Australian Competition & Consumer Commission

Draft Determination

Applications for authorisation

lodged by

Medicines Australia Limited

in respect of

Medicines Australia Code of Conduct Edition 16

Date: **16 October 2009**

Commissioners: Samuel
Kell
Schaper
Walker
Willett

Authorisation nos.: A91150, A91155, A91156, A91183 & A91184

Public Register no.: C2009/1275

Summary

The ACCC proposes to grant authorisation to Medicines Australia Limited for its Code of Conduct edition 16. The ACCC proposes to grant authorisation for a period of five years.

Medicines Australia has sought authorisation of edition 16 of its Code of Conduct (the Code) which sets the standards for the marketing and promotion of prescription pharmaceutical products in Australia. All member companies of Medicines Australia must adhere to the Code although membership of Medicines Australia is voluntary.

Edition 15 of the Code was authorised by the ACCC subject to a public reporting condition in 2006. The condition imposed by the ACCC required the public disclosure of hospitality provided by pharmaceutical companies to healthcare professionals at educational events. The authorisation was subject to a review by the Australian Competition Tribunal which granted authorisation subject to a similar reporting condition in 2007.

Edition 16 of the Code fully incorporates the public reporting requirements as well as a number of amendments.

The promotional and educational activities of pharmaceutical companies can affect the way doctors make decisions in terms of the treatment recommended and the particular drugs prescribed. The relationship between pharmaceutical companies and healthcare professionals, if not appropriately managed, can result in significant consumer detriment, for example through inappropriate prescribing by healthcare professionals.

The Code provides a framework for appropriate relationships by providing transparency around the provision of hospitality and other benefits by pharmaceutical companies to healthcare professionals. The ACCC considers that the requirement in the Code that member companies publicly report on the provision of hospitality associated with educational events brings greater accountability on the part of member companies. Further, the imposition of appropriate sanctions for breaches of the Code and the reporting of such sanctions contribute significantly to the effectiveness of the Code in regulating member behaviour.

The ACCC considers that any anti-competitive detriment resulting from the Code will be minimal. While the Code restricts the promotional activities of Medicines Australia members, the ACCC accepts that the Code does this to address potential market failures which may otherwise arise.

Through the consultation process there have been calls for Medicines Australia's Code, or similar standards that address the potential for conflicts of interest, to apply across the industry more broadly. The ACCC considers there is significant benefit in regulating the provision of benefits by all manufacturers of therapeutic products including manufacturers of generic drugs, prosthetics and other medical devices.

However, the ACCC is not able, through this authorisation, to impose conditions requiring non-members of Medicines Australia to comply with Medicines Australia's Code or a similar Code. It is however open for other industry associations or groups to develop a code with similar standards of conduct and to seek authorisation from the ACCC.

The ACCC is satisfied that the public benefits from edition 16 of the Code outweigh the public detriments and proposes to grant authorisation. The ACCC considers the reporting requirement is important to the effectiveness of the Code. Should this requirement be changed or removed

from the Code, the public benefits and public detriments associated with the Code would be changed significantly. This would constitute a material change in circumstances and the ACCC would review the authorisation.

The ACCC will now seek further submissions from the applicant and interested parties in relation to this draft determination prior to making a final decision. The applicant and interested parties may also request that a conference be held to make oral submissions on the draft determination.

Contents

List of abbreviations

ACCC	Australian Competition and Consumer Commission
AGPN	Australian General Practice Network
AMA	Australian Medical Association
Appeals Committee	Code Appeals Committee
ARTG	Australian Register of Therapeutic Goods
ASCEPT	Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
CHF	Consumers Health Forum of Australia
Code Committee	Code of Conduct Committee
Code	Code of Conduct Edition 16
HCO	Health Consumer Organisations
Medicines Australia	Medicines Australia Limited
NHMRC	National Health and Medical Research Council
OTC	Over-the-counter
PBS	Pharmaceutical Benefits Scheme
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
TG Act	*Therapeutic Goods Act 1989* (Cth)
TGA	Therapeutic Goods Administration
TPA	*Trade Practices Act 1974* (Cth)
Tribunal	Australian Competition Tribunal

1. The applications

1.1. On 30 June 2009 Medicines Australia Limited (Medicines Australia) lodged applications for the revocation of authorisations A90994-A90996 and the substitution of authorisations A91150 and A91155-A91156 for the ones revoked. In addition, on 12 August 2009 Medicines Australia lodged applications for authorisation A91183 and A91184[1] (collectively these applications will be referred to as the applications for authorisation).

1.2. Authorisation is a transparent process where the ACCC may grant immunity from legal action for conduct that might otherwise breach the *Trade Practices Act* 1974 (TPA). 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.

1.3. The ACCC conducts a public consultation process when it receives an application for authorisation, inviting interested parties to lodge submissions outlining whether they support the application or not. Further information about the authorisation process is contained in Attachment A.

1.4. The holder of an authorisation may apply to the ACCC to revoke an existing authorisation and grant another authorisation in substitution. In certain circumstances the ACCC may also review an authorisation with a view to revoking it and substituting a new authorisation in its place. In order for the ACCC to re-authorise conduct, the ACCC must consider the substitute authorisation in the same manner as the standard authorisation process.

1.5. Medicines Australia is seeking the revocation of authorisations A90994-A90996 and their substitution with authorisations:

- A91150 which was made under section 88(1) of the TPA to make and give effect to a contract, arrangement or understanding, a provision of which is or may be an exclusionary provision within the meaning of section 45 of the TPA
- A91155 which was made under section 88(1) of the TPA to make and give effect to a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of the TPA and
- A91156 which was made under section 88(8) of the TPA to engage in conduct that constitutes or may constitute, exclusive dealing.

1.6. Further, Medicines Australia is seeking authorisation:

- A91183 which was made under section 88(1A) of the TPA to make and give effect to a contract, arrangement or understanding, a provision of which is or may be a

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[1] Applications A91183 and A91184 are to take account of amendments introduced by the *Trade Practices Amendment (Cartel Conduct and Other Measures) Act 2009* which commenced on 24 July 2009. The applications relate to and are in the same terms as applications A91150, A91155 and A91156 lodged with the ACCC on 30 June 2009 under section 88(1) of the TPA.

cartel provision which would also be, or might also be, an exclusionary provision within the meaning of section 45 of the TPA and

- A91184 which was made under section 88(1A) of the TPA to make and give effect to a provision of a contract, arrangement or understanding that is, or may be, a cartel provision.

1.7. In particular, Medicines Australia seeks authorisation of its Code of Conduct edition 16 (Code) for five years. The Code sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. All member companies of Medicines Australia must adhere to the Code although membership of Medicines Australia is voluntary. A summary of the main provisions of the Code can be found at paragraphs 3.4 to 3.64.

1.8. A chronology of the significant dates in the ACCC's consideration of these applications is contained in Attachment B.

Previous authorisation

1.9. In 2006, the ACCC granted conditional authorisation to Medicines Australia for its Code of Conduct edition 15. The condition imposed by the ACCC required the public disclosure of hospitality provided by pharmaceutical companies to healthcare professionals at educational events. The authorisation was subject to a review by the Australian Competition Tribunal (application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation to edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT*)). On 27 June 2007 the Tribunal granted conditional authorisation to Medicines Australia. The condition imposed by the Tribunal was similar to that imposed by the ACCC.

Other parties

1.10. Medicines Australia seeks authorisation on behalf of current and future member companies of Medicines Australia. Under section 88(6) of the TPA, any authorisation granted by the ACCC is automatically extended to cover any person named in the authorisation as being a party or proposed party to the conduct.

2. Background to the applications

Prescription medicines

2.1. Prescription medicines are those medicines which require a doctor's prescription in order to access them. The supply and marketing of prescription medicines in Australia is subject to regulation designed to maintain public health and safety, and affordable access to medicines for consumers.

2.2. Any prescription medicine intended to be supplied in Australia must be approved and registered by the Therapeutic Goods Administration (TGA) in accordance with the *Therapeutic Goods Act 1989* (TG Act). The TG Act provides a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and medical devices.[2] It also sets out the legal requirements for the import, export, manufacture and supply of medicines in Australia, and includes details regarding product advertising, labelling and product appearance.

2.3. The TGA tests the quality, safety and efficacy of medicines and approves them before they can be supplied in Australia.[3] The TGA carries out a range of assessment and monitoring activities to ensure that all therapeutic goods available in Australia are of an acceptable standard.[4] All prescription medicines must be registered or listed in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

2.4. All prescription medicines registered or listed on the ARTG must be accompanied with a Product Information sheet which provides a description of the characteristics of the medicine including its name and chemical structure, as well as information about side effects and storage of the medicine.[5]

2.5. The TGA issues a marketing approval letter to a pharmaceutical company when the company's application for a particular prescription medicine to be listed or registered on the ARTG has been approved.

2.6. The price consumers pay for around 80% of the prescription medicines dispensed in Australia is subsidised by the Australian Government under the Pharmaceutical Benefits Scheme (PBS). For those medicines listed on the PBS, the consumer pays a base cost and the government subsidises the remainder of the cost.

2.7. The advertising of prescription medicines is subject to a number of requirements in the TG Act, as well as the TPA and other relevant laws. The TG Act prohibits the promotion of prescription medicines to the general public. Promotion to healthcare

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[2] Department of Health and Ageing Therapeutic Goods Administration website, *Regulation of therapeutic goods in Australia,* April 2005, http://www.tga.gov.au/DOCS/HTML/tga/tgaginfo.htm. Accessed on 21 July 2009.
[3] Department of Health and Ageing Therapeutic Goods Administration website, *Medicines regulation and the TGA,* April 2005, http://www.tga.gov.au/docs/html/medregs.htm. TG Act, Chapter 2.
[4] TG Act, Chapter 2.
[5] Department of Health and Ageing Therapeutic Goods Administration website, *Australian Regulatory Guidelines for Prescription Medicines*, June 2004, http://www.tga.gov.au/pmeds/argpmap08.pdf. Accessed 29 September 2009.

professionals is allowed under the TG Act and is regulated by the self-regulatory scheme operated by Medicine Australia through its Code of Conduct.

2.8. The TGA's marketing approval letter requires the *promotion* of all prescription medicines (whether a member or non-member of Medicines Australia) to comply with the requirements of the Medicines Australia's Code.[6]

2.9. Complaints about advertisements of prescription medicines directed to healthcare professionals are handled by Medicines Australia. If a complaint is made about the advertising activities of a non-member, the complaint is forwarded to the non-member with an invitation to have the complaint adjudicated by the Medicines Australia Code of Conduct Committee (Code Committee). If the non-member declines, Medicines Australia may forward the complaint to the TGA or the ACCC where relevant.

Branded vs Generic medicines

2.10. A generic medicine is a copy of a branded medicine. It is chemically equivalent to its branded counterpart and must meet the same standards of quality and safety as branded drugs.

2.11. Not all drugs have a generic equivalent. In particular, newly developed medicines are protected by a patent and only when this expires can generic versions be produced. Generally, generic drugs are cheaper than branded drugs because the manufacturers do not spend the same amount of money on research and development.

2.12. In 2005 approximately 18% of prescriptions dispensed on the PBS were generic drugs. Where there are two or more brands of the same drug listed on the PBS, the subsidy applies to each brand to the same amount – up to the cost of the lowest priced brand which in many cases is a generic brand. A brand price premium applies to the more expensive brand.[7]

2.13. Generic drug manufacturers are able to become members of Medicines Australia however the ACCC understands that few companies have chosen to do so. The Generic Medicines industry Association (GMiA) supports the generic pharmaceutical industry and provides a set of operating principles which its members adhere to. The GMiA represents 98% of generic prescription medicines dispensed in Australia.[8]

Medicines Australia

2.14. Medicines Australia advises that it represents the interests of the innovative medicines industry in Australia. Its member companies comprise more than 80% of the prescription pharmaceuticals market, and are engaged in the research, development,

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[6] TGA website, *Regulation of advertising of therapeutic goods in Australia*, www.tga.gov.au/docs/pdf/advreg.pdf. Accessed on 21 July 2009.
[7] CHOICE website, *Buy generic drugs and save*, 25 November 2008, http://www.choice.com.au/Reviews-and-Tests/Food-and-Health/General-health/Medicines/Generic-Drugs/Page/More%20about%20generic%20drugs.aspx. Accessed 29 September 2009.
[8] GMiA website, http://www.gmia.com.au/. Accessed 6 October 2009.

manufacture, supply and export of prescription medicines.[9] In particular Medicines Australia states that it:

- participates in health and industry policy development
- builds and maintains relationships with government to ensure the continuation of a viable pharmaceutical industry
- actively engages with key consumer groups to better understand their needs and issues and educating the general community about the industry in Australia
- administers the Code which sets the standard for the ethical marketing and promotion of prescription medicines and
- works with other health professional organisations to discuss issues of mutual concern.[10]

2.15. Medicines Australia's membership is defined in Rule 2 of its Objects and Rules. There are four principal classes of membership:

- Class One – for research based prescription pharmaceutical companies (innovators)
- Class Two – for non-research based prescription pharmaceutical companies (generics)
- Class Three – for companies significantly engaged in research into potential pharmaceutical products but which have not yet commenced commercial production
- Class Four – being firms or companies ineligible for other classes of membership which are significantly engaged in the development, testing or registration of prescription pharmaceutical products or which are in the opinion of the Board of Medicines Australia engaged with the research-based pharmaceutical industry for a significant part of their business.

2.16. Medicines Australia has 36 Class One members, 5 Class Two members, 1 Class Three member and 9 Class Four members. It is a condition of membership to any class to adhere to the Code in its entirety.

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[9] Medicines Australia website, http://medicinesaustralia.com.au/pages/page2.asp. Accessed on 20 July 2009.
[10] ibid.

3. Medicines Australia Code of Conduct edition 16

3.1. Medicines Australia seeks authorisation of edition 16 of its Code.[11] The Introduction to the Code states that it sets standards of conduct for the activities of companies when engaged in the promotion of prescription products used under medical supervision as permitted by Australian legislation. The Code provides the mechanism for the pharmaceutical industry to establish and maintain an ethical culture through a committed self regulatory approach and should be viewed as the minimum set of standards required to promote prescription products in Australia.

3.2. The Code encourages pharmaceutical companies which are not members to accept and observe the Code in total in addition to their obligations for product registration under the TG Act.[12]

3.3. Some of the key provisions of the Code are outlined below.

Educational and promotional material directed at healthcare professionals

Nature and availability of information and claims

3.4. The Code states that companies, their employees and advisers are responsible for ensuring that the content of all promotional and medical claims are balanced, accurate, correct and fully supported by the Product Information.[13]

3.5. Any information used to support a medical claim or promotional claim must include sufficient detail and be adequate to allow evaluation of the claim.[14] All product information must be current and not be misleading, and any claims or qualifying statements must be referenced clearly and be conveyed in accordance with strict print size.[15]

3.6. It is a requirement that all promotional and educational material must conform to generally accepted standards of good taste and recognise the professional standing of the recipients.[16]

3.7. Products that have not yet been approved for registration in Australia by the TGA must not be promoted.[17]

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[11] The Code includes explanatory notes which elaborate on the provisions of the Code. It is supported by the Code of Conduct Guidelines (version 3) which are to be read in conjunction with the Code as they provide guidance to both pharmaceutical companies and to the Code Committee that is responsible for considering alleged breaches. There are also Guidelines for Determining Code Sanctions which aim to provide information on the general principles and factors the Code and Appeals Committees take into account when considering and determining a sanction under the Code.

[12] Medicines Australia Code of Conduct Edition 16, Introduction.

[13] ibid, s 1.1. Product Information means either the current Australian Approved Product Information or in the case of a product whose registration pre-dates the current regulatory review the document registered as the Full Product Information. This Product Information must comply with the format specified in the TGA *Australian Regulatory Guidelines for Prescription Medicines*. Product Information may also be presented as an Abridged Product Information or Minimum Product Information.

[14] ibid, s 1.2.

[15] ibid, s 1.3.

[16] ibid, s 1.4.

[17] ibid, s 1.3.1.

Promotional material directed at healthcare professionals

3.8. The Code contains specific provisions for a range of promotional material however as a general principle the content of all promotional material must be current, accurate, balanced and fully supported by Product Information.

3.9. Promotional material should be clearly distinguishable as such and advertisements should not be designed to resemble editorial matter unless clearly identified as an advertisement or editorial.[18]

3.10. Advertising must not be placed in any section of prescribing software packages.[19]

3.11. Only items that are educational and/or directly related to the practice of medicine or pharmacy are suitable for use as brand name reminders.[20] An item which is more likely to be used outside the practice is not acceptable as a brand name reminder, such as stationary items, pens, sticky notepads, mugs, clocks. Items which are acceptable include tongue depressors, anatomical models, surgical gloves and peak flow meters.[21]

3.12. A brand name reminder should be of token value and should not bring discredit to the industry.[22]

Educational material directed at healthcare professionals[23]

3.13. The Code states that all items of an educational nature, whether intended for the education of healthcare professionals or to be used by the healthcare professional in consultation with a patient, must be dedicated to improving the quality use of medicines and/or assisting a patient in their understanding of a condition or disease.

Company Representatives

3.14. Company representatives are required to, at all times, maintain a high standard of ethical conduct and professionalism in the discharge of their duties,[24] and ensure their visits do not cause inconvenience to the healthcare professional.[25]

3.15. The Code states that companies have a responsibility to maintain high standards of ongoing training for company representatives and should posses sufficient medical and technical knowledge to present information on the company's products. It is a requirement that relevant medical representatives must complete an endorsed

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[18] Medicines Australia Code of Conduct Edition 16, s 2.
[19] ibid, s 2.5. Edition 15 permitted advertising in electronic prescribing software, however such advertisements could not be placed in those parts of electronic prescribing software which may be used by a prescriber for consultation or discussion with a patient, edition 15 s 3.9.
[20] ibid, s 2.6.
[21] ibid Explanatory Notes s 2.6.
[22] ibid, s 2.6.
[23] Edition 16 has developed the educational material directed at healthcare professionals in a separate chapter, and encompasses all medical education provided via print, audiovisual and electronic media, websites, posters and anatomical models. Medicines Australia Code of Conduct Edition 16, chapter 4.
[24] ibid, s 5.2.
[25] ibid, s 5.5.

Medicines Australia education program,[26] and must also undertake training on Australian Privacy legislation and Trade Practices legislation.[27]

Product Starter Packs

3.16. The distribution of starter packs must be carried out in a reasonable manner. A starter pack is defined as a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists, also referred to as 'samples'.

3.17. The Code sets out the conditions for supplying starter packs, the maximum quantity able to be supplied and the records that must be kept upon supplying starter packs.[28]

Relationship with healthcare professionals

3.18. The Code provides that as a general principle involvement by pharmaceutical companies in activities with healthcare professionals must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste. The primary objective for the interaction must be to enhance medical knowledge and improve the quality use of medicines in Australia.[29]

3.19. The Code states that no financial or material benefits should be conditional upon any obligation by the healthcare professional to recommend, prescribe, dispense or administer a company's prescription product.[30]

Educational events

3.20. The Code acknowledges that educational events are important for the dissemination of knowledge and experience to healthcare professionals.

3.21. The Code requires that the educational value of the event must be displayed in, for example an invitation or agenda, clearly describing the educational purpose, content, meeting start and finish time and duration of educational sessions.[31]

3.22. The venue chosen for an educational event should have suitable facilities to support the provision of education and be situated so that only the healthcare professionals in attendance are able to hear and view the medical education content. The choice of venue must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.[32] The venue must not be chosen for its leisure, sporting or recreational facilities.[33]

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[26] Medicines Australia Code of Conduct Edition 16, ss 6.1-6.3. Medicines Australia offers 5 core modules of continuing education programs provided as formal and compulsory training for medical representatives employed by Medicines Australia members. The modules are: The Medicines Australia Code of Conduct; The Pharmaceutical Industry; An Introduction to Pharmacology; Understanding Product Information; and Understanding Clinical Trials and Scientific Literature. http://medicinesaustralia.com.au/pages/page6.asp.
[27] ibid, s 6.6.
[28] ibid, s 7.
[29] ibid, s 9.1
[30] ibid, s 9.1.
[31] ibid, s 9.4.1.
[32] ibid, s 9.4.2.
[33] ibid, Explanatory Notes, s 9.4.2.

3.23. The Code states that meals and beverages offered to healthcare professionals should not be excessive and must be secondary to the educational content and must be appropriate for the content and duration of the meeting.[34]

3.24. A company may provide travel to delegates only if justified by the educational content. Air travel for healthcare professionals must be economy class only.[35] A company must not subsidise or pay for the hospitality, travel or other expenses of any guest or family member.[36]

3.25. Delegates must not be paid for their attendance at a company educational event. Faculty, speakers and/or chairpersons may receive remuneration provided it is commensurate with the work involved. Any remuneration offered should form part of a formal agreement.[37]

3.26. Interactions between pharmaceutical companies and healthcare professionals must not contain entertainment.[38]

3.27. Companies may sponsor healthcare professionals to attend both Australasian and international educational events. The Code specifies that sponsorship must not be conditional upon any obligation by the healthcare professional to recommend, prescribe, dispense or administer a company's product.[39]

Trade displays

3.28. Trade displays which include promotional materials for prescription products must be directed only to healthcare professionals.[40] All promotional materials used at trade displays must comply with the Code requirements.[41] Starter packs must not be made available for collection from unattended trade display stands.[42]

3.29. Gifts or offers provided by a company to encourage a healthcare professional to visit a trade display are prohibited.[43]

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[34] Medicines Australia Code of Conduct Edition 16, s 9.4.3. Edition 15 required the hospitality to be consistent with the professional standing of the delegates, edition 15 s 6.2.2. Medicines Australia submit this caused some confusions and has not been included in edition 16 of the Code.
[35] ibid, s 9.4.4. Edition 15 provided that travel should be economy class unless there are circumstances where business class travel may be appropriate, edition 15 s 6.8.
[36] ibid, s 9.4.8.
[37] ibid, s 9.4.7.
[38] ibid, s 9.4.6. Edition 15 provided that educational meetings of two or more days duration could include a modest opportunity for unstructured and individual recreational activities at the individual's own expense, edition 15 s 10.1.
[39] ibid, s 9.7.
[40] ibid, 9.6.1.
[41] ibid, ss 9.6.1, 9.6.4. Edition 16 moves this section from the guidelines into the Code of Conduct.
[42] ibid, s 9.6.6.
[43] ibid, 9.6.5.

Consultants and advisory boards

3.30. Companies may seek the services of suitably qualified and experienced healthcare professionals to provide a service, advice and/or guidance. Such professionals can be offered remuneration and reimbursement for reasonable travel, accommodation or hospitality in association with the consulting services.[44]

3.31. A legitimate need for a consultant or advisory board must be demonstrated and documented.[45] The purpose and objective of the interaction must be clearly articulated in a written contractual agreement outlining the nature and direction of the services to be provided.[46]

3.32. Given the purpose of the advisory board the size of the group must be such that would withstand public and professional scrutiny and adhere to the principles for the quality use of medicines.[47]

Relationship with the general public

3.33. Consistent with the TG Act, the Code does not allow companies to promote prescription products to the general public. Any activities with, or materials provided to, members of the general public must not bring discredit upon, or reduce confidence in the pharmaceutical industry.[48] Any information provided to the general public must be educational.[49]

Disease education

3.34. The Code recognises that disease education activities may provide information, promote awareness and educate the public about health, disease and their management.[50] However the Code prohibits referencing of a specific product and should not be designed for the purpose of encouraging members of the public to ask their doctor to prescribe a specific prescription product.[51]

3.35. Companies may use the internet to provide current, accurate and balanced information about a prescription product. Such information must be non-promotional.[52] The promotion of products to the general public via social media[53] is also prohibited.

Relationship with Health Consumer Organisations (HCOs)

3.36. Companies may enter into relationships with health consumer organisations (HCOs) to enhance the quality use of medicines and support better health outcomes. The

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[44] Medicines Australia Code of Conduct Edition 16, ss 9.8.1, 9.8.4.
[45] ibid, ss 9.8.1, 9.8.2, 9.9.1.
[46] ibid, s 9.8.2.
[47] ibid, Explanatory Notes s 9.9.2.
[48] ibid, s 12.1.
[49] ibid, s 12.3.
[50] ibid, s 12.7.
[51] ibid, s 12.7.
[52] ibid, s 12.8.
[53] Social media is an umbrella term that defines the various activities that integrate technology, social interaction, and the creation of content including Facebook, YouTube, MySpace, Twitter, blogs and wikis.

relationships between HCOs and companies must be independent, achieve and maintain public trust, be fair, open, transparent and accountable.[54]

3.37. No company may request that it be the sole funder of an HCO, and a company must not make public use of an HCO's logo or proprietary material without the HCO's agreement.[55] Further, a company must not seek to influence the text of the HCO's material in a manner favourable to its own commercial interests.[56]

3.38. Each company must make publicly available on its website a list of the HCO's to which is provides financial support and/or significant derect/indirect non-financial support.[57]

Code administration

3.39. The administration of the Code is supervised by the Code of Conduct Committee (Code Committee) and the Code Appeals Committee (Appeals Committee), which will be responsible to the Medicines Australia Board.

Complaints

3.40. 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 may refer the complaint to the TGA or the ACCC.[58]

3.41. Appendix 1 to the Code sets out guidelines for the attempted resolution of the complaint prior to a formal complaint being lodged with Medicines Australia. Where a complaint is generated by an industry participant, inter-company dialogue is encouraged as an initial course of action. Medicines Australia will not accept an industry generated complaint unless it has been clearly demonstrated that inter-company dialogue has taken place and that despite efforts on all parties, resolution of the matter has not been achievable.[59]

3.42. The formal complaints process in the Code can be summarised as:

- written complaint received by Medicines Australia
- Medicines Australia will forward the complaint to the subject company and acknowledge receipt of the complaint to the complainant. The subject company may obtain external advice in order to respond to the complaint.
- the subject company must provide a written response to Medicines Australia within ten working days
- the written complaint and response provided to the Code Committee for a determination

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[54] Medicines Australia Code of Conduct Edition 16, s 13.
[55] ibid, ss 13.1, 13.2.
[56] ibid, s 13.3.
[57] ibid, s 13.4.
[58] ibid, s 21.
[59] ibid, Appendix 1.

- the decision of the Code Committee is provided to the complainant and subject company within two working days
- the decision and reasons for the decision are provided to the complainant and subject company within ten working days
- notification of intent to appeal (by either the complainant or subject company) provided to Medicines Australia within five working days of receiving the decision and reasons for the decision
- written appeal submission provided to Medicines Australia within five working days of the notification of intent to appeal
- if no appeal is lodged the complaint is deemed finalised
- if an appeal is lodged a meeting of the Appeals Committee meeting is convened as soon as practical
- the decision of the Appeals Committee is provided to the complainant and subject company within two working days
- the decision and reasons for the Appeals Committee decision is provided to the complainant and subject company within ten working days
- on receipt of the decision and reasons for the decision the complaint is deemed finalised. No further action by the complainant or subject company in relation to this complaint will be accepted by the Code Committee.

3.43. All documents relating to a complaint are required to be kept confidential until the complaint is deemed finalised.[60]

3.44. All findings and/or sanctions of the Code Committee shall remain confidential and shall not be released to any third party until the subject company and complainant have exhausted all appeal procedures and the outcome of any appeal is known.[61]

Code Committee

3.45. The membership of the Code Committee comprises:

Full membership

- Chairman (a lawyer with trade practices experience)
- one representative of the Australian Medical Association (AMA)
- one representative of the Royal Australian College of General Practitioners (RACGP)

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[60] Medicines Australia Code of Conduct Edition 16, s 19.1.1.
[61] ibid, s 19.1.2.

- one representative of the Australian General Practice Network (AGPN)
- one specialist nominated by the Royal Australasian College of Physicians (RACP)
- one representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- one consumer representative nominated by the Consumers Health Forum of Australia (CHF). Where a complaint is made in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed.[62]
- two representatives from Medicines Australia members
- two Medicines Australia member medical/scientific directors
- one Medicines Australia member marketing director

Observers (no voting rights)

- one representative of the TGA
- maximum of two employees of Medicines Australia member companies
- one observer nominated by Medicines Australia

Secretariat (no voting rights)

- Code Secretary
- Medicines Australia Chief Executive or delegate
- Medicines Australia officer responsible for the Ethical Conduct Program.

3.46. Members to the Code Committee are appointed for a period of three years.

3.47. The Code also provides a process for ensuring that members of the Code Committee hearing a complaint do not have conflict of interest.[63]

Sanctions

3.48. The Code Committee can impose a range of sanctions including a requirement for:

- the cessation of the conduct and withdrawal of any promotional activity

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[62] Medicines Australia Code of Conduct Edition 16, s 20.1.
[63] ibid, s 20.2.

- corrective action such as retraction statements, corrective letters and advertising. As a general rule there will be a requirement for corrective action to be taken where moderate or severe breaches have been found.

- a monetary fine as determined by the Code Committee. Broadly fines range from $100 000 to $250 000.

3.49. Where corrective action has not been actioned within 30 calendar days from receipt of the decision, the Code Committee may impose a fine of up to $50 000 for the breach of not actioning the corrective action. In addition, Medicines Australia shall have the right, but not the obligation:

- to forward the complaint, the decision of the Code or Appeals Committee, and the failure of the subject company to take the corrective action to the TGA or the ACCC and

- publicise the failure of the subject company to take the corrective action.[64]

3.50. Where a decision by the Code Committee is appealed, the Appeals Committee has the power to affirm, set aside or vary the findings and/or any sanction imposed by the Code Committee.[65]

3.51. When a subject company or industry complainant submits an appeal, the company must lodge a bond of $20 000 with Medicines Australia. A non-industry complainant will not be required to lodge an appeal bond. The bond is used to defray the costs of the Code and Appeals Committee meetings and contribute to Code education programs.[66]

3.52. The membership of the Appeals Committee is:

Full membership

- Chairman (a lawyer with trade practices experience)

- one representative from the College and/or Society associated with the therapeutic class of the product subject to appeal

- one general practitioner from the AMA, RACGP or AGPN

- one consumer representative nominated by the CHF. Where an appeal relates to an activity or material directed at the general public or patients, a second consumer representative will be appointed.[67]

- one representative from ASCEPT

- one member company senior executive

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[64] Medicines Australia Code of Conduct Edition 16, s 24.2.
[65] ibid, Explanatory notes, s 25.1.
[66] ibid, s 25.1.3.
[67] ibid, s 26.1.

- one Medicines Australia member company medical/scientific director
- one Medicines Australia member company marketing director

Secretariat (no voting rights)

- Code Secretary
- Medicines Australia CEO or delegate
- Medicines Australia officer responsible for the Ethical Conduct program.

3.53. No member of the Appeals Committee can have been a member of the Code Committee which heard the original complaint.

3.54. The Code provides a process for ensuring that members of the Appeals Committee hearing a complaint do not have conflict of interest.[68]

Monitoring

3.55. To promote compliance with the Code and thereby support the quality use of medicines, the Monitoring Committee will proactively monitor selected promotional material and activities of member companies on a regular and ongoing basis to encourage compliance with the Code. The aims of monitoring are to encourage compliance with the Code, provide advice on compliance where necessary, obtain and publish statistical data on the degree of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code.[69]

3.56. The Monitoring Committee will review three types of promotional material (for example advertisements, printed promotional material, brand name reminders) across three different therapeutic classes (for example cardiovascular, respiratory and immunology) and three different types of conduct (for example websites, PFPs, patient aids) over a specified three month period.[70]

3.57. At the end of each financial year, the Monitoring Committee will also review the educational meetings and symposia provided by member companies in accordance with the educational event reporting provision (see paragraphs 3.63 to 3.64). The Monitoring Committee will review information about educational meetings held during the three months selected at random from the preceding 12 month period.[71]

3.58. 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.[72]

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[68] Medicines Australia Code of Conduct Edition 16, s 26.2.
[69] ibid, s 28.1.
[70] ibid, s 28.2.1.
[71] ibid, s 28.2.2
[72] ibid, s 30.

3.59. The Monitoring Committee will contribute to the Medicines Australia Code of Conduct annual report including information on the therapeutic categories and type of promotional activities reviews, the number of items reviewed, the number and type of breaches detected and the number of Code complaints generated.[73]

3.60. The following are members of the Monitoring Committee:[74]

Permanent members

- Chairman (a consultant with industry experience in marketing and knowledge of the Code)
- one representative of the RACGP
- one representative of the AMA
- one consumer representative of the CHF. Where the review is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed.[75]

Rotating members

- one representative of the College and/or Society from the therapeutic class being reviewed
- one Medicines Australia member company medical director
- one Medicines Australia member company marketing director

Secretariat

- Code Secretary
- Medicines Australia officer responsible for the Ethical Conduct Program.

3.61. The Code provides a process for ensuring that members of the Monitoring Committee hearing a complaint do not have a conflict of interest.[76]

Reporting, Reviews and Compliance

3.62. Medicines Australia will conduct a review of the Code seeking external input no later than every three years.[77] Medicines Australia will also issue an annual report on the activities of the Code, Appeals and Monitoring committees,[78] and quarterly reports on the outcomes of all complaints finalised during the reporting period.[79]

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[73] Medicines Australia Code of Conduct Edition 16, s 31.
[74] ibid, s 29.1.
[75] ibid, s 29.1.
[76] ibid, s 29.2.
[77] ibid, s 33.
[78] ibid, s 35.1.
[79] ibid, s 35.2.

Educational event reporting[80]

3.63. In addition, the Code requires each member company to provide a report to Medicines Australia on all educational meetings and symposia held or sponsored by that company:

(a) by completing a table (see table 2.1) for each month of the financial year and

(b) by providing a copy of the completed table for two six-month periods each year (October – March and April – September) to Medicines Australia within 30 days of the end of each six-month period.[81]

3.64. Medicines Australia will 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.[82]

Table 2.1: Educational event reporting template

Summary of Events Sponsored by Member Companies
Reporting Period (For example, October 2010 - March 2011)

Company Name:

Number of events held:

Description of function including duration of educational content delivered	**Venue**	**Professional status of attendees**	**Hospitality provided**	**Total cost of hospitality**	**No. of attendees**	**Total cost of function**
Companies to provide as much information as they feel necessary to explain the educational component For example: • Type of function • Nature of education provided • Program accreditation eg CPD points • Length of educational component	Specify: • Venue name • Location	Specify: For example: • Anaesthetists • General Practitioners	Specify: The nature of the hospitality provided and whether it included any of the following elements: • Food and/or beverages • Accommodation • Travel • Entertainment	$ cost This must state the total cost of the items listed in the hospitality column. A breakdown of those costs may be provided if desired.	XX	$ cost Including: • Speaker fees • Venue hire • Transportation costs • Materials provided to attendees etc

Source: Medicines Australia Code of Conduct Edition 16, Appendix 3.

[80] Medicines Australia Code of Conduct Edition 16, s 35.4.
[81] The table which has been incorporated into the Code is consistent with the condition imposed by the Australian Competition Tribunal with exception for the reporting periods. Currently the six-month periods are January to June and July to December. Edition 16 changes the periods to October to March and April to September.
[82] Medicines Australia Code of Conduct Edition 16, s 35.4.

4. Submissions received by the ACCC

4.1. The ACCC tests the claims made by the applicant in support of an application for authorisation through an open and transparent public consultation process. To this end the ACCC aims to consult extensively with interested parties that may be affected by the proposed conduct to provide them with the opportunity to comment on the application.

4.2. Broadly, **Medicines Australia** submits that the 16th edition of the Code will result in greater public benefit than the previously authorised edition 15, and would not result in any material anti-competitive detriment or other public detriment. Medicines Australia submits that the amendments in edition 16 are designed to maximise and increase the public benefit by appropriately increasing the restrictions around advertising and relationships with healthcare professionals and otherwise introducing new measures that will increase the effectiveness of the Code and transparency of industry conduct.

4.3. Medicines Australia has identified the following improvements to the Code made since edition 15:

- the standard required for medical and promotional claims has been raised
- substantial increases in fines for breaches of the Code
- increased consumer representation on the Code, Appeals and Monitoring Committees
- further limits on advertising by member companies by absolutely banning advertising in prescribing software and limiting the provision of brand name reminders to health care professionals to practice-related items
- increase in the transparency of the relationships between pharmaceutical companies and health consumer organisations by requiring publication on a company's website of a list of health consumer organisations to which it provides support and the nature of that support.

4.4. The ACCC sought submissions from 122 interested parties potentially affected by the applications, including Medicines Australia member companies, non-member companies, industry and consumer groups and government. A summary of the public submissions received from interested parties follows:

- **The Royal Australasian College of Physicians** (RACP) overall supports the amendments made to edition 16 of the Code. The RACP submits that there should be greater transparency regarding the use of monies collected from fines. The RACP also submits that a condition should be imposed on Medicines Australia to increase fines to a more realistic level. Further, the RACP submits that a condition requiring the addition of a generic industry representative to the Code Committee be imposed, in return for a commitment that the Code in its entirety apply to the generic industry.
- **Janssen-Cilag** submits that edition 16 of the Code sets higher standards for the advertising and promotion of pharmaceuticals and will result in a public benefit.

Janssen-Cilag submits that the Code is desirable as a matter of public policy. Janssen-Cilag also notes that edition 16 increases consumer representation on the Code, Appeals and Monitoring Committees.

- **National Health and Medical Research Council** (NHMRC) supports the applications for authorisation of the 16th edition of the Code. In particular the NHMRC supports the changed status of the TGA as an observer on the Code Committee in order to maintain the Committee's independence, and the inclusion of natural justice principles providing a company with the ability to comment on its complaint before the Code Committee's discussion. The NHMRC encourages the ACCC to support strengthening the wording of the Code so that it is applies to non-members of Medicines Australia.

- **Dr Ken Harvey** supports the amendments to the Code, and in particular, the removal of any promotion of products in prescribing software. Dr Harvey submits that the ACCC should consider requiring the level of fines to be increased further.

  Dr Harvey notes concern that an anti-competitive environment exists between prescription medicines, over-the-counter (OTC) and complementary medicines. A higher standard of ethical conduct is expected for originator companies compared with generic companies. Dr Harvey submits that there should be one Code to apply to the entire industry which provides one complaints process, one monitoring process and one set of sanctions, to be administered by an independent committee representative of all stakeholders.

- The **TGA** supports the amendments made to the Code strengthening the requirements for the advertising of prescription medicines in edition 16 of the Code, which are consistent with Australia's co-regulatory system of advertising for therapeutic goods and will further enhance the public benefit of the Code.

- **Queensland Health** submits that edition 16 will result in higher standards in the promotion of prescription medicines through various means including the regulation of promotional claims, increased training for company representatives, increased fines for breaches of the Code and additional consumer representations on relevant committees, increased transparency regarding the relationship between pharmaceutical companies and HCOs, as well as the inclusion of the general principle that company support must be able to successfully withstand public and professional scrutiny.

  Queensland Health supports the notion that interactions with healthcare professionals must have the primary objective of enhancing medical knowledge and improving the quality use of medicines in Australia, and believes that the proposed enhancements to the Code support this.

- The **Australian Medical Association** (AMA), **the Pharmacy Guild of Australia**, the **Pharmaceutical Society of Australia** and **Pfizer Australia** support the amendments made in edition 16 of the Code and did not provide any further comments on the Code.

4.5. The views of Medicines Australia and interested parties are outlined in the ACCC's evaluation of the Code in Chapter 5 of this draft determination. Copies of public submissions may be obtained from the ACCC's website (www.accc.gov.au/AuthorisationsRegister) and by following the links to this matter.

5. ACCC evaluation

5.1. The ACCC's evaluation of edition 16 of the Code is in accordance with tests found in sections 90(5A), 90(5B), 90(6), 90(7) and 90(8) of the TPA.

5.2. For more information about the tests for authorisation and relevant provisions of the TPA, please see Attachment C.

The market

5.3. The first step in assessing the effect of the conduct for which authorisation is sought is to consider the relevant market(s) affected by that conduct.

5.4. Medicines Australia submits the relevant market is the market for prescription medicines in Australia. Interested parties did not provide submissions with respect to the market.

5.5. The ACCC does not accept that all prescription medicines are substitutable for one another and considers that there are likely to be individual product markets for the different types of drugs. However, the ACCC does not consider that a precise definition of the market is necessary for the assessment of Medicines Australia's Code. The ACCC notes that the Code regulates the activities surrounding the promotion of prescription products on an industry-wide basis across all classes of prescription medicines.

5.6. The ACCC recognises that the prescription medicines industry is subject to 'market failures' which are common to many parts of the health sector. These market failures may arise from the principal-agent problem intrinsic to the asymmetry of information in the relationship between patients and health care professionals, and between pharmaceutical companies and health care professionals, the quantum and complexity of information which may be relevant to the prescribing practices of health care professionals and the potential for pharmaceutical companies to inappropriately influence those practices. The patient goes to a health care professional because they do not have the expert knowledge required to diagnose and treat their condition. The professional orders the treatment considered necessary from a medical perspective, but that perspective will be influenced by the nature of the information available and how it is presented. To address the potential for conflicts of interest and inappropriate influence over prescribing practices, it may be necessary to regulate the marketing of pharmaceuticals and the relationship between pharmaceutical companies and health care professionals and create incentives that reduce the risk that the agent is not acting in the principal's best interests.

5.7. The following characteristics are relevant to the consideration of the public benefits and detriments:

- The sale of prescription medicines is dependant upon the decisions of medical practitioners about which medicines they prescribe. The Tribunal noted that members of the public cannot purchase prescription medicines unless they have been prescribed by a healthcare professional and are reliant upon the healthcare professionals expertise and judgement to prescribe the medicine most appropriate to them.

- Members of the public are prohibited by law from receiving advertising about prescription medicines.

- Subject to those elements of specific and general Commonwealth, or state and territory statutes in place, there is no regulation under Commonwealth, state or territory law of the ways in which prescription medicines can be advertised and promoted to healthcare professionals.

- The decisions of healthcare professionals about which medicines to prescribe are unlikely to have an effect on the price of such medicines due to the PBS regulating the price paid by the public for most prescription medicines.

- Healthcare professionals may not have the time to absorb large volumes of information about particular medicines and may heavily rely on product information and other information provided by pharmaceutical companies.

- The promotional and educational activities of pharmaceutical companies can affect the way doctors make decisions in terms of the treatment recommended and the particular drugs prescribed.

- Originator pharmaceutical companies compete in the development of new drugs. Pharmaceutical companies obtain patents for the development of new medicines which restrict generic companies from manufacturing a copy of the medicine for the time period of the patent.

- Both originator and generic pharmaceutical companies compete in the supply of medicines that are no longer subject to patent. The quality of generic prescription drugs is underpinned by the TG Act.

The counterfactual

5.8. The ACCC applies the 'future with-and-without test' established by the Tribunal to identify and weigh the public benefits and public detriments generated by arrangements for which authorisation has been sought.[83]

5.9. Under this test, the ACCC compares the public benefit and public detriment 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 referred to as the 'counterfactual'.

5.10. Medicines Australia note that the Tribunal considered that in the absence of edition 15 of the Code there would be:

- no voluntary mechanism within the industry for industry members to enforce, as against each other, standards of conduct in relation to the matters which it covers

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[83] Australian Performing Rights Association (1999) ATPR 41-701 at 42,936. See also for example: Australian Association of Pathology Practices Incorporated (2004) ATPR 41-985 at 48,556; Re Media Council of Australia (No.2) (1987) ATPR 40-774 at 48,419.

- no mechanism for governing other relationships between pharmaceutical companies and healthcare professionals such as appointment to company advisory boards
- no requirement for the adoption of internal compliance procedures by companies
- no mechanism for enforcement of the Royal Australasian College of Physicians Guidelines and
- no external regulatory system in place to constrain the conferring of benefits on healthcare professionals by pharmaceutical companies.

5.11. No interested party commented on what the most appropriate counterfactual should be.

5.12. The ACCC considers that the most likely counterfactual in the absence of authorisation is that edition 16 of the Code as currently drafted will not come into effect. The ACCC considers it unlikely that Medicines Australia and its member companies would choose to enforce the Code without immunity from legal action under the TPA.

5.13. Therefore, in the counterfactual, edition 15 of the Code would continue to operate until the authorisation currently in place expires in 2012. It may be that some form of the Code that did not give rise to a potential breach of the TPA would continue, however it is likely that any such code would not contain disciplinary measures and it is difficult to envisage how it would be enforced and effectively regulate behaviour.

5.14. The ACCC notes that existing legislation in the TG Act, the TPA and relevant state and territory fair trading legislation, extends only to the advertising and promotion of pharmaceutical products to health care professionals and the public, as well as misleading and deceptive claims about pharmaceutical products. Without the Code, the provision of benefits to healthcare professionals by pharmaceutical companies would not be regulated, and as noted by the Tribunal, while a culture of restraint and sensitivity to public criticism may moderate the development of the practice of conferring benefits to healthcare professionals, there is a real chance that, absent any mechanism for their limitation, some companies would break out of that culture, and the conferring of benefits may take new and more subtle forms.[84]

Public benefit

5.15. Public benefit is not defined in 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.[85]

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[84] Application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation of edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT)* at ¶314.
[85] Re 7-Eleven Stores (1994) ATPR 41-357 at 42,677. See also Queensland Co-operative Milling Association Ltd (1976) ATPR 40-012 at 17,242.

5.16. Medicines Australia submits that edition 16 of the Code will deliver public benefits, including:

- protection of the public from exposure to inappropriate advertising
- regulation of relationships between pharmaceutical companies and health consumer organisations
- ensuring a high, consistent and industry-specific standard for medical and promotional claims
- creation of an effective framework for appropriate relationships between pharmaceutical companies and healthcare professionals, including around the conduct of research/clinical trials and the prohibition of financial or material benefits influence prescribing practices
- the requirement for stringent internal company compliance procedures.

5.17. The ACCC's assessment of the likely public benefits from the Code follows.

Protection of public from inappropriate advertising

5.18. Medicines Australia submits that the Code contains an overarching general principle that pharmaceutical companies cannot promote their products to the general public. Medicines Australia submits that edition 16 of the Code strengthens the implementation of this principle by:

- adopting the same definition of advertising as is in the TG Act
- explicitly covering 'social media' so that promotion of prescription products via the internet is prohibited
- strengthening clauses relating to electronic prescribing software so that advertisements for prescription products are now prohibited in any section of prescribing software packages
- specifically regulating disease education/awareness campaigns. Such activities/campaigns must contain balanced coverage of treatment options in a language suitable for a non-medical audience. Disease education activities should emphasise the condition and its recognition rather than on treatment options, and must not include any reference to a specific prescription product.
- strengthening provisions relating to product specific media statements. In particular, promotional statements or product claims and comparisons to other products may not be included in a media statement to the general media.
- introduction of a new section regulating market research conducted with the general public to ensure the sole purpose is the collection of data and market research is not used as a means to promote a product.

- requiring that trade displays including promotional materials for prescription products be directed only to healthcare professionals.

5.19. The ACCC accepts that strengthening the Code in the manner outlined facilitates protection of the public from inappropriate advertising.

5.20. The complete prohibition of advertising in electronic prescribing software alleviates previous concerns of the ACCC and interested parties about the ability for patients to view advertisements in software packages used by GPs. The ACCC was concerned that the previous version of the Code did not ensure full compliance with the legislative prohibition on advertising to consumers as consumers could view advertisements on the GPs computer screen.[86] Submissions in support of the prohibition were received by Dr Ken Harvey, Janssen-Cilag and Queensland Health.

5.21. The ACCC accepts that the Code encourages compliance with legislative prohibitions on advertising to the public and results in a public benefit. As noted by the Tribunal there are limits to legislation and the Code has a potentially wider coverage.[87] Further there are costs associated with the investigations and judicial processes involved in the enforcement of statutory regulation. These costs and limits on government resources can limit the extent of enforcement coverage.

Standards for medical and promotional claims

5.22. The Code contains provisions that:

- require all promotional claims to be consistent with Product Information approved by the TGA
- specify the content and layout of Product Information, abridged Product Information and minimum Product Information and the circumstances in which each must be used
- prohibit the use of abstracts and poster presentations as primary evidence to support a promotional claim and specifies the circumstances in which such information may be used as secondary evidence.

5.23. Medicines Australia submits that the Code ensures a high, consistent and industry-specific standard for medical and promotional claims. This includes specifying what product information must accompany or be included within promotional material, and how such information is presented. Medicines Australia submits this Code creates a regime under which companies can determine with ease how they may present their promotional claims and ensure healthcare professionals have up to date and accurate information.

5.24. Janssen-Cilag submits that edition 16 of the Code sets even higher standards for the advertising and promotion of pharmaceutical products.

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[86] ACCC Determination, *Applications for Revocation and Substitution lodged by Medicines Australia Inc in respect of Medicines Australia Inc Code of Conduct 15th Edition*, 26 July 2006, p. 39.
[87] Application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation of edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT)* at ¶342.

5.25. The TGA supports the strengthening of the requirements for advertising of prescription medicines.

5.26. The Tribunal found there was substantial public benefit in the provisions which set standards for medical and promotional claims. The ACCC agrees that medical practitioners might not always possess perfect information on the range of remedies available and may not have sufficient time to absorb the volume of scientific studies and research available on pharmaceutical products. As a result medical practitioners might rely heavily on information provided by pharmaceutical manufacturers and it is important this information is balanced and accurate.

5.27. While there are general prohibitions against misleading and deceptive conduct that apply with or without the Code the ACCC notes that standards in the Code are more specific and contain specific enforcement mechanisms for a breach of the Code.

Relationships between pharmaceutical companies and health consumer organisations (HCOs)

5.28. Medicines Australia submits that edition 16 of the Code contains specific provisions dealing with relationships between pharmaceutical companies and health consumer organisations. Such relationships are now regulated by 5 key principles:

- respect for independence
- achieving and maintaining public trust
- fairness
- openness and transparency and
- accountability.[88]

5.29. Medicines Australia advises these new provisions specifically provide that:

- no pharmaceutical company may request that it be the sole funder of an HCO
- a pharmaceutical company may not use an HCO's logo without permission
- a pharmaceutical company must not seek to influence the text of an HCOs material
- a pharmaceutical company must make available on its website a list of the HCOs to which it provides support and the nature of that support
- sponsorship of an HCO representative to attend education events will be regulated in the same way as that of the sponsorship of health care professionals.

5.30. Janssen-Cilag and Queensland Health particularly submit that increasing the transparency of the relationships between pharmaceutical companies and HCOs by

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[88] Medicines Australia Code of Conduct edition 16, s 13.

requiring publication on a company's website of a list of the HCOs to which it provides support and the nature of the support is an improvement in the Code.

5.31. The ACCC considers the provisions provide greater transparency around the relationships between pharmaceutical companies and HCOs and will help reduce the potential for conflicts of interest that may arise when pharmaceutical companies enter into relationships with HCO's and fund their activities. The ACCC considers this results in a public benefit.

Framework for relationships between pharmaceutical companies and healthcare professionals

5.32. Medicines Australia submits that the Code articulates the fundamental principle of prohibiting the offering of financial or material benefits to healthcare professionals to influence them in their prescribing practices. Medicines Australia submits that this ensures healthcare professionals are not inappropriately influenced and the industry is not brought into disrepute.

5.33. Edition 16 of the Code has consolidated sections 6, 7 and 10 of edition 15[89] into one section titled 'Relationship with healthcare professionals' (section 9). Section 9 is subject to the overriding general principle that:

> Companies may choose to support, initiate or become involved in activities with healthcare professionals. Such involvement either by financial or other means must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste.[90]

5.34. Medicines Australia submits the consolidation highlights that the principles in the new section 9 are universal with respect to educational symposia, congresses, sponsorship and the general relationship between healthcare professionals and pharmaceutical companies.

5.35. Medicines Australia notes that section 9 in edition 16 further restricts the circumstances in which benefits may be provided to healthcare professionals, thereby reducing the influence on prescribing patterns, including that:

- no entertainment may be provided. Edition 15 provided that educational meetings of two or more days duration could include a modest opportunity for unstructured and individual recreational activities at the individual's own expense.

- any meals and beverages provided by pharmaceutical companies to healthcare professionals must be appropriate for the educational content and direction of the meeting and should not be excessive. Hospitality must be secondary to the educational content. Edition 15 required all hospitality to be consistent with the professional standing of the delegates attending the event. Medicines Australia notes that this phrase was the source of some confusion and it has not been included in edition 16.

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[89] Section 6 of edition 15 was titled 'Involvement in educational symposia, congresses and satellite meetings', section 7 was titled 'Sponsorship' and section 10 was titled 'Relations with healthcare professionals'.
[90] Medicines Australia Code of Conduct edition 16, section 9.1.

- delegates must not be paid for their attendance at a company educational event. Any remuneration provided to faculty, speakers or chairpersons should be commensurate with the work involved and should be part of a formal agreement.

- there are additional formalities around the sponsorship of healthcare professionals to attend Australasian and international educational events, such as the development of guidelines in relation to the awarding of sponsorship to healthcare professionals which can be publicly disclosed if required.

- air travel must be economy class only. Edition 15 provided that travel within Australia should be economy class unless there are circumstances where business class travel may be appropriate.

- companies must consider the appropriateness of venue selection and hospitality. Venues must be justified and must have suitable facilities to support the provision of education and be able to withstand public scrutiny.

5.36. Medicines Australia notes that edition 16 of the Code also prohibits pharmaceutical companies from providing items or services to healthcare professionals unless they fall within one of the following exceptions:[91]

- product brand name reminders to a limited extent (subject to the requirements of s 2.6)

- company branded items of stationery provided to delegates attending a company educational event (ss 9.4.9 and 5.9.9)

- educational material directed to healthcare professionals or patients (s 4)

- prizes for a complying competition (prizes must be for genuine competitions which test medical knowledge and the prize is directly relevant to the practice of medicine or pharmacy, of low monetary value or an item of educational material)

- sponsorship to attend an educational event (s 9.7)

- hospitality at an educational event, which must withstand public scrutiny (ss 9.4.3, 9.4.4, 9.4.5 and 9.5.5).

Brand name reminders

5.37. The ACCC notes that edition 16 of the Code limits the exception for brand name reminders such that:

> Only items that are educational and/or directly related to the practice of medicine or pharmacy are suitable for use of brand name reminders. Items that are more likely to be used outside the practice or be regarded as being for use in the home or for recreational activities are unacceptable.[92]

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[91] Medicines Australia Code of Conduct edition 16, s 9.12.
[92] ibid, s 2.6.

5.38. In this regard, the ACCC notes that edition 16 goes further than edition 15 of the Code which permitted pharmaceutical companies to provide brand name reminders, up to a $20 limit.

5.39. Janssen-Cilag and Queensland Health note that limiting the provision of brand name reminders to healthcare professionals to practice-related items is an improvement in the Code.

Clinical trials and research

5.40. Medicines Australia also notes that section 10 of the Code extends the appropriate interactions between a company and healthcare professionals providing consulting services to also apply to interactions that occur when conducting research and clinical trials. Queensland Health supports this clarification. In particular, the Code states that Post-Marketing Surveillance studies must have scientific or medical merit and objectivity and not be designed for, or conducted as, a promotional exercise. Similarly, market research with both the general public and healthcare professionals must have the sole purpose to collect data.

5.41. Medicines Australia notes that the TG Act, the *NHMRC National Statement on Ethical Conduct in Human Research* and other guidelines and policies govern good clinical and ethical conduct in carrying out research and clinical trials involving humans. Medicines Australia submits that edition 16 of the Code promotes compliance with these guidelines and policies and therefore results in a public benefit.

Starter packs

5.42. The Code also regulates the distribution, storage and information to be included with starter packs (see paragraphs 3.16 to 3.17). In edition 15 of the Code, the provisions relating to starter packs were expanded to account for the repeal of various state and territory legislation relating to starter packs in 2006. The ACCC notes that at that time there was generally support for the amendments as they appeared to improve accountability and standards around the possession and handling of starter packs.

5.43. The ACCC has not received any submissions regarding the operation of these provisions in the Code following the repeal of the relevant legislation.

Alternate codes and guidelines

5.44. The ACCC notes that various industry bodies have developed guidelines which attempt to outline standards of ethical behaviour expected of doctors, in the context of the doctor-patient relationship, such as the *AMA Code of Conduct.*

5.45. The Australian Medical Council also released a code of practice in August 2009, developed in consultation with industry participants, in preparation for the introduction of the national medical registration system to take effect in July 2010. The *Good Medical Practice: A Code of Conduct for Doctors in Australia* represents the understanding of both the community and medical professional about the accepted standards of good professional conduct of Australia's doctors in modern medical practice.

5.46. These Codes do not, however, go so far as to outline the relationship between healthcare professionals and pharmaceutical companies and the conferral of benefits to healthcare professionals.

5.47. The RACPs *Guidelines for ethical relationships between physicians and industry* aim to assist healthcare professionals in managing their relationships with industry. The guidelines make a number of recommendations for individual practitioners regarding promotions of products by industry, use of therapeutic devices, support for meetings and educational activities, employment and remuneration and research and development. Some recommendations include:

- medical professionals should not accept a fee from company representatives of the industry for seeing them in a promotional capacity
- gifts and offers of entertainment should be refused
- careful consideration should be given before accepting offers of sponsorship. Accepting sponsorship to cover the cost of travel, attendance or meals at conferences or meetings for family or friends, is inappropriate
- endorsement of specific products should be avoided.

5.48. However the RACPs guidelines are advisory only and are not binding.

The importance of an appropriate framework to regulate the relationship between pharmaceutical companies and healthcare professionals

5.49. The ACCC notes that the promotional and educational activities of pharmaceutical companies can affect the way healthcare professionals make decisions about treatment options for patients. If not appropriately managed, the offer of hospitality, sitting fees, travel costs and other forms of benefits provided by pharmaceutical companies to healthcare professionals can result in significant consumer detriment. In this regard the Tribunal stated:

> In our opinion, unless strictly limited and audited, the provision of financial benefits directly to healthcare professionals by pharmaceutical companies, whether it be by way of hospitality, the cost of travel and accommodation at conferences, sitting fees for advisory committees and other forms of benefits that have been described in the evidence, risks distortion of the medical decision-making processes of healthcare professionals. It may also include the opinion leaders in the field. It is difficult to accept that pharmaceutical companies would go to the effort of providing such benefits if they did not think there was likely to be a positive return.[93]

5.50. While there may be alternative codes which provide guidance about the ethical behaviour and relationships between pharmaceutical companies and healthcare professionals, they are guidelines only. Medicines Australia's Code provides an enforcement mechanism which means that companies who overstep the boundaries outlined in the Code may be subject to a sanction, including fines.

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[93] Application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation of edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT)* at ¶345.

5.51. Absent the Code there is no equivalent regulation of the conferral of benefits by pharmaceutical companies upon healthcare professionals.

> To some extent the Code provisions may reflect a greater consciousness in the industry of public suspicion of non-armslength relationships between pharmaceutical companies and healthcare professionals. The existence of Code provisions restricting the provision of such benefits and the existence of an enforcement mechanism through which complaints can be and are made, is a public benefit in two respects:
>
> - it is likely to give rise to a degree of restraint in the conferral of benefits upon healthcare professionals and, to that extent, to mitigate the detriment or potential for detriment associated with the provision of such benefits
> - it will enhance a degree of public confidence that such conduct does not go unscrutinised and that there is a mechanism by which it can be reviewed.[94]

5.52. The Tribunal noted that public confidence will only result and be maintained if the Code is transparent and if there is a real incentive for complaints about the conferral of benefits to healthcare professionals to be made.[95]

5.53. The ACCC considers that providing a framework for appropriate relationships between pharmaceutical companies and health care professionals helps to address the principal-agent problem and the scope for the prescribing practices of health care professionals to be inappropriately influenced by pharmaceutical companies to the detriment of patients. By regulating the relationship between pharmaceutical companies and healthcare professionals, and the conferral of benefits to healthcare professionals as a means for influencing their prescribing patterns, the Code results in a public benefit, although the ACCC recognises that the benefit is dependent on the Code being enforced effectively.

5.54. The question remains whether the Code is in fact being effectively enforced (see paragraphs 5.68 to 5.111).

Internal company compliance procedures

5.55. Medicines Australia submits that edition 16 of the Code will strengthen the internal company compliance procedures, and it specifically recommends that compliance with the Code forms part of the overall performance assessment of company representatives.

5.56. The Code places responsibility on the pharmaceutical company to ensure that an internal compliance procedure exists, and that company representatives should maintain a high standard of ethical conduct and professionalism in the discharge of their duties. The Code requires company representatives to participate in formal training with respect to the Code, Australian privacy legislation and Australian trade practices legislation (see paragraphs 5.105 to 5.107).

5.57. The ACCC considers that an internal compliance program to ensure that company representatives are not only aware of the Code, but comply with the Code and maintain a level of professionalism in their dealings with healthcare professionals, will result in a public benefit. The ACCC encourages member companies to take up Medicines

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[94] Application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation of edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT)* at ¶355.
[95] ibid, at ¶355.

Australia's recommendation that compliance with the Code form part of a company representative's performance assessment. The ACCC accepts that encouraging compliance with the Code results in a public benefit.

ACCC conclusion on public benefits

5.58. The ACCC accepts that the following public benefits are likely to result from edition 16 of the Code:

- enhancing compliance with legislation and protecting the general public from inappropriate advertising
- setting consistent standards for medical and promotional material thereby reducing misleading claims about medicines
- providing for greater transparency around the relationships between pharmaceutical companies and HCOs
- outlining the boundaries for appropriate relationships between pharmaceutical companies and healthcare professionals to limit the potential conflicts of interest
- requiring pharmaceutical companies to have an internal compliance procedure promoting compliance by all company employees.

5.59. The ACCC notes that these public benefits will only result to the extent that the Code is effectively enforced. This is discussed further in paragraphs 5.68 to 5.111.

Public detriment

5.60. Public detriment is not defined in the TPA but the Tribunal has given the concept a wide ambit, including:

> ...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.[96]

5.61. Medicines Australia submits that the Code does not result in any anti-competitive detriment or any other public detriment. Medicines Australia submits that the Code is effective and that it is administered to ensure the industry is regulated according to prevailing community standards and that members' conduct is accountable to such standards.

5.62. Interested parties raised particular concerns about:

- the lack of transparency around how fines are spent by Medicines Australia
- the level of fines with some interested parties submitting that they should be increased further and

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[96] Re 7-Eleven Stores (1994) ATPR 41-357 at 42,683.

- the unequal coverage of the Code across the entire industry (see paragraphs 5.131 to 5.140).

Anti-competitive detriment

5.63. The ACCC notes that the Code restricts the ability of Medicines Australia's members to compete through the advertising and promotion of their products to healthcare professionals. Although as noted, the ACCC considers that the Code restricts such behaviour as a means for addressing market failures which may arise in the health sector (paragraphs 5.3 to 5.7),

5.64. The Tribunal was satisfied that 'there is little in the way of significant anti-competitive detriment' resulting from the Code and that the:

> restrictions imposed by the Code do not strike at the heart of competitive conduct as to price and quality and lawful communications of the benefits and characteristics of pharmaceutical products to appropriately qualified healthcare professionals.

5.65. The ACCC considers there is minimal anti-competitive detriment resulting from the Code.

Other public detriment

5.66. While the effectiveness of the Code is relevant to the extent and degree of the benefits flowing from the Code, the ACCC also considers that a Code which is not enforced effectively may give rise to public detriment. The ACCC considers that public detriment may arise where there is the appearance of an effective Code in place however that code is not appropriately enforced.

5.67. The ACCC's consideration of whether Medicines Australia's Code is effectively enforced follows.

Effectiveness of the Code

5.68. The ACCC notes that the effectiveness of the enforcement of the Code was a primary issue in its consideration of edition 15 of the Code. Further, the Tribunal noted that the enforcement mechanism in edition 15 of the Code was weak and open to lenient interpretation, providing little deterrent to contravention or incentive to comply.[97]

5.69. The ACCC notes that there have been a number of improvements since the version of the Code last considered by the ACCC and Tribunal.

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[97] Application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation of edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT)* at ¶360.

The role of the Monitoring Committee in reviewing promotional materials, activities and educational events

5.70. Previously the ACCC has been concerned that the Monitoring Committee did not actively and effectively review promotional materials and activities by member companies.

5.71. The Tribunal imposed a condition requiring the Monitoring Committee to review educational events for three random months in a 12 month period. Edition 16 of the Code now requires the Monitoring Committee to meet certain minimum standards in proactively reviewing promotional materials and activities and reviewing educational events held by member companies throughout the financial year.

5.72. In a financial year the Monitoring Committee will review three types of promotional material across three different therapeutic classes and three different types of conduct covered by the Code across all therapeutic classes.

5.73. The Code also requires the Monitoring Committee to review educational event reporting. In its review the Monitoring Committee undertakes a detailed review of the cost of the hospitality and function as a whole, accounting for the number of attendees, and the qualitative descriptions of the function and duration of the education provided by member companies held during the three months selected by the committee at random from the preceding 12 month period.

5.74. The Monitoring Committee may request further information from member companies, and member companies must comply with any request.

5.75. In 2007-08 the Monitoring Committee examined 2087 items of promotional material as outlined in Table 5.1.

Table 5.1: Summary of materials and activities reviewed by the Monitoring Committee in 2007-08

Therapeutic Class	Type of materials or activity subject to review	Number of companies	Number of items	Number of meetings to complete review
All therapeutic classes	Company websites available to the general public & patients*	26	103	1*
All therapeutic classes	Advertisements in prescribing software	10	25	1
All therapeutic classes	Invitations to educational meetings	32	683	2
Central Nervous System	Advertisements	7	36	1
Neoplastic Disorders	Printed Promotional Material	13	234	1
All therapeutic classes	Educational Event Reports	42	951	3
Cardiovascular System	Competitions	9	22	1
All therapeutic classes	Corporate websites	33	33	1
TOTAL			2087	11

* Reviewed in 2006/2007 and finalised in 2007/2008 (1 meeting in 2006/2007)

Source: Medicines Australia Code of Conduct Edition 16, p. 201.

5.76. The Monitoring Committee reviewed 951 educational events in compliance with the reporting condition imposed by the Tribunal. The Monitoring Committee requested further information in relation to 312 of the events. Following a review of the additional information, the Monitoring Committee referred 52 events to the Code Committee for a determination on potential breaches of the Code.[98]

5.77. Medicines Australia advises that in the 2008 financial year the Monitoring Committee reviewed the full data for the months of October 2007, March 2008 and May 2008, covering approximately 8000 education events.[99]

Educational event reporting is publicly available

5.78. Consistent with the condition imposed by the Tribunal, the Code requires member companies to disclose on the Medicines Australia website the following information:

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[98] Medicines Australia, *Medicines Australia Code of Conduct Annual Report*, p. 206.
[99] Medicines Australia, *Medicines Australia submission to ACCC Authorisation of edition 16 of Code of Conduct*, 30 June 2009, p. 24.

- a description of the function including duration of the educational content delivered
- venue
- professional status of attendees
- hospitality provided
- total cost of hospitality
- number of attendees and
- total cost of function.

5.79. Member companies are required to provide the information in table format for two six-month periods each year and Medicines Australia must make this information available on its website within 3 months of the end of each six-month period.

5.80. Amendments to edition 16 change these time periods to October to March and April to September rather than January to June and July to December. Medicines Australia submits that the change will assist companies to comply with the obligation without the competing demands of yearly and half-yearly financial reporting. In addition, companies will have 30 days, rather than the previous 14 days, to provide Medicines Australia with their completed tables. Medicines Australia submits that this will not affect the time at which the reports are required to be published on the Medicines Australia website, and that they will still be made available within three months of the end of each six-month period.

5.81. The Tribunal considered that the reporting requirement provides an incentive to comply with the provisions of the Code relating to hospitality provided at educational events. The Tribunal noted that this incentive is best secured by a combination of internal review and evaluation of such benefits and their accessibility to public scrutiny.[100]

5.82. The ACCC considers that unrestricted relationships between pharmaceutical companies and healthcare professionals, particularly where there is some form of benefit provided to healthcare professionals, result in potential conflicts of interest and inappropriately influence prescribing practices. As noted by the Tribunal:

> ...detriment lies in the effect that such conduct may have upon the prescribing practices of healthcare professionals directly influenced by it or by the views of professional opinion leaders who have links to particular companies. If the prescribing practices of healthcare professionals are influenced directly or indirectly by sympathies for particular products because of benefits derived from or links to the manufacturer or distributor of those products, patient care may be compromised. Patients in need of treatment will not necessarily be provided with that which is best for them. In an indirect sense there is also an anti-competitive detriment to the extent that key decisions in the relevant market may be affected by factors extraneous to the quality of the product and its cost.[101]

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[100] Application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation of edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT)* at ¶360.
[101] Ibid, at ¶315.

5.83. The ACCC considers the reporting requirements in the Code provide transparency around the provision of hospitality to healthcare professionals and serves as a disincentive for inappropriate behaviour.

5.84. The ACCC notes that the amendments to the time periods provide for a transition such that a separate 3 month report for the period January to March 2010 would be published on Medicines Australia's website. The next 6 month report would then be for the period April to September. The ACCC does not consider that this amendment alters the transparency achieved by the Code in this regard.

Complaints process and sanctions for breaches of the Code

5.85. Medicines Australia submits that there is an effective complaints procedure that is easily accessible to stakeholders. The complaints process is summarised at paragraphs 3.42 to 3.46. Medicines Australia submits that the complaints process provides an appropriate forum for the hearing of complaints, and submits that it is being more widely utilised by various stakeholders including health professionals and organisations, not just member companies.

5.86. Medicines Australia advises that in 2008-09 there were 57 complaints in total. The Monitoring Committee referred 26 of the complaints relating to the provision of benefits at educational events. There were 31 other complaints received: 13 from member companies; 11 from healthcare professionals; 3 from the TGA; 2 from medical colleges/societies; one from a consumer organisation and one from an academic.

5.87. Medicines Australia notes that the Code Committee or Appeals Committee impose sanctions for a breach of the Code, namely:

- requirement to modify or discontinue a practice
- corrective statements and
- fines.

5.88. In considering edition 15 of the Code the ACCC found that the Code Committee was more likely to require a company to take corrective action than to impose a fine, and if a fine was imposed it was usually at the lower end of the range.[102]

5.89. Medicines Australia submits that the imposition of fines have become much more common (see Figure 5.2). In 2007-08 a fine was the most common sanction imposed on companies for breach of the Code, with a total of 33 fines imposed.

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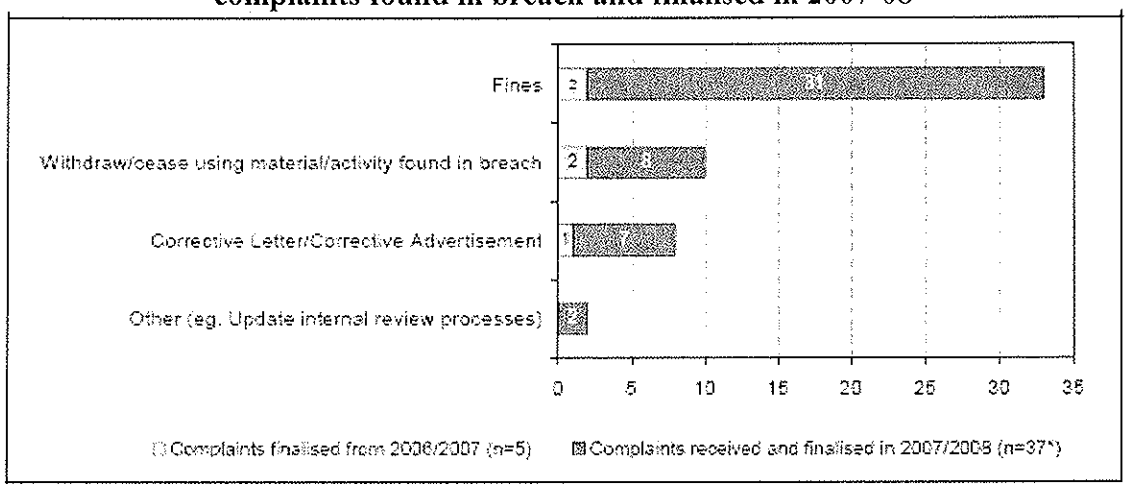
[102] ACCC Determination, *Applications for Revocation and Substitution lodged by Medicines Australia Inc in respect of Medicines Australia Inc Code of Conduct 15th Edition*, 26 July 2006, pp. 24, 54.

Figure 5.2: Sanctions imposed by the Code and Appeals Committees on companies with complaints found in breach and finalised in 2007-08

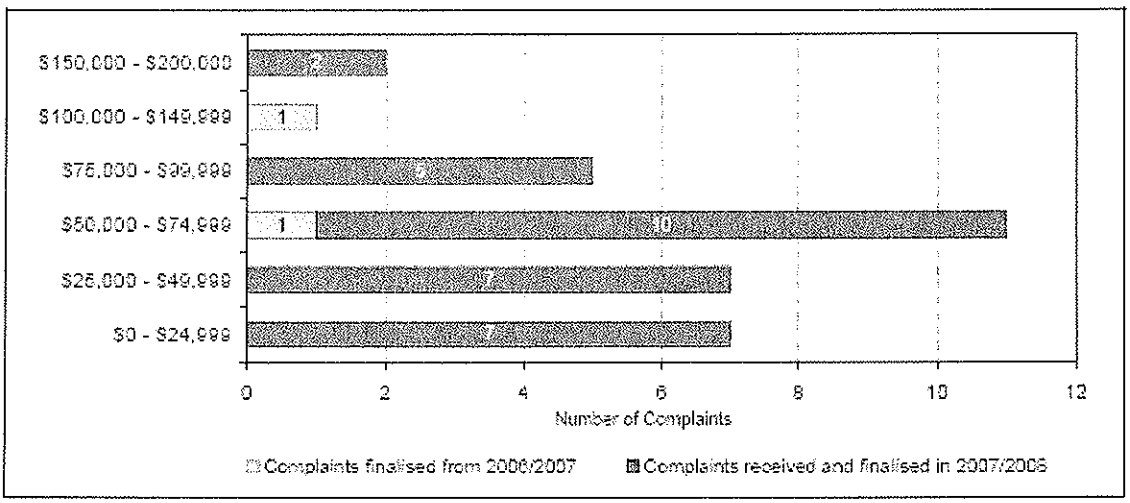


The number of sanctions may not add up to the number of complaints as a single complaint could be in breach of multiple sections of the Code and therefore could attract multiple sanctions.

Source: Medicines Australia Code of Conduct Annual Report 2007/2008, p. 22.

5.90. The ACCC notes that in 2007-08 one-third of all fines were between $50 000 and $75 000. Two fines of $175 000 and $200 000 were imposed which are the highest fines so far imposed.

Figure 5.3: Fines imposed by the Code and Appeals Committees on companies with complaints found in breach and finalised in 2007-08



Source: Medicines Australia Code of Conduct Annual Report 2007/2008, p. 22.

5.91. Medicines Australia also advises that where corrective action has not been actioned within 30 calendar days from receipt of a decision, the Code Committee may impose a fine of up to $50 000 for that breach of not actioning the corrective action.

5.92. The ACCC notes that some interested parties submit that the level of fines should be increased even further than provided by edition 16. The RACP submits that fines could be increased to a more realistic level. Dr Harvey notes fines for Code offences should be substantially increased on the grounds that existing sanctions do not appear to deter repeated Code offences. Dr Harvey considers that the increases made in edition 16 are modest only.

5.93. In contrast, Janssen-Cilag and Queensland Health note that fines for breaches were substantially increased resulting in an improvement in the Code.

5.94. In response to interested parties, Medicines Australia notes that edition 16 of the Code substantially increases fines for moderate, severe and repeat breaches by 50%, 100% and 100% respectively and does not consider any further increase necessary at this time.

5.95. Under edition 15 the maximum fine was $200 000. The Code now provides for:

- the maximum fine for a moderate breach is increased to $150 000 and the maximum fine for a severe breach is increased to $200 000
- the maximum fine for a severe breach where activities have been completed and there is no opportunity for correction is increased from $200 000 to $250 000
- the maximum fine for a repeat of a previous breach is increased from $200 000 to $250 000
- $50 000 for failure to pay a fine within 30 days
- the Code Committee is explicitly empowered to impose a fine for each individual breach, to a maximum of $300 000.

5.96. Further, Medicines Australia publishes quarterly and annual reports which detail the results of individual complaints and provide an overall analysis of complaints including any sanction imposed. The public reports provide transparency around the imposition of sanctions and fines and for the types of conduct they have been imposed.

5.97. The ACCC considers that appropriate sanctions will act as a deterrent to companies breaching the Code. The ACCC notes that the level of the fines have been increased in edition 16 of the Code. Whether these higher levels will act as a deterrent is yet to be tested. The ACCC notes that while the maximum level of fines have increased, fines may still be small relative to the money spent on hospitality by pharmaceutical companies. For example, between January and June 2009, $15.6 million was spent by Medicines Australia members on food and beverages, accommodation and travel expenses associated with educational events.[103]

5.98. Importantly the ACCC considers the transparency and public reporting around the imposition of fines and other sanctions helps to ensure that the relevant Committee's impose effective and appropriate sanctions. Further, the negative publicity surrounding the imposition of a fine may act as even more of a deterrent to breaching the Code than the fine itself.

5.99. On a related issue the RACP requests greater transparency regarding the spending of fine revenue by Medicines Australia. The RACP notes that Medicines Australia had

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[103] Medicines Australia website, *Educational event reporting*, http://medicinesaustralia.com.au/pages/page136.asp. Accessed 29 September 2009.

advised in May 2009 that fines were to go into the Medicines Australia Special Code Account and would be donated to an organisation that had no association with industry.

5.100. Medicines Australia advises that on 28 June 2008 the Medicines Australia Board resolved to establish a Special Purpose Fund (the Fund) which is to be financed by fines imposed under the Code and used to finance corporate social initiatives. Medicines Australia advises that the details of two proposed major projects valued together at over $1.1 million are currently being finalised with an indigenous health organisation. Medicines Australia advises it will publish the details of the projects in its annual report which will be available on its website.

Medicines Australia actively promotes understanding of the Code

5.101. The Code specifically requires that company representatives are trained on the requirements of the Code. In addition, Medicines Australia publishes written Code Guidelines, conducts other formal training and education sessions, and provides a substantial amount of informal guidance on the operation of the Code.

5.102. Medicines Australia advises that it promotes understanding of the Code and assists companies to comply with the Code through the established Board Taskforce which develops and publishes written Code Guidelines. Medicines Australia submits that the Guidelines are regularly updated.

5.103. Medicines Australia also provides formal training and information sessions on the Code and advises that participation has been increasing. In 2008-09 Medicines Australia staff participated in 70 training or information sessions with a total audience of 1570 people.

5.104. As noted in paragraph 5.56, Medicines Australia requires company representatives to participate in formal training on the requirements of the Code, Australian privacy legislation and Australian trade practices legislation. Medicines Australia also encourages companies to assess their representative's compliance with the Code to form part of their performance review.

5.105. The requirement that members participate in education programs either supplied by Medicines Australia or otherwise endorsed by Medicines Australia constitutes exclusive dealing under the TPA. Medicines Australia has sought authorisation for the requirement that certain persons participate in an education program endorsed by Medicines Australia from time to time, where the education is not supplied by Medicines Australia. The Tribunal noted:

> While it is possible that external providers could compete for the provision of such training courses for company representative's considerations of consistency and efficacy support the conclusion that those responsible for the formulation and administration of the Code are likely to be in the best position to provide effective education to employees of member companies.

5.106. The ACCC considers that this requirement goes to ensuring that representatives are aware and familiar with the provisions of the Code and other information critical to the role.

5.107. The ACCC accepts that promotion of the Code by Medicines Australia through both formal and informal measures increases the effectiveness of the Code.

Code is regularly updated after wide-ranging and extensive consultation

5.108. The Code is reviewed every three years. Medicines Australia 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.

5.109. Medicines Australia notes that the most recent review process entailed inviting submissions from various individuals and organisations, holding consumer workshops providing an additional opportunity to involve consumer organisations and individual consumers in the review. HCOs and individual representatives were invited to attend workshops. Medicines Australia also offered to meet with those who made submissions.

5.110. Medicines Australia notes that the Tribunal accepted the review process will result in the public benefit delivered by the Code being significantly enhanced.

5.111. The ACCC considers that regular reviews of a Code are an effective way to ensure the Code keeps up to date with changes in the industry and provides the opportunity for stakeholders to give feedback on its operation.

Conclusion on the effectiveness of the Code

5.112. The ACCC considers that the features of the Code discussed above go to the Code's effectiveness. The ACCC considers that the effectiveness of the Code reduces public detriment associated with the Code.

ACCC conclusion on public detriments

5.113. The ACCC considers that any anti-competitive detriment resulting from the Code will be minimal. While the Code restricts the promotional activities of Medicines Australia members, the ACCC accepts that the Code does this to address potential market failures which may arise.

5.114. The ACCC is satisfied that the following features of the Code contribute to its effectiveness and limit any public detriment from having a Code which is not enforced appropriately including:

- the role of the Monitoring Committee to actively review promotional materials, activities and educational events
- educational event reporting is made publicly available resulting in increased public transparency
- there is an accessible complaints process which is widely utilised by industry participants and the Code and Appeals Committee are able, and do, impose sanctions for breaches of the Code.
- promotion of the Code through both formal and informal measures
- regular Code reviews ensure the Code keeps up to date with changes in the industry.

Balance of public benefit and detriment

5.115. In general, the ACCC may only grant authorisation if it is satisfied that, in all the circumstances, the Code is likely to result in a public benefit, and that public benefit will outweigh any likely public detriment.

5.116. In the context of applying the net public benefit test at section 90(8)[104] of the TPA, the Tribunal commented that:

> ... something more than a negligible benefit is required before the power to grant authorisation can be exercised.[105]

5.117. For the reasons outlined in this chapter the ACCC considers the public benefits likely to result from the Code are:

- enhancing compliance with legislation and protecting the general public from inappropriate advertising
- setting consistent standards for medical and promotional material thereby reducing misleading claims about medicines
- providing for greater transparency around the relationships between pharmaceutical companies and HCOs
- outlining the boundaries for appropriate relationships between pharmaceutical companies and healthcare professionals to limit the potential conflicts of interest
- requiring pharmaceutical companies to have an internal compliance procedure promoting compliance by all company employees.

5.118. The ACCC considers that any anti-competitive detriment resulting from the Code will be minimal. While the Code restricts the promotional activities of Medicines Australia members, the ACCC accepts that the Code does this to address potential market failures which may arise.

- Further, the ACCC is satisfied that there are a number of features of the Code which contribute to its effectiveness and limit any public detriment from having a Code which is not enforced appropriately.

5.119. Accordingly, the ACCC considers the public benefit that is likely to result from the Code is likely to outweigh any anti-competitive detriment or other public detriment.

5.120. The ACCC notes that interested parties have suggested conditions of authorisation requiring:

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[104] The test at 90(8) of the TPA is in essence that conduct is likely to result in such a benefit to the public that it should be allowed to take place.
[105] Re Application by Michael Jools, President of the NSW Taxi Drivers Association [2006] ACompT 5 at paragraph 22.

- the Code apply to generic manufacturers and industry more broadly
- the level of fines be increased further.

5.121. The TPA allows the ACCC to grant authorisation subject to conditions.[106] Generally, the ACCC may impose conditions to ensure that the net public benefit test is met or continues to be met over the proposed period of authorisation.

5.122. As noted, the ACCC is unable to impose conditions requiring non-members to comply with Medicines Australia's Code. Further, the level of fines have been increased in edition 16. The ACCC considers the level of the sanction and its public reporting underpin the Code's effectiveness.

5.123. The ACCC notes that authorisation of edition 15 of the Code was granted subject to a reporting condition. This reporting requirement has been fully incorporated into edition 16 of the Code therefore the ACCC does not propose to impose a similar condition in this authorisation. However the ACCC notes that public reporting is an important feature of the Code, providing transparency around the relationships between pharmaceutical companies and healthcare professionals. Should this requirement be changed or removed from the Code, the public benefits and public detriments associated with the Code would be changed significantly. This would constitute a material change in circumstances and the ACCC would review the authorisation.

Length of authorisation

5.124. The TPA allows the ACCC to grant authorisation for a limited period of time.[107] The ACCC generally considers it appropriate to grant authorisation for a limited period of time, so as to allow an authorisation to be reviewed in the light of any changed circumstances.

5.125. In this instance, Medicines Australia seeks authorisation for a period of 5 years. Medicines Australia submits that this is consistent with the term of authorisation granted by the Tribunal for edition 15 of the Code.

5.126. The Tribunal considered that a period of five years was appropriate as it would allow adequate time for assessment of the effectiveness of the amended Code and the working of the condition.[108]

5.127. The ACCC notes that Medicines Australia conducts a review of the Code every three years which may result in amendments to the Code. If significant amendments are made, Medicines Australia would be likely to seek authorisation of any new version of the Code as it has done with the current applications.

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[106] Section 91(3).
[107] Section 91(1).
[108] Application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation of edition 15 of Medicines Australia's Code of Conduct (*Medicines Australia Inc [2007] ACompT)* at ¶374.

5.128. The ACCC proposes to grant authorisation for a period of five years which provides sufficient time for Medicines Australia to review the Code, finalise amendments and seek revocation and substitution if necessary, before the current authorisation expires.

Variations to the Code

5.129. The ACCC notes that any amendments to edition 16 of the Code during the proposed term of this authorisation would not be covered by the proposed authorisation.

5.130. The ACCC would review the authorisation if any changes were made to edition 16 of the Code which constituted a material change in circumstances. In particular, should the public reporting requirement be changed or removed from the Code, the public benefits and public detriments associated with the Code would be changed significantly and the ACCC would review the authorisation.

Scope of the authorisation regarding the application of the Code to the industry more broadly, including to manufacturers of generic pharmaceutical products and prosthetics

5.131. The NHMRC, Dr Harvey and RACP consider that the Code or similar provisions of the Code should apply more broadly in the industry including to also cover generic drug manufacturers and suppliers of prosthetics and medical devices.

5.132. Dr Harvey submits that the continued improvement of Medicines Australia's Code has resulted in an anticompetitive environment with respect to different sections of the Australian medicines industry. For example between prescription medicines – originator versus generic, and also across over-the-counter products and complementary medicines.

5.133. Dr Harvey considers that the discrepancy was highlighted by a recent advertisement by Sigma Pharmaceuticals Limited promoting a 10 day luxury Mediterranean cruise for doctors and pharmacists. However, as Sigma is not a member of Medicines Australia, the complaint regarding this event was not able to be considered by Medicines Australia.

5.134. Dr Harvey suggests that one code be applicable to all therapeutic claims and promotional practices, providing one complaint and appeal process, one monitoring process and one set of sanctions which would include corrective advertising orders and fines related to the sales income of the product and company involved. Dr Harvey suggests this code should be developed and overseen by government and funded by industry.

5.135. The ACCC notes that the Code in its entirety applies to members of Medicines Australia. There is a membership class that enables manufacturers of generic prescription medicines to join Medicines Australia. However the ACCC understands that few generic companies have chosen to become members of Medicines Australia and therefore become subject to the entire Code.

5.136. Non-member companies, including generic manufacturers are required to comply with those provisions of the Code relating to promotional material by virtue of the TGA's

marketing approval letter. However, the ACCC understands that the requirement in the TGA marketing approval letter does not extend to the provision of hospitality at educational events and other aspects of the manufacturer/healthcare provider relationship. Further, potential breaches of the standards in the Code by non-members may not amount to a breach of the TG Act or the TPA. The ACCC notes that few complaints against non-members companies are referred to the ACCC for investigation as a potential breach of the TPA.

5.137. Breaches of the standards set by the Code, even by non-member companies, particularly around the provision of inappropriate hospitality to healthcare professionals impact the reputation of the industry as a whole. Further, inconsistencies in the standards expected of different groups within an industry create an unequal playing field.

5.138. More concerning is that relationships between pharmaceutical companies not subject to the Code and healthcare professionals are largely unrestricted and not transparent. The ACCC notes the creation of an arms length and transparent relationship between pharmaceutical companies and healthcare professionals addresses the concern about potential conflicts of interest, particularly that unrestricted relationships, may influence the prescribing practices of healthcare providers, and may ultimately compromise patient care.

5.139. The ACCC considers there is significant benefit in regulating the provisions of benefits by all manufacturers of therapeutic products including manufacturers of generic drugs, prosthetics and other medical devices. However, the ACCC is not able to impose conditions through this authorisation requiring non-members of Medicines Australia to comply with this Code, or a similar Code. It is however open for other industry associations or groups to develop a code with similar standards of conduct and to seek authorisation from the ACCC.

5.140. Whether other industry sectors should be required to comply with similar standards as contained in Medicines Australia's Code is ultimately a decision for those industry sectors or government.

6. Draft determination

The application

6.1. On 30 June 2009 Medicines Australia Limited (Medicines Australia) lodged applications for the revocation of authorisations A90994-A90996 and the substitution of authorisations A91150 and A91155-A91156 with the Australian Competition and Consumer Commission (the ACCC). On 12 August 2009 Medicines Australia lodged applications for authorisation A91183 and A91184. These additional applications are for conduct that is identical to that sought in applications A91150 and A91155-A91156 and were lodged to take account of amendments introduced by the *Trade Practices Amendment (Cartel Conduct and Other Measures) Act 2009* which commenced on 24 July 2009.

6.2. Application A91150 was made using Form FC, Schedule 1, of the Trade Practices Regulations 1974. The application was made under subsection 88 (1) of the TPA to make and give effect to a contract, arrangement or understanding, a provision of which is or may be an exclusionary provision within the meaning of section 45 of the TPA.

6.3. Application A91155 was made using Form FC, Schedule 1, of the Trade Practices Regulations 1974. The application was made under subsection 88 (1) of the TPA to make and give effect to a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of the TPA.

6.4. Application A91156 was made using Form FC, Schedule 1, of the Trade Practices Regulations 1974. The application was made under subsection 88(8) of the TPA to engage in conduct that constitutes or may constitute, exclusive dealing.

6.5. Application A91183 was made using Form A, Schedule 1, of the Trade Practices Regulations 1974. The application was made under subsection 88(1A) of the TPA to make and give effect to a contract, arrangement or understanding, a provision of which is or may be a cartel provision which would also be, or might also be, an exclusionary provision within the meaning of section 45 of the TPA.

6.6. Application A91184 was made using Form B, Schedule 1, of the Trade Practices Regulations 1974. The application was made under subsection 88(1A) of the TPA to make and give effect to a provision of a contract, arrangement or understanding that is, or may be, a cartel provision.

6.7. In particular, Medicines Australia seeks authorisation for its Code of Conduct edition 16 for give years.

6.8. Medicines Australia seeks authorisation on behalf of current and future members.

The net public benefit test

6.9. For the reasons outlined in Chapter 5 of this draft determination, the ACCC considers that in all the circumstances the Code is likely to result in a public benefit that would

outweigh the detriment to the public constituted by any lessening of competition arising from the arrangements.

6.10. The ACCC is satisfied that the Code is likely to result in such a benefit to the public that the arrangements should be allowed to take place.

6.11. The ACCC therefore **proposes to grant** authorisation to applications A91150, A91155, A91156 A91183 and A91184.

Conduct for which the ACCC proposes to grant authorisation

6.12. The ACCC proposes to grant authorisation to Medicines Australia Code of Conduct edition 16 for a period of five years.

6.13. Any changes to the Code of Conduct edition 16 during the term of the proposed authorisation would not be covered by the proposed authorisation.

6.14. This draft determination is made on 16 October 2009.

6.15. The attachments to this determination are part of the draft determination.

Further submissions

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

Attachment A — the authorisation process

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.

The TPA, however, allows the ACCC to grant immunity from legal action in certain circumstances for conduct that might otherwise raise concerns under the competition provisions of the TPA. One way in which parties may obtain immunity is to apply to the ACCC for what is known as an 'authorisation'.

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.

The ACCC conducts a public consultation process when it receives 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.

After considering submissions, the ACCC issues a draft determination proposing to either grant the application or deny the application.

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

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 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 benefit to the public or reduce the public detriment.

Attachment B — chronology of ACCC assessment for applications A91150, A91155, A91156, A91183 and A91184

The following table provides a chronology of significant dates in the consideration of the application by Medicines Australia.

DATE	ACTION
30 June 2009	Applications A91150, A91155 and A91156 for revocation and substitution lodged with the ACCC.
29 July 2009	Closing date for submissions from interested parties in relation to the substantive application for authorisation.
12 August 2009	Applications A91183 and A91184 lodged with the ACCC.
20 August 2009	Submission received from Medicines Australia in response to interested party submissions.
16 October 2009	Draft determination issued.

Attachment C — the tests for authorisation and other relevant provisions of the TPA

Trade Practices Act 1974

Section 90—Determination of applications for authorisations

(1) The Commission shall, in respect of an application for an authorization:

(a) make a determination in writing granting such authorization as it considers appropriate; or

(b) make a determination in writing dismissing the application.

(2) The Commission shall take into account any submissions in relation to the application made to it by the applicant, by the Commonwealth, by a State or by any other person.

Note: Alternatively, the Commission may rely on consultations undertaken by the AEMC: see section 90B.

(4) The Commission shall state in writing its reasons for a determination made by it.

(5) Before making a determination in respect of an application for an authorization the Commission shall comply with the requirements of section 90A.

Note: Alternatively, the Commission may rely on consultations undertaken by the AEMC: see section 90B.

(5A) The Commission must not make a determination granting an authorisation under subsection 88(1A) in respect of a provision of a proposed contract, arrangement or understanding that would be, or might be, a cartel provision, unless the Commission is satisfied in all the circumstances:

(a) that the provision would result, or be likely to result, in a benefit to the public; and

(b) that the benefit would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if:

(i) the proposed contract or arrangement were made, or the proposed understanding were arrived at; and

(ii) the provision were given effect to.

(5B) The Commission must not make a determination granting an authorisation under subsection 88(1A) in respect of a provision of a contract, arrangement or understanding that is or may be a cartel provision, unless the Commission is satisfied in all the circumstances:

(a) that the provision has resulted, or is likely to result, in a benefit to the public; and

(b) that the benefit outweighs or would outweigh the detriment to the public constituted by any lessening of competition that has resulted, or is likely to result, from giving effect to the provision.

(6) The Commission shall not make a determination granting an authorization under subsection 88(1), (5) or (8) in respect of a provision (not being a provision that is or may be an exclusionary provision) of a proposed contract, arrangement or understanding, in respect of a proposed covenant, or in respect of proposed conduct (other than conduct to which subsection 47(6) or (7) applies), unless it is satisfied in all the circumstances that the provision of the proposed contract, arrangement or understanding, the proposed covenant, or the proposed conduct, as the case may be, would result, or be likely to result, in a benefit to

the public and that that benefit would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if:

(a) the proposed contract or arrangement were made, or the proposed understanding were arrived at, and the provision concerned were given effect to;

(b) the proposed covenant were given, and were complied with; or

(c) the proposed conduct were engaged in;

as the case may be.

(7) The Commission shall not make a determination granting an authorization under subsection 88(1) or (5) in respect of a provision (not being a provision that is or may be an exclusionary provision) of a contract, arrangement or understanding or, in respect of a covenant, unless it is satisfied in all the circumstances that the provision of the contract, arrangement or understanding, or the covenant, as the case may be, has resulted, or is likely to result, in a benefit to the public and that that benefit outweighs or would outweigh the detriment to the public constituted by any lessening of competition that has resulted, or is likely to result, from giving effect to the provision or complying with the covenant.

(8) The Commission shall not:

(a) make a determination granting:

(i) an authorization under subsection 88(1) in respect of a provision of a proposed contract, arrangement or understanding that is or may be an exclusionary provision; or

(ii) an authorization under subsection 88(7) or (7A) in respect of proposed conduct; or

(iii) an authorization under subsection 88(8) in respect of proposed conduct to which subsection 47(6) or (7) applies; or

(iv) an authorisation under subsection 88(8A) for proposed conduct to which section 48 applies;

unless it is satisfied in all the circumstances that the proposed provision or the proposed conduct would result, or be likely to result, in such a benefit to the public that the proposed contract or arrangement should be allowed to be made, the proposed understanding should be allowed to be arrived at, or the proposed conduct should be allowed to take place, as the case may be; or

(b) make a determination granting an authorization under subsection 88(1) in respect of a provision of a contract, arrangement or understanding that is or may be an exclusionary provision unless it is satisfied in all the 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.

(9) The Commission shall not make a determination granting an authorization under subsection 88(9) in respect of a proposed acquisition of shares in the capital of a body corporate or of assets of a person or in respect of the acquisition of a controlling interest in a body corporate within the meaning of section 50A unless it is satisfied in all the circumstances that the proposed acquisition would result, or be likely to result, in such a benefit to the public that the acquisition should be allowed to take place.

(9A) In determining what amounts to a benefit to the public for the purposes of subsection (9):

(a) the Commission must regard the following as benefits to the public (in addition to any other benefits to the public that may exist apart from this paragraph):

(i) a significant increase in the real value of exports;

(ii) a significant substitution of domestic products for imported goods; and

(b) without limiting the matters that may be taken into account, the Commission must take into account all other relevant matters that relate to the international competitiveness of any Australian industry.

Variation in the language of the tests

There is some variation in the language in the Act, particularly between the tests in sections 90(6) and 90(8).

The Australian Competition Tribunal (the Tribunal) has found that the tests are not precisely the same. The Tribunal has stated that the test under section 90(6) is limited to a consideration of those detriments arising from a lessening of competition but the test under section 90(8) is not so limited.[109]

However, the Tribunal has previously stated that regarding 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.[110]

Consequently, when applying either test, the ACCC can take most, if not all, public detriments 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.

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). Further, as the wording in sections 90(5A) and 90(5B) is similar, this approach will also be applied in the test for conduct that may be a cartel provision.

Conditions

The Act allows the ACCC to grant authorisation subject to conditions.[111]

Future and other parties

Applications to make or give effect to contracts, arrangements or understandings that might substantially lessen competition or constitute exclusionary provisions may be expressed to extend to:

- persons who become party to the contract, arrangement or understanding at some time in the future[112]

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[109] *Australian Association of Pathology Practices Incorporated* [2004] ACompT 4; 7 April 2004. This view was supported in *VFF Chicken Meat Growers' Boycott Authorisation* [2006] AcompT9 at paragraph 67.

[110] 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.

[111] Section 91(3).

- persons named in the authorisation as being a party or a proposed party to the contract, arrangement or understanding.[113]

Six-month time limit

A six-month time limit applies to the ACCC's consideration of new applications for authorisation[114]. It does not apply to applications for revocation, revocation and substitution, or minor variation. The six-month period can be extended by up to a further six months in certain circumstances.

Minor variation

A person to whom an authorisation has been granted (or a person on their behalf) may apply to the ACCC for a minor variation to the authorisation.[115] The Act limits applications for minor variation to applications for:

> ... a single variation that does not involve a material change in the effect of the authorisation.[116]

When assessing applications for minor variation, the ACCC must be satisfied that:

- the proposed variation satisfies the definition of a 'minor variation' and
- if the proposed variation is minor, the ACCC must assess whether it results in any reduction to the net benefit of the arrangements.

Revocation; revocation and substitution

A person to whom an authorisation has been granted may request that the ACCC revoke the authorisation.[117] The ACCC may also review an authorisation with a view to revoking it in certain circumstances.[118]

The holder of an authorisation may apply to the ACCC to revoke the authorisation and substitute a new authorisation in its place.[119] The ACCC may also review an authorisation with a view to revoking it and substituting a new authorisation in its place in certain circumstances.[120]

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[112] Section 88(10).
[113] Section 88(6).
[114] Section 90(10A).
[115] Subsection 91A(1).
[116] Subsection 87ZD(1).
[117] Subsection 91B(1).
[118] Subsection 91B(3).
[119] Subsection 91C(1).
[120] Subsection 91C(3).