australia's monitoring and reporting of educational events. Medicines Australia responded to this letter on 25 July 2006, proposing a revised table very similar to what the ACCC sought to achieve.

6.226 While Medicines Australia submitted that the ACCC should not extend the reporting period, the ACCC considers, for the reasons outlined above, that extending the monitoring and reporting periods is important to ensure the necessary level of transparency.

6.227 Accordingly, the ACCC imposes the following condition:

1. Medicines Australia will require member companies to, with regard to all educational meetings and symposia as defined in sections 6, 7 and 10 of the Code held or sponsored by that company:

a. complete the table set out at Attachment A for each month of the financial year

b. provide a copy of the completed table for two six month periods every year (July to December; January to June) to Medicines Australia at the end of each six month period.

Medicines Australia is required to:

c. make publicly available on its website the completed table provided by each member company within three months of the end of each six month period

d. at the end of each financial year the Monitoring committee must scrutinise the detail of three random months selected from information provided by the members.

2. Further to the above, where the Monitoring Committee suspects a potential breach of the Code, it may request further information such as a copy of the invitation to the meeting and a copy of any printed material provided to attendees.

3. 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.

4. The reporting and monitoring requirement will come into effect on 1 October 2006.

5. The Monitoring Committee shall also provide a detailed report on its other activities to Medicines Australia for publication in the Code of

[166] ACCC to Medicines Australia, 7 June, 2006.

Conduct Annual Report. This report shall also list any concerns that were forwarded to the Code of Conduct Committee as a complaint, setting out the name of the member company and the date it was referred.

Other proposed amendments

6.228 The ACCC notes that some interested parties recommended additional amendments and/or conditions be imposed. The ACCC considers that the operation of the Code could be improved, for example, by:

- strengthening the restriction on advertising in electronic prescribing software
- strengthening the sections of the Code covering companies' provision of information to consumers to better distinguish this from promotional activities and
- considering ways to expand its coverage to include *all* activities that may result in promotion of a company's products, even those not specifically covered by sections of the Code (see discussion at 6.44 – 6.45 and 6.159).

6.229 As noted throughout, it is not the role of the ACCC to design the perfect code. Accordingly, the ACCC does not intend to impose such conditions. This said, the ACCC would expect Medicines Australia to make progress in these areas. Failure to move on community expectations would be relevant in any future consideration of the Medicines Australia Code of Conduct.

Duration of authorisation

6.230 Medicines Australia sought authorisation for five years.

6.231 ACT Health, the ACA, Dr Ken Harvey and CHF all submitted that the period of authorisation should be less than five years, with ACT Health and Dr Harvey suggesting a three year period. The ACA and CHF did not suggest a period, but noted that there was a need for the Code to be 'monitored and improved on a regular basis'.[167] CHF also noted that:

> consumer organisations should have the right to provide input to Medicines Australia and the ACCC in a timely manner, as issues relating to the Code emerge. For example, CHF has raised with Medicines Australia the emerging issue of pharmaceutical company sponsorship of travel or hospitality for a consumer representative, which is not currently regulated anywhere or by any code.

6.232 Section 11.4 of the Code states that Medicines Australia will carry out a review of the Code, including seeking input from interested parties, every three years.

6.233 Such a review may result in significant amendments to the Code (including, but not only, if a new edition of the Code were developed). The ACCC considers that in this situation, it is likely that Medicines Australia would need to seek a revocation of these authorisations – which relate to Edition 15 – and their

[167] ACA 20 January 2006, p7.

substitution with fresh authorisations. The process for revocation and substitution is discussed at paragraphs 1.3 – 1.9.

6.234 Given this, the ACCC considers it would be more appropriate to grant authorisation for the same time as Edition 15 is likely to remain current. The ACCC therefore grants authorisation for a period of three years.

Other issues

Authorisation is not endorsement

6.235 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 ACCC of the Medicines Australia Code.

7. Determination

7.1 On 30 November 2005, Medicines Australia lodged applications for revocation of authorisations A90779 and A90780 and their substitution with authorisations A90994, A90995 and A90996 with the Australian Competition and Consumer Commission (the ACCC).

7.2 Applications A90994 and A90995 were made under section 91C of the *Trade Practices Act 1974* (the TPA) to revoke authorisations A90779 and A90780 in respect of Edition 14 of the Medicines Australia Code of Conduct (the Code), and substitute them with authorisations relating to the Edition 15 of the Code.

7.3 Application A90996 was made under section 88(8) of the TPA to engage in conduct that constitutes or may constitute the practise of exclusive dealing, within the meaning of section 47 of the TPA.

7.4 Authorisation was sought in relation to the Code to:

- make or give effect to a contract, arrangement or understanding where a provision of the contract, arrangement or understanding is, or may be, an exclusionary provision within the meaning of section 45 of the TPA (A90994)

- make or give effect to a provision of a contract, arrangement or understanding, a provision of which has or may have the effect, of substantially lessening competition within the meaning of section 45 of the TPA (A90995) and

- engage in conduct that constitutes or may constitute the practice of exclusive dealing (A90996).

7.5 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.

7.6 Medicines Australia sought authorisation for a period of five years.

Statutory test

7.7 Having regard to the public benefits and detriments likely to flow from the authorisations the ACCC is satisfied:

- Pursuant to section 91C(7) of the TPA, that the conduct for which authorisation is sought under A90994 is likely to result in such a benefit to the public that the arrangements should be allowed to occur.

- Pursuant to section 91C(7) of the TPA, that the conduct for which authorisation is sought under A90995 is likely to result in public benefits that outweigh the public detriment constituted by any lessening of competition that would be likely to result from the arrangements.

- Pursuant to section 88(8) of the TPA, that the conduct for which authorisation is sought under A90996 is likely to result in such a benefit to the public that the arrangements should be allowed to occur.

Determination

7.8 The ACCC therefore **grants** authorisation to applications A90994, A90995 and A90996 for **three** years for the conduct described at paragraphs 7.2 – 7.3.

Interim authorisation

7.9 The ACCC granted interim authorisation to the Medicines Australia Code of Conduct on 26 April 2006. Interim authorisation protects the parties from action under the TPA until the date this determination comes into effect or until a decision to revoke interim authorisation is made.

Conditions

7.10 The ACCC grants authorisation subject to the following condition:

7.11 Accordingly, the ACCC imposes the following condition:

1. Medicines Australia will require member companies to, with regard to all educational meetings and symposia as defined in sections 6, 7 and 10 of the Code held or sponsored by that company:

b. complete the table set out at Attachment A for each month of the financial year

b. provide a copy of the completed table for two six month periods every year (July to December; January to June) to Medicines Australia at the end of each six month period.

Medicines Australia is required to:

c. make publicly available on its website the completed table provided by each member company within three months of the end of each six month period

d. at the end of each financial year the Monitoring committee must scrutinise the detail of three random months selected from information provided by the members.

2. Further to the above, where the Monitoring Committee suspects a potential breach of the Code, it may request further information such as a copy of the invitation to the meeting and a copy of any printed material provided to attendees.

3. 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.

4. The reporting and monitoring requirement will come into effect on 1 October 2006.

5. The Monitoring Committee shall also provide a detailed report on its other activities to Medicines Australia for publication in the Code of Conduct Annual Report. This report shall also list any concerns that were forwarded to the Code of Conduct Committee as a complaint, setting out the name of the member company and the date it was referred.

Date authorisation comes into effect

7.12 This determination is made on 26 July 2006. If no application for review of the determination is made to the Australian Competition Tribunal (Competition Tribunal), it will come into force on 17 August 2006. If an application for review is made to the Competition Tribunal, the determination will come into effect:

- 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.

ATTACHMENT A

SUMMARY OF EVENTS SPONSORED BY MEMBER COMPANIES: MONTH, YEAR 2006

Company name: **X**
Number of events held: **80**

Venue	Description of function including duration of educational content delivered	Professional Status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total Cost of Function
Specify venue name and location	*Companies to provide as much information as they feel is necessary to explain the educational component, eg type of function, nature of education provided etc.*	*Specify, eg: GPs, anaesthetists, Occupational Therapists*	Specify all meals/ refreshments: - *breakfast, morning tea, lunch, refreshments, dinner etc* Specify whether the following was provided: - alcohol - accommodation for attendees - entertainment *(if yes, specify the nature of the entertainment)*	$ cost *This should include the cost of all of the items listed in the hospitality column*	xx	*$cost* *Including speakers fees, venue hire, transportation cost, materials provided to attendees etc.*

ATTACHMENT B: EXAMPLE OF EXCERPT OF COMPLETED TABLE

SUMMARY OF EVENTS SPONSORED BY MEMBER COMPANIES, JANUARY 2006

Company name: **ABC Pharmaceuticals Pty Ltd**
Number of events held: **80**

Venue	Description of function including duration of educational content delivered	Professional Status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total Cost of Function
Palm Sugar, North Shore, Sydney	One hour presentation to senior consultants with special interest in leukaemia.	XX	Five course dinner with alcohol provided. Held in the private function room Accommodation provided to 25 Attendees	$15,000	50	$20,000
Sitar, Toorak, Melbourne	One hour presentation to senior consultants with special interest in multiple myeloma.	XX	Four course lunch with alcohol provided. Held in the private function room	$5000	20	$6000
Ripe, Double Bay, Sydney	Twenty minute presentation on recent developments in diabetes management	XX	Dinner with alcohol. Accommodation was provided for attendees in Auckland	$18,000	60	$22,000
Hospital Lunch Room, Mount Eclipse Hospital	Forty-five minute demonstration on new scalpel	XX	None	$0	45	$675