Draft Determination

Applications for authorisation

lodged by

Medicines Australia Limited

in respect of

Medicines Australia Code of Conduct
edition 17

Date: 26 October 2012

Authorisation numbers: A91316, A91317, A91318, A91319 & A91320

Commissioners: Sims
Rickard
Schaper
Court
Dimasi
Willett

Summary

The ACCC proposes to grant authorisation to Medicines Australia Limited for edition 17 of its Code of Conduct. Authorisation is proposed to be granted for three years.

Medicines Australia Limited (Medicines Australia) seeks authorisation for edition 17 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 17 of the Code incorporates amendments that are intended to:

- increase transparency around the interactions between pharmaceutical companies and healthcare professionals, third parties and patients – including requiring member companies to report on the sponsorship of healthcare professionals to attend or speak at educational meetings, and on any payments made to healthcare professionals to act on advisory boards or to provide consultancy services;

- increase the level of restriction on member companies regarding their interactions with healthcare professionals – including absolutely banning brand name reminders and the provision of prizes to healthcare professionals following competitions; and

- increase clarity regarding the application of the Code – for example, by removing separate Explanatory Notes to the Code and including those notes in the body of the Code's text.

A significant number of interested parties have identified areas where the Code could be further improved. These include: a proposal that pharmaceutical companies disclose on an individual level payments made to healthcare professionals (consistent with developments in the US); improving the accessibility of the complaints process; and providing the educational event reporting tables in a more accessible format (such as Microsoft Excel).

The ACCC accepts that the Code provides a framework for interactions between pharmaceutical companies and healthcare professionals and that the Code is likely to result in public benefits including protecting the general public from inappropriate advertising, setting consistent standards for medical and promotional material and providing for greater transparency around the relationships between pharmaceutical companies and healthcare professionals.

However, the ACCC considers that it is important that the Code continue to reflect community expectations about the level of transparency of relationships between the pharmaceutical industry and healthcare professionals. In this regard, the ACCC raised the issue of disclosing payments to individual healthcare professionals in its consideration of edition 16 of the Code in 2009. The ACCC notes that Medicines Australia has since convened a transparency working group, inviting participation from consumer, healthcare professional and pharmaceutical industry groups, which will look into ways that payments at an individual level can be disclosed appropriately. Medicines Australia advises that this working group will report by December 2013.

The ACCC also notes that the ability for the public to make complaints and access and utilise the reporting tables is an important feature of increasing the transparency around the relationship of the industry with healthcare professionals.

The ACCC is currently satisfied that the public benefits from edition 17 of the Code outweigh the public detriments. However, in order to ensure that the Code continues to meet community expectations the ACCC proposes to grant authorisation for only three years rather than the five years sought by Medicines Australia. During this authorisation period, Medicines Australia will be able to complete the work it has already commenced on the level of transparency provided by the Code and make any necessary changes to the Code.

The ACCC will seek further submissions in relation to this draft determination before making its final decision. Medicines Australia and interested parties may also request a pre-decision conference to be held to allow oral submissions on the draft determination.

Authorisation does not represent ACCC endorsement of a code. Rather, it provides statutory protection from court action for conduct that might otherwise raise concerns under the competition provisions of the *Competition and Consumer Act 2010*.

Contents

Abbreviations

ACCC	Australian Competition and Consumer Commission
AMA	Australian Medical Association
ARTG	Australian Register of Therapeutic Goods
CHF	Consumers Health Forum of Australia
Code Committee	Code of Conduct Committee
Commission	Trade Practices Commission
DHA	Department of Health and Ageing
FSM	Friends of Science and Medicine
GMiA	Generic Medicines industry Association of Australia
GSK	GlaxoSmithKline Australia Pty Ltd
Medicines Australia	Medicines Australia Limited
Monitoring Committee	Medicines Australia Monitoring Committee
MSD	Merck Sharp and Dohme (Australia) Pty Ltd
PBS	Pharmaceutical Benefits Scheme
PFP	product familiarisation program
Pharmacy Guild	Pharmacy Guild of Australia
Roche	Roche Products Pty Ltd
Sanofi	Sanofi-Aventus Australia Pty Ltd
Sunshine Act	US Physician Payment Sunshine Act (Patient Protection and Affordable Care Act)
TG Act	*Therapeutic Goods Act 1989*
TGA	Therapeutic Goods Administration
the Act	*Competition and Consumer Act 2010*
the Code	Medicines Australia Code of Conduct
Tribunal	Australian Competition Tribunal

The applications for authorisation

1. On 4 July 2012 Medicines Australia Limited (Medicines Australia) lodged an application for the revocation of authorisations A91150, A91155-A91156 and A91183-A91184 and the substitution of new authorisations A91316-A91320 for the ones revoked (collectively these applications will be referred to as the applications for authorisation).

2. Authorisation is a transparent process where the ACCC may grant protection from legal action for conduct that might otherwise breach the *Competition and Consumer Act 2010* (the Act). 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, inviting interested parties to lodge submissions outlining whether they support the application or not. Before making its final decision on an application for authorisation the ACCC must first issue a draft determination.[1]

The conduct

3. Medicines Australia has applied for authorisation of edition 17 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.

4. Medicines Australia submits that the amendments in edition 17 of the Code provide greater transparency around the sponsorship provided to healthcare professionals by pharmaceutical companies to attend educational events.

5. Medicines Australia submits that the key amendments in this regard are:

    - member companies will now be required to provide detailed information in the educational event reporting tables about the sponsorship of healthcare professionals to attend educational meetings held by third parties;

    - member companies will now be required to provide detailed information in the educational event reporting tables about the sponsorship of healthcare professionals to speak at educational meetings;

    - member companies will now be required to provide two separate reports on any payments made to healthcare professionals to act on advisory boards, and where healthcare professionals are engaged to provide other consulting services. The information to be disclosed will be made publicly available on the Medicines Australia website every six months; and

[1] See the ACCC's Guide to Authorisation (available from the ACCC website) for details about the authorisation process.

- in addition to publishing a list of health consumer organisations[2] to which financial support is provided, member companies must now also provide Medicines Australia with a report for publication on its website annually which specifies the aggregate value of that financial support.

6. Medicines Australia submits other key amendments are:

    - a total prohibition on the provision of brand name reminders to healthcare professionals;[3]

    - a total prohibition on the provision of prizes to healthcare professionals following a competition or quiz;

    - a new section which provides that companies must also include in the report to Medicines Australia on consultancies any payments made to consultants in relation to market research, with these reports to be published by Medicines Australia;

    - additional clarification as to the principles with which member companies must comply in relation to social media; and

    - the inclusion of a pharmacist representative on the Code of Conduct Committee (Code Committee) and Appeals Committee in relation to any complaints regarding the activities of, or materials directed to, the practice of pharmacy.

7. Medicines Australia seeks authorisation for five years.

Other parties

8. Medicines Australia seeks authorisation on behalf of current and future member companies of Medicines Australia. Under section 88(6) of the Act, 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.

The applicant

9. Medicines Australia represents the interests of the innovative medicines industry in Australia. Its member companies comprise 86% of the prescription pharmaceuticals market, and are engaged in the research, development,

[2] Medicines Australia submits that health consumer organisations are not-for-profit organisations that represent the interests and views of consumers of healthcare. They may range from small volunteer groups to large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.

[3] A brand name reminder is an item of low monetary value which is intended to remind healthcare professionals of the existence of a product. This may include medical items such as tongue depressors, anatomical models, surgical gloves or peak flow meters. It may also refer to non-medical items such as stationery items, pens, sticky notepads, mugs or clocks.

manufacture, supply and export of prescription medicines.[4] In particular Medicines Australia states that it represents the innovative medicines industry by:

- engaging with government and government departments, the Australian medicines industry, consumer groups and health professionals to develop health and industry policy;
- building and maintaining relationships with government for fair reimbursement of medicines (through the Pharmaceutical Benefits Scheme (PBS)) to ensure the continuation of a viable medicines industry;
- administering the Code which sets the standard for the ethical marketing and promotion of prescription medicines;
- working with other health professional and consumer organisations on issues of mutual concern;
- providing specialist advice to member companies; and
- educating the community about industry activities.[5]

10. Medicines Australia's membership is divided into 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.

11. Medicines Australia has 30 Class One members, six Class Two members, five Class Three members and 12 Class Four members. It is a condition of membership to any class to adhere to the Code in its entirety.

[4] Medicines Australia website, http://medicinesaustralia.com.au/about-us/. Accessed 4 September 2012.
[5] ibid.

Previous authorisations

12. The Medicines Australia Code was first introduced in 1960 and has undergone numerous revisions since that time. The ACCC has authorised several versions of the Code since 1977.

13. In 1977, the Trade Practices Commission (Commission) granted clearance[6] to the 4th edition of the Code pursuant to the then subsection 92 (2) of the *Trade Practices Act 1974* (C23698). On 1 July 1977, section 92 was repealed. Clearances granted under that section were deemed to be authorisations granted by the Commission.

14. In 2001, the Australian Pharmaceutical Manufacturers Association (now Medicines Australia) sought reauthorisation of the Code due to the possibility the numerous amendments to the Code since 1977 would not be covered by the existing authorisation. In 2003, the ACCC granted authorisation to Medicines Australia for edition 14 of the Code for three years.

15. In 2006, the ACCC granted conditional authorisation to Medicines Australia for its Code 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 (the Tribunal).[7] 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.

16. Most recently, in 2009 the ACCC granted authorisation to Medicines Australia for edition 16 of the Code for five years until 31 December 2014.[8] Edition 16 of the Code incorporated the conditions previously imposed by the Tribunal and the ACCC did not impose further conditions of authorisation.

Background

Prescription medicines

17. 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.

[6] From 1974 until 1977 businesses were able to apply to the Commission for 'clearance' of certain conduct. The Commission granted the clearance if the conduct did not have a significant effect on competition. The granting of a clearance deemed conduct not to be a breach of the *Trade Practices Act 1974*.

[7] 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*).

[8] Although Medicines Australia's existing authorisation does not expire until 2014, the current applications are to take account of amendments made to the Code between editions 16 and 17.

18. 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.[9] 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.

19. The TGA tests the quality, safety and efficacy of medicines and approves them before they can be supplied in Australia.[10] 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.[11] All prescription medicines must be registered or listed in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

20. 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.[12]

21. 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.

22. The price consumers pay for around 80% of the prescription medicines dispensed in Australia is subsidised by the Australian Government under the PBS.[13] For those medicines listed on the PBS, the consumer pays a base cost and the government subsidises the remainder of the cost.

23. The advertising of prescription medicines is subject to a number of requirements in the TG Act, as well as the Act and other relevant laws. The TG Act prohibits the promotion of prescription medicines to the general public. Promotion to healthcare professionals is allowed under the TG Act and is regulated by the self-regulatory scheme operated by Medicine Australia through its Code.

24. 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 in the relevant sections of Medicines Australia's Code.[14]

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[9] DHA TGA website, *Regulation basics*, http://www.tga.gov.au/industry/basics.htm; *How therapeutic goods are regulated in Australia*, http://www.tga.gov.au/about/tga-regulates-how.htm. Accessed 1 October 2012.
[10] DHA TGA website, *TGA Basics, Medicines regulation and the TGA*. Accessed 1 October 2012.
[11] See the TG Act**.**
[12] DHA TGA website, *Australian Regulatory Guidelines for Prescription Medicines*, June 2004, http://www.tga.gov.au/pdf/pm-argpm.pdf. Accessed 1 October 2012.
[13] DHA, *About the PBS*, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-faq.htm. Accessed 9 October 2012.
[14] TGA website, *Regulation of therapeutic goods advertising in Australia*, http://www.tga.gov.au/industry/advertising-regulation.htm. Accessed 4 October 2012.

25. 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 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

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

27. 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. Even once a patent has expired branded drugs tend to sell at a premium to generics, as consumers perceive the product as in some way superior.

28. In 2007-08 approximately 37% of prescriptions dispensed on the PBS were generic drugs.[15] Where there are two or more brands of the same drug listed on the PBS, each brand receives the same subsidy – up to the cost of the lowest priced brand which in many cases is a generic brand. A brand price premium paid by the consumer applies to the more expensive brand.[16]

29. Although membership of Medicines Australia is open to generic drug manufacturers, the majority are represented by the Generic Medicines industry Association of Australia (GMiA). GMiA members supply over 30% of all prescriptions dispensed under the PBS and manufacture 80% of all generic medicines dispensed in Australia.[17]

30. On 31 March 2010 the GMiA applied for authorisation of its Code of Practice (2nd edition) which includes provisions for taking disciplinary action against GMiA members who breach the GMiA Code of Practice.

31. On 3 November 2010 the ACCC issued a final determination granting authorisation subject to conditions for a period of three years. The conditions:

    - extended the educational event reporting requirements in the GMiA Code of Practice to all healthcare professionals (as defined in the GMiA Code of Practice) regardless of whether a healthcare professional prescribes prescription medicines or not;

[15] Victoria University Centre for Strategic Economic Studies, *The Impact of PBS reforms on PBS expenditure and savings,* Table 6.5, http://medicinesaustralia.com.au/files/2010/02/The-impact-of-PBS-reforms-on-PBS-expenditure-and-savings.pdf. Accessed 9 October 2012.
[16] 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 4 October 2012.
[17] GMiA website, *GMiA members contribute to growth and employment*, http://www.gmia.com.au/gmia_members_co.html**.** Accessed 4 October 2012.

- required the GMiA's members to report annually on the accumulated total cost of non-price benefits, other than more favourable trading terms, provided to pharmacists as well as listing the types of the non-price benefits involved.

Submissions received by the ACCC

32. The ACCC tests the claims made by the applicant in support of an application for authorisation through an open and transparent public consultation process.

33. The ACCC sought submissions from 118 interested parties potentially affected by the applications, including pharmaceutical companies, government agencies, hospitals, industry representative bodies, consumer organisations and academics. A summary of the public submissions received from Medicines Australia and interested parties follows.

Medicines Australia

34. Broadly, Medicines Australia submits that edition 17 of the Code incorporates new measures that will increase transparency and continue the trend of increasing the level of restriction on member companies regarding their interactions with healthcare professionals and increases clarity regarding the application of the Code.

Interested parties

Pharmaceutical companies

35. Roche Products Pty Ltd (Roche) endorses edition 17 of the Code and supports the move towards greater transparency within the pharmaceutical industry including the disclosure of aggregate support to institutions, doctors and health consumer organisations. In addition, Roche submits that disclosing the details of support received by individual healthcare professionals raises privacy, legal and security concerns. Roche notes that healthcare professionals may receive support from a number of sources and that transparency will only work when there is disclosure from all parties and not those limited to the pharmaceutical industry.

36. Merck Sharp and Dohme (Australia) Pty Ltd (MSD) supports the authorisation of edition 17 of the Code and the changes which provide for aggregate reporting of payments to doctors and consumer groups. MSD submits that some of its competitors are not subject to the Code and therefore will not be subject to the increasing transparency and compliance burdens that would result. MSD notes these burdens would be greater if the ACCC required Medicines Australia member companies to disclose payments made to individual healthcare professionals.

37. Sanofi-Aventus Australia Pty Ltd (Sanofi) submits that the changes proposed under edition 17 of the Code will provide greater transparency. Sanofi submits that it opposes disclosure at an individual level as it believes that it will have a negative impact on the quality and quantity of medical education undertaken in Australia. Sanofi also submits that individual disclosure is a breach of the *Privacy Act 1988*.

38. GlaxoSmithKline Australia Pty Ltd (GSK) supports the authorisation of edition 17 of the Code. GSK submits that it is a strong advocate for increased disclosure and notes that there is a widespread community expectation of increased transparency in commercial relationships between pharmaceutical companies and healthcare professionals. GSK notes that it is an advocate for individual payment disclosure but submits that this cannot be done in isolation. GSK submits that the inclusion of individual disclosure provisions in edition 17 of the Code would be premature without garnering the views of all parties affected, looking at the practicalities of disclosure and learning from the experiences of the Physician Payment Sunshine Act (Patient Protection and Affordable Care Act) (Sunshine Act) which is being introduced in the US.

Consumer groups

39. The ACCC received submissions from Choice, the Friends of Science and Medicine (FSM) and the Consumers Health Forum of Australia (CHF). All three organisations submit that:

    - the aggregate reporting measures do not provide a sufficient level of transparency and that individual reporting is required to enable sufficient public scrutiny; and

    - some companies have repeatedly breached the Code over the years and that this evidences that the present level of fines under the Code is not an effective deterrent.

40. Choice and the FSM submit that:

    - the monitoring of the effectiveness of the Code could be improved if Medicines Australia published its reporting data in a spread sheet format rather than its existing PDF format; and

    - the effectiveness of the Code could be improved through the addition of consumer and health professional representatives to the governing body that conducts the review of the Code every three years.

41. The FSM submits that:

    - the Code should contain transparent reporting of individual payments and gifts;

    - Medicines Australia has never monitored the behaviour of pharmaceutical representatives when interacting with health professionals, despite this activity representing a substantial proportion of promotional budget; and

- the Code should provide for random monitoring of drug representative compliance.

42. The CHF supports the additional requirements regarding social media, the increased transparency of company sponsorship of health consumer organisations, the transparency requirements around patient support programs and the explicit prohibition on accessing data from dispensary software systems.

43. The CHF submits that:

    - sponsors should be required to proactively engage with clinicians and the regulator regarding safety concerns during product familiarisation programs (PFPs) rather than relying on spontaneous reporting of adverse events; and

    - it has concerns relating to sections of the Code relating to patient support programs which permit companies to include information about the availability of a patient support program as an insert in the product package. The CHF considers that these inserts are arguably advertising material and could result in consumers disregarding other information contained in the package that is essential to the safe use of the medicine.

Industry associations

44. The Pharmacy Guild of Australia (Pharmacy Guild) supports the Code and submits that the revisions will further increase the effectiveness of the Code.

45. The Australian Medical Association (AMA) supports the reauthorisation of the Code, and supports changes which require aggregate reporting. The AMA submits that public reporting of pharmaceutical payments to individual medical practitioners does not inform the public about the nature of the interaction. The AMA submits that this may result in members of the public making incorrect judgements about the independence of medical practitioners.

46. The GMiA submits that amendments to the Code prohibiting the provision of brand name reminders to healthcare professionals will remove an important element of competition in the generic medicines market. The GMiA submits that brand name reminders are not used to induce prescribing, rather, they are regularly used by GMiA members to remind a pharmacist that there are substitutable (and often lower cost) generic medicines available. The GMiA submits that the amendment which prohibits brand name reminders be rejected, or in the alternative, not apply to the generic medicines market. The GMiA notes that the marketing and promotion of medicines by both members and non-members must comply with the Code.

Government departments

47. The ACT Health Directorate notes that the ACT adopts the Code, as authorised by the ACCC, by reference in local regulation. The ACT Health

Directorate did not make a submission in relation to the substance of the Code.

48. The Department of Health and Ageing (DHA) submits that a number of provisions in the Code require disclosure to the wrong Government body. The DHA also raises concerns that some of the consumer medicine information and product information provisions under the Code may, in certain circumstances, breach the TG Act.

49. The DHA also submits that the inclusion of a company's name or link to their website in any disease education program may be considered a 'de-facto' promotional activity. The DHA submits that Medicines Australia should develop a mechanism for de-identifying company references in such programs. The DHA also raises a number of concerns about the operation of patient support programs. The DHA also submits that the definition of 'promote' differs between the Code and the TG Act.

Healthcare professionals and academics

50. The ACCC received a number of submissions from healthcare professionals and academics. These included:

    - Associate Professor Ian Haines
    - Dr Jon Jureidini
    - Ray Moynihan
    - Bruce Arnold
    - Dr Agnes Vitry
    - Gavin Mooney
    - Professor Phillip Morris
    - Professor Anthony Smith
    - David Meller
    - Dr Robert Purssey
    - Dr Paul Atkins
    - Professor Thomas Faunce
    - Chris Del Mar
    - An interested party.

51. All these submissions indicated support for full disclosure of individual payments and gifts to health professionals from pharmaceutical companies.

52. A number of these parties also suggested that the ACCC should consider imposing a condition that the maximum fine under the Code be increased to $1 million in order to strengthen the effectiveness of the Code.

53. Dr Purssey, Dr Atkins and an interested party submit that the effectiveness of the Code could be improved if Medicines Australia published its reporting data in a more searchable format.

54. An interested party submits that the complaints process under the Code is ineffective as it relies too heavily on the complainant and lacks elements of procedural fairness.

55. Dr Vitry submits that PFPs should be banned under the Code on the basis that they can lead to a very rapid intake of new drugs whose safety is very uncertain. Dr Vitry also submits that patient support programs should be prohibited under the Code.

56. Dr Vitry also submits that the provision of educational information to the general public by drug companies should not be allowed under the Code because of inherent conflicts of interest. Dr Vitry further submits that unbranded product advertising and the use of pseudo branding or similar techniques should be explicitly prohibited.

Members of the public

57. The ACCC received a submission from Glenys Nall which advocated for greater regulation of the pharmaceutical industry.

58. The ACCC also received a submission from an interested party (who is a participant in the pharmaceutical industry) who submits that the current system of self-regulation does not act as an adequate incentive for member companies to operate within the Code and that companies continue to breach the Code. The interested party also submits that companies should be restricted to sponsoring a healthcare professional once in a 24 month period, that healthcare professionals serving on the TGA or relevant committees should not be sponsored, and limits should be placed on sponsorship of healthcare professionals travelling to attend meetings.

Submissions from Medicines Australia in response to interested parties

59. Medicines Australia submits in response to the interested party submissions that:

    - it is not necessary to increase the quantum of fines. Medicines Australia submits that fines under the Code remain substantially higher than those in similar industry codes, that the effectiveness of the Code's sanctions in providing a deterrent effect is demonstrated by the increased level of compliance with the Code and that the TG Act provides for additional penalties (including fines and imprisonment) that can be imposed on pharmaceutical companies and individuals who contravene the provisions of the TG Act;

- it is not appropriate to require member companies to report on the sponsorship of individual doctors by name. Medicines Australia submits that it has already taken considerable steps to increase transparency, that it is committed to increasing transparency further and that there has been implementation issues in other jurisdictions which have required individual disclosure;

- there is already consumer and healthcare professional representation on the three Code committees;

- prohibiting brand name reminders will not reduce the level of competition between pharmaceutical companies since there are other avenues available to members to promote their products;

- an effective voluntary code that complements and extends beyond the reach of statutory regulation is of significant public benefit; and

- the proposed patient support program section of the Code does not require amendment, aside from the minor wording amendment suggested by the DHA. Medicines Australia has provided an amended version of the Code to incorporate this change.

ACCC evaluation

60. The ACCC's evaluation of the proposed edition 17 of the Code is in accordance with the relevant net public benefit tests[18] contained in the Act. While there is some variation in the language of the tests, in broad terms, the ACCC is required to identify and assess the likely public benefits and detriments, including those constituted by any lessening of competition, and weigh the two. In broad terms, the ACCC may grant authorisation if it is satisfied that the benefit to the public would outweigh the public detriments.

61. In order to measure and assess the effect of the Code and the public benefits and detriments likely to result the ACCC identifies the relevant areas of competition and the likely counterfactual which will apply in the future should authorisation not be granted.

The relevant area of competition

62. Medicines Australia submits the relevant market is the market for prescription medicines in Australia. No interested party made submissions on the appropriate area of competition that the ACCC should consider.

63. The ACCC does not accept that all prescription medicines are substitutable for one another and, depending on the nature of the conduct, considers that there are likely to be individual product markets for different types and/or classes of drugs. However, the ACCC does not consider that a precise definition of the market is necessary for the assessment of the Code. The ACCC notes that

[18] Sections 90(6), 90(7), 90(5A) and 90(5B), 90(8). The relevant tests are set out in full at Attachment A.

the Code regulates the activities surrounding the promotion of prescription products on an industry-wide basis across all classes of prescription medicines.

64. The ACCC recognises that the prescription medicines industry is subject to 'market failures' which are common to many parts of the health sector:

    - The principal agent problem – the patient (principal) engages a healthcare professional (agent) because the patient does not have the expert knowledge required to diagnose and treat their condition. To the extent that the objectives of the patient and the healthcare professional differ, market failure may occur because the patient is unable to properly observe or evaluate the healthcare professional's actions owing to the information asymmetry between them.

    - Information asymmetry – exists in markets where one party in a transaction knows a material fact that the other does not. Given the complexity of the relevant products, Medicines Australia's members may have the ability and incentive to engage in opportunistic behaviour such as misrepresenting or withholding facts from healthcare professionals, third parties and patients.

    - Bounded rationality – some healthcare professionals and patients may lack the training and capacity to understand all the relevant information held by pharmaceutical companies. Even those healthcare professionals with relevant training may be time poor and unable to process the relevant information comprehensively. Given the complex nature of the relevant products, Medicines Australia's members may have the incentive and ability to engage in various practices that exploit the bounded rationality of patients, healthcare professionals and other third parties.

65. To address the potential for market failures, it appears necessary to regulate the marketing of pharmaceuticals and the relationship between pharmaceutical companies and healthcare professionals.

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

    - The sale of prescription medicines is dependent 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 professional's expertise and judgement to prescribe the medicine most appropriate to them.

    - Advertising of prescription medicines to members of the public is prohibited by law.

    - Subject to those elements of specific and general Commonwealth laws, 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 PBS regulates 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 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 future with and without test

67. The ACCC applies a 'future with-and-without test' to identify and weigh the public benefit and public detriment generated by conduct for which authorisation has been sought.[19]

68. Under this test, the ACCC compares the public benefit and anti-competitive detriment generated by arrangements in the future if the authorisation is granted with those generated if the authorisation is not granted.

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

70. The ACCC considers that the most likely counterfactual in the absence of authorisation is that edition 17 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 statutory protection from legal action under the Act.

71. Therefore, in the counterfactual, edition 16 of the Code would continue to operate until the authorisation currently in place expires on 31 December 2014. Beyond this date, it may be that some form of the Code that did not give rise to a potential breach of the Act would operate, but 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.

72. Existing legislation in the Act, the TG Act and relevant state and territory fair trading legislation extends only to the advertising and promotion of

[19] *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.

pharmaceutical products to healthcare 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. 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 (and doctors) would break out of that culture, and the conferring of benefits may take new and more subtle forms.

Public benefit

73. Public benefit is not defined in the Act. 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.[20]

74. Medicines Australia submits that edition 17 of the Code gives rise to public benefits by:

- incorporating new measures that will increase transparency surrounding the interactions between member companies and healthcare professionals, third parties, and patients. Medicines Australia submits these measures include:
    - a requirement for member companies to report on the sponsorship of healthcare professionals to attend or speak at educational meetings, including the total amount paid for such sponsorship. This information will be published by Medicines Australia on its website;
    - a requirement for member companies to report on any payments made to healthcare professionals to act on advisory boards. This information will be published by Medicines Australia on its website;
    - a requirement for member companies to report on any payments made to healthcare professionals to provide consulting services. This information will be published by Medicines Australia on its website;
    - in addition to publishing a list of health consumer organisations to which member companies provide financial support, companies will be required to also specify the value of that financial support. This information will be published by Medicines Australia on its website; and

[20] *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.

- additional requirements for member companies implementing patient support programs, including a requirement that any payments to healthcare professionals for work done in relation to such programs be disclosed to a patient in writing prior to his or her enrolment in the program;

- continuing the trend of increasing the level of restriction on member companies regarding their interactions with healthcare professionals. Amendments in edition 17 of the Code include further limiting advertising by member companies by absolutely banning brand name reminders and the provision of prizes to healthcare professionals following competitions; and

- increasing clarity regarding the application of the Code by, for example, removing the separate Explanatory Notes to the Code and including those notes in the body of the Code's text. This ensures that those notes are given prominence in the Code and the prescriptive force of Code provisions, while also creating an edition of the Code that is clear, unambiguous and easy to understand.

75. The ACCC's assessment of the likely public benefits from the proposed conduct follows.

Protection of public from inappropriate advertising

76. Medicines Australia submits that the Code contains an overarching general principle that pharmaceutical companies cannot promote to the general public. Medicines Australia submits that edition 17 of the Code strengthens the implementation of this principle because of:

    - new requirements specifying that the purpose of interactions with lay media must be to enhance the quality use of medicines and to provide current, accurate and balanced information about prescription products;

    - new requirements which require companies to fully brief independent spokespeople (if they have been asked by the company to speak to the media) on the requirements of the Code and in particular the prohibition on direct to consumer advertising. Companies must be able to produce documentary evidence of this briefing and its contents, which can be publicly disclosed if required;

    - a new requirement which states that when the initial approach is made to participants "it must be clear to a participant that the market research is being conducted by or on behalf of a pharmaceutical company", but the name of the company need not be disclosed in recognition that this may bias the research; and

    - amendments to patient aid regulations which require that the content of such material must be designed to assist with patient education, compliance and the quality use of medicines, by providing information which clarifies, for example, dose, timing and methods of administration, precautions, special instructions and similar information.

77. The ACCC has previously accepted 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. 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.

78. The ACCC considers that this is likely to continue and accepts that strengthening the Code in the manner outlined above further facilitates protection of the public from inappropriate advertising and thus constitutes a public benefit.

Standards for medical and promotional claims

79. Medicines Australia submits that the Code ensures a high, consistent and industry-specific standard for medical and promotional claims. This includes which form of product information must accompany or be included within promotional material, and how such information is presented. Medicines Australia notes that 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 and minimum product information[21] and the circumstances in which each must be used; and

    - 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.

80. Medicines Australia submits that edition 17 of the Code contains additional provisions which aim to strengthen these standards, including:

    - additional information and data requirements for member companies to substantiate or support a medical or promotional claim;

    - additional requirements around the provision of information around unapproved products;

    - additional requirements for companies sponsoring healthcare professionals to speak at an educational event to be familiar with the product they are promoting;

    - requirements about when a product can be described as ‘new’;

[21] Medicines Australia submits that ‘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 ('grandfathered product') the document registered is known 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 a minimum product information.

- additional requirements about comparative statements;
- clarifying the types and content of product information that must be included with promotional material directed at healthcare professionals; and
- additional requirements around minimum product information.

81. The Tribunal has previously found there was substantial public benefit in the provisions which set standards for medical and promotional claims. The ACCC has previously agreed 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.

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

83. For this reason the ACCC considers that it is likely that the strengthening of the Code in this regard will continue to give rise to public benefits.

Relationships between pharmaceutical companies and health consumer organisations and third parties

Health consumer organisations

84. Medicines Australia submits that the Code currently regulates the relationship between member companies and health consumer organisations. Medicines Australia submits that the Code has been amended in edition 17 to further strengthen the transparency associated with these relationships. Medicines Australia submits that relationships between health consumer organisations and companies should involve the following components:
    - respect for independence;
    - achieving and maintaining public trust;
    - fairness;
    - openness and transparency; and
    - accountability.

85. Medicines Australia submits that edition 17 of the Code has introduced new amendments which strengthen the existing provisions through the requirement that each pharmaceutical company must make available on its website a list of health consumer organisations to which it provides direct financial support and/or significant direct/indirect non-financial support, and the nature of that support. Member companies must make available for public reporting:

    - the name of the health consumer organisation;
    - a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support; and
    - the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.

86. The report must be submitted to Medicines Australia by 30 April 2014 and cover activities commenced on or after 1 January 2013 or ongoing on that date. Thereafter, the report must be provided to Medicines Australia on an annual basis by 30 April each year covering the previous calendar year. The timing of these reports is designed to align the date of submission and publication of all required reports.

87. The ACCC has previously considered that these provisions provide transparency around the relationships between pharmaceutical companies and health consumer organisations and will help reduce the potential for conflicts of interest that may arise when pharmaceutical companies enter into relationships with health consumer organisations and fund their activities.

88. The ACCC considers that the reporting requirements included in edition 17 of the Code provide additional transparency. The ACCC considers this constitutes a public benefit.

Patient support programs

89. Medicines Australia submits that edition 17 of the Code has introduced a new section that relates to patient support programs. This section provides that:

    - a patient support program is a company developed program that is intended to assist patients in gaining benefit from their medical treatment, to improve health outcomes and promote the quality use of medicines;
    - patient support programs may only be offered to patients who have already been prescribed a prescription only product;
    - the healthcare and wellbeing of patients must be the primary objective of a patient support program;
    - the obligation to be open and transparent about the conduct and management of a patient support program is also central; and

- this obligation is the basis for the requirement to communicate to patients about any payments that are made to a healthcare professional in association with a patient support program.

90. Medicines Australia advises that the patient support program section also now confirms that any information provided to patients may be product specific, but may not be promotional. Medicines Australia notes that the section has also been amended so that companies:

    - must develop a rationale for each patient support program (amended from "should" develop in edition 16); and

    - must ensure compliance with a set of requirements if they are considering being involved in a patient support program (amended from "should" develop in edition 16).

91. Medicines Australia also notes that the requirements of edition 17 of the Code now provide that:

    - if a company provides, or offers to provide any payment to a healthcare professional in return for work undertaken in such programs (including administrative work) associated with enrolling a patient in the program, this payment (including its amount and scope) must be disclosed to the patient in writing prior to their involvement in the program;

    - any payment for the work undertaken by the healthcare professional must be commensurate with the work undertaken and should not be capable of influencing, or intended to influence, the prescribing or dispensing of a specific prescription product;

    - information provided to patients must inform the patient that they may opt out of the program at any time, who will be holding any details disclosed in the enrolment form and what those details will be used for;

    - the information provided to patients prior to their enrolment must include balanced, accurate and correct information about the potential risks of the medicine;

    - the consumer medicine information document for the medicine must be given to the patient prior to their enrolment, or must be one of the first documents provided to a patient following their enrolment in the program; and

    - the data collected from these programs must not be used for any purpose other than to increase positive health outcomes and never for promotional activities, although individual patient data may be collected in a de-identified manner for the purpose of safety monitoring.

92. Medicines Australia submits that the TGA has agreed that a patient enrolment form for a patient support program may be included within a medicine package as long as it complies with the prohibition on promotion to consumers and states that the patient support program is not authorised or approved by the TGA.

93. The DHA submits that patient support programs could be used as brand promotion late in the patient cycle to support/develop ongoing patient preference for innovator medicine in the face of generic competition. The DHA submits that Medicines Australia should have suitable criteria for these programs in the Code which would identify whether they could be considered of a promotional nature.

94. The DHA submits that some provisions in the Code could allow for the promotion of medicines via wording that is not as strong as in previous editions of the Code. The DHA cites statements such as "The healthcare and wellbeing of patients must be the primary objective of a Patient Support Program". The DHA notes this could allow promotion as a secondary objective of the company. The DHA submits that if the statement were strengthened to read "The healthcare and wellbeing of patients must be the only objective of a Patient Support Program" there could be no misinterpretation.

95. The DHA also submits that there should be consideration as to whether verbal disclosure to the patient of payments to healthcare professionals should be required prior to the patient enrolling in the program, to ensure this information is fully disclosed. The DHA further submits that these payments should be included in reporting by pharmaceutical companies.

96. The DHA notes that the statement in the Code "no incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs" appears to inadvertently exclude services and products from being able to be provided (e.g. telephone support, pedometer, blood glucose monitor).

97. The DHA also submits that the Code should reflect that all information provided in relation to patient support programs should be balanced, accurate and correct and not just information relating to the potential risks of the medicine.

98. The DHA notes that the consumer medicine information document provided to the patient must be the same version published on the TGA website, otherwise it would be considered promotional.

99. The DHA submits that the collection of data must be in accordance with the TG Act and privacy legislation.

100. Dr Vitry submits that the development of industry supported patient support programs has blurred the boundaries between drug promotion and health information. Dr Vitry notes that if patients are to be able to make informed choices about their health, there needs to be a clear distinction between information and promotion.

101. Dr Vitry notes that most patient support programs aim to improve treatment compliance; that is the notion that a patient follows a treatment prescribed by a doctor or recommended by a pharmacist. Dr Vitry notes that a patient may have good reasons for stopping treatment, because of adverse effects or inefficacy. Dr Vitry submits that the role of pharmaceutical companies in this area is inevitably compromised because of their inherent conflicts of interest.

102. Dr Vitry submits that recommendations on compliance with treatment must be independent of companies that have a financial incentive to keep patients

compliant. Independent medicine information should be provided to consumers by health professionals, doctors, pharmacists and organisations such as the National Prescribing Service.

103. The CHF expressed support for the amendments to the provisions surrounding patient support programs.

104. The CHF however questioned the appropriateness of including information on patient support programs, including information about the availability of programs and instructions on how to enrol, as pack inserts into product (medication) packages. The CHF notes that the TGA is currently reviewing the practice of pack inserts. The CHF submits that the inclusion of additional information, such as patient support program information, may result in consumers disregarding other information contained in the package that is essential to the safe use of the medicines.

105. Medicines Australia submits in response to the interested party submissions that the amendments under edition 17 of the Code provide an increased level of transparency and that the Code provides stringent procedural and disclosure requirements in relation to such programs and contains suitable criteria in order to ensure that such programs are not promotional.

106. Medicines Australia also submits that the Code regulates the activities of member companies, not the activities of healthcare professionals. Medicines Australia notes that it cannot require pharmacists to disclose to patients verbally any payments that the healthcare professional may receive in association with administering these programs. Medicines Australia submits that the Code requires member companies to disclose any payments made to a healthcare professional prior to a patient's enrolment in the program.

107. Medicines Australia has amended the section about patient support programs to reflect the change suggested by the DHA to read that the information "must include balanced, accurate and correct information, *including* about the potential risks of the medicine".

108. The ACCC notes that the Code requires that any material, including consumer medicine information, that is provided to the patient must not be promotional (where promotional means a statement about the positive attributes of a product which go beyond a simple non-qualitative or quantitative description).

109. Medicines Australia also submits in response to the CHF submission that the TGA has agreed that a patient enrolment form for a patient support program may be included within a medicine package so long as it complies with the prohibition on promotion to consumers and states that the patient support program is not authorised or approved by the TGA. The Medicines Australia Monitoring Committee (Monitoring Committee) also intends to review these enrolment forms during one of its regular reviews of the activities of member companies.

110. The ACCC considers that the Code recognises that patient support programs may assist patients to understand their condition and better manage their health, or encourage adherence to the medicines they have been prescribed.

111. The ACCC accepts that the Code does regulate the way in which Medicines Australia members operate patient support programs, and encourages

compliance with the legislative prohibitions on advertising to the public. The ACCC accepts that these constitute public benefits that would not be realised absent authorisation.

112. The ACCC does, however, consider it essential that Medicines Australia members ensure that the boundaries between activities that aim to inform consumers and direct-to-consumer advertising do not become blurred and acknowledge interested party concerns to this effect.

113. The ACCC encourages Medicines Australia to consider further the potential for patient support programs to be viewed as promotional rather than educational and continue to work with industry to develop provisions which address the concerns which remain about the potential for the boundaries between the provision of information and the promotion of medicine to be blurred. The ACCC notes that Medicines Australia must carry out a review of the provisions of the Code no later than every three years. Medicines Australia should review the provisions relating to patient support programs at this time.

Relationships between pharmaceutical companies and healthcare professionals

Reporting requirements of pharmaceutical companies regarding their interactions with healthcare professionals

114. Medicines Australia submits that edition 17 of the Code strengthens considerably the reporting requirements of members regarding their interactions with healthcare professionals and the transparency of those interactions.

115. Medicines Australia advises that edition 17 of the Code contains new reporting requirements for events held on or after 1 January 2013. The educational event reporting table which member companies already complete must now also include:

- details of sponsorships of healthcare professionals or non-healthcare professionals to attend any educational event. Sponsorship in this context includes registration fees, costs of accommodation and travel related expenses. The information which must be disclosed is the total amount paid for each educational event or meeting in respect of all recipients of sponsorship and the total number of recipients; and

- details of any payments made to speakers to attend and give a presentation at an educational meeting. The details of payments for speakers include any honorarium, registration fees, costs of accommodation and travel related expenses. The information which must be disclosed is the total amount paid to speakers for each educational event or meeting in respect of all speakers and the total number of speakers receiving payments.

116. Medicines Australia advises that it will make publicly available on its website the completed table provided by each member company within three months of the end of each reporting period. The first report in which this information must be disclosed includes the period 1 January 2013 to 31 March 2013,

which member companies must submit to Medicines Australia by 30 April 2013 for publication.

117. Medicines Australia also advises that edition 17 of the Code will require member companies to report on payments made to healthcare professional consultants and advisory board members.

118. Each member company must provide reports to Medicines Australia on all fees paid to healthcare professional consultants and advisory board members by completing the tables provided at Appendices 4 and 5 to the Code and submitting them to Medicines Australia. Medicines Australia will make the tables publicly available on its website within three months of the end of each reporting period.

119. MSD, Roche, GSK, Sanofi and the AMA all support the increased aggregate reporting measures.

120. 17 interested parties consider that the proposed aggregate reporting measures do not provide a sufficient level of transparency and that individual reporting is required to enable sufficient public scrutiny. A number of these parties submit that individual disclosure should be a condition of authorisation.

121. Choice notes that the proposed aggregate reporting measures fall short of the full disclosure of payments made to individual healthcare professionals which many consumer and health professional groups argued for in edition 16 of the Code.

122. A number of interested parties also submit that pharmaceutical companies have become more comfortable with individual disclosure because of the impending introduction of the US Physician Payment Sunshine Act which requires from 2013 that pharmaceutical companies disclose on an individual level payments made to healthcare professionals.

123. The ACCC notes in this regard that in submissions to the Medicines Australia 2011/2012 review of the Code:[22]

- Eli Lilly supported individual disclosure, provided it had the consent of the healthcare professional;

- Pfizer Inc supported disclosure on an individual level of payments made to healthcare professionals; and

- AstraZeneca Pty Ltd stated that it does not believe that continuing the current practice of sponsoring healthcare professionals, including the provision of disclosure, will address public perception that sponsorship acts as an inducement to a healthcare professional to prescribe or recommend the use of a particular product. AstraZeneca Pty Ltd also considered that disclosure of sponsorships has the potential to highlight this area and damage the industry's reputation.

[22] Medicines Australia, *Submissions to 2011/2012 Code Review*, http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-review/submissions-to-20112012-code-review/. Accessed 4 October 2012.

124. The ACCC also notes that a Galaxy Research Survey commissioned by GSK[23] found that there is widespread scepticism and little support for the current system in which pharmaceutical companies pay undisclosed fees to healthcare professionals and that nine in ten Australians have some concerns about pharmaceutical companies paying fees to healthcare professionals, with the biggest concern being the potential for the payments to influence the advice that doctors give to patients.

125. The Galaxy Research Survey found that 65% of Australians would prefer that pharmaceutical companies disclose each and every individual sponsorship of doctors and specialists.[24]

126. GSK itself submits that it is an advocate for individual payment disclosure but that it cannot be implemented in isolation. GSK submits that the inclusion of individual disclosure provisions in edition 17 of the Code would be premature without garnering the views of all parties affected, looking at the practicalities of disclosure and learning from the experiences of the Physician Payment Sunshine Act which is being introduced in the US.

127. The ACCC notes that a number of interested parties oppose disclosure on an individual level.

128. The AMA submits that public reporting of pharmaceutical payments to individual medical practitioners does not inform the public about the nature of the interaction and may result in the public making incorrect judgements about the independence of medical practitioners.

129. Sanofi submits that it opposes disclosure at an individual level as it believes that it will have a negative impact on the quality and quantity of medical education undertaken in Australia. Sanofi also submits that individual disclosure is a breach of the *Privacy Act 1988*.

130. Roche and MSD submit that there are a number of privacy, legal and security concerns around disclosing the details of support which individual healthcare professionals receive.

131. In response to interested party submissions, Medicines Australia submits that:

- it has already taken considerable steps to increase transparency and that the reporting requirements represent a significant change from edition 16 of the Code and serve to increase the existing public benefits associated with the Code;

- interested parties who suggest that edition 17 of the Code should be amended to reflect disclosure requirements contained in the US Physician Payment Sunshine Act do not take account of the significant

[23] A sample of 1007 Australians aged between 18 and 64 years took the online survey which asked for the respondents' views about the fees paid to healthcare professionals by pharmaceutical companies.

[24] GSK, *Australians seek greater clarity on payments to doctors*, Media release, 10 February 2012, http://www.gsk.com.au/resources.ashx/MediaCentreChildDataAssociatedDownloads/230/File/441CC93E300C7B69F93AE81693B88070/FINAL_M-Rel_sponsorship_survey_FinalMR.pdf. Accessed 10 October 2012.

implementation problems and subsequent delays associated with the implementation of that Act in the US. Medicines Australia also submits that interested parties do not take into account the fact that alternative transparency models (such as healthcare professional based approaches) are available and should be assessed for relevance to Australia;

- there has been particular concern in the US around the formulation of the rules surrounding disclosure requirements. Medicines Australia notes that the final rules are yet to be published;

- it has established a transparency working group which will focus on how to implement the most effective transparency model in Australia, while avoiding the problems experienced internationally in relation to certain transparency models.

132. Medicines Australia submits that it is not appropriate to amend edition 17 of the Code to require member companies to report on the sponsorship of individual doctors by name. Medicines Australia considers that the most effective way to ensure that this issue is addressed effectively is to engage in a thorough, detailed process of stakeholder consultation before simply adopting one particular transparency model.

133. In authorising edition 16 of the Code in 2009, the ACCC noted:

> ...there is likely to be merit in providing greater transparency around the sponsorship provided to healthcare professionals by pharmaceutical companies to attend educational events. However more work is needed to be done to address the issues such as privacy and the effects of greater transparency on a range of stakeholders.
>
> The ACCC encourages industry and Medicines Australia to consider these issues with respect to the disclosure and transparency of such sponsorship.

134. The ACCC remains of the view that there is merit in providing greater transparency around the sponsorship provided to healthcare professionals by pharmaceutical companies to attend educational events. The ACCC considers that there is growing community expectation that such payments will be disclosed, which is reflected in developments such as the introduction of the US Physician Payment Sunshine Act.

135. The ACCC acknowledges that Medicines Australia has included new aggregate reporting requirements in edition 17 of the Code, and that these represent an improvement over edition 16. The ACCC accepts that these reporting measures result in public benefits that would not be available in the absence of authorisation of the Code.

136. However, the ACCC considers that these benefits may be undermined if the Code were to depart too widely from community expectations. The ACCC considers that the effectiveness of voluntary codes is enhanced when the standards incorporated are meeting identified objectives and current community expectations. The ACCC notes that the Code explicitly states that "therapeutic industry codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which

they engage, the effectiveness of which is assessed through the eyes of the relevant community".[25]

137. Accordingly, the ACCC encourages Medicines Australia to consider ways in which the Code can continue to reflect community expectations about the level of transparency on relationships between the pharmaceutical industry and healthcare professionals.

138. The ACCC notes that Medicines Australia has announced a transparency working group which "will develop new measures to increase transparency of pharmaceutical company payments to healthcare professionals". The terms of reference of the working group provide that it will provide a final report by December 2013. The ACCC encourages Medicines Australia to prioritise the issue of individual disclosure as a matter to be considered by the working group and looks forward to receipt of the final report.

Promotional material directed at healthcare professionals

139. Medicines Australia submits that edition 17 of the Code will strengthen the provisions which aim to regulate effectively other interactions between member companies and healthcare professionals. Medicines Australia submits that amendments in relation to promotional material include:

- requiring that all printed promotional material directed at healthcare professionals and digital forms of promotional material must specify the date that the material was prepared or last revised;
- requiring all social media activities or interactions directed at healthcare professionals to comply with the Code;
- the prohibition of brand name reminders to healthcare professionals;
- the prohibition on the provision of competitions which include the provision of a prize to healthcare professionals;
- the Explanatory Notes relating to relationships with healthcare professionals have been moved into the main body of the text.

140. The ACCC has recognised in authorising previous editions of the Code that limiting brand name reminders to healthcare professionals may provide public benefits. The ACCC notes that edition 17 of the Code prohibits all brand name reminders. The ACCC considers that this may result in increased public benefits in the form of reducing inducements for healthcare professionals to prescribe various drugs.

141. The ACCC notes that the GMiA opposes the prohibition of brand name reminders. This is discussed in more detail under public detriments.

[25] Medicines Australia Code, introduction, page 6.

Market research with healthcare professionals

142. Medicines Australia submits that amendments in edition 17 of the Code in relation to market research include:

- clarifying that market research may be undertaken about an unapproved product or indication but that market research must not be used as a means to promote an unapproved product or indication;
- requiring that it must be clear that the market research is being conducted on behalf of a pharmaceutical company. The name of the company is not required to be disclosed to participants in market research in recognition of the potential for this to bias the research;
- noting that companies must make publicly available details of payments made to healthcare professional consultants in relation to market research.

Product Familiarisation Programs (PFPs)

143. Medicines Australia defines a PFP as a program run by a pharmaceutical company with the aim of allowing the medical profession to evaluate and become familiar with the product following TGA approval and/or approval of new indications. Healthcare professionals enrol patients in a PFP who are then supplied with the product for a fixed period.

144. Medicines Australia submits that amendments in edition 17 of the Code in relation to PFPs include:

- additional specificity as to when a PFP can be used. Specifically, the Code now provides that only one PFP may be conducted for a particular indication;
- requiring that starter packs in hospitals comply with individual hospital requirements;
- prohibiting trade packs being supplied with PFPs, bringing the Code in line with relevant state based legislation;
- the enrolment period for patients into the PFP must not exceed six months. At the expiry of the enrolment period companies may extend the period of enrolment where there is a strong clinical rationale for such an extension;
- a number of requirements on company representatives to: be aware of individual institutional requirements for PFPs in specific hospitals, particularly the requirements for management and distribution of the product within the institution; and be familiar with and comply with the requirements of the Council of Australian Therapeutic Advisory Groups - Guiding Principles for Medication Access Programs in Australian public hospitals when undertaking a PFP in a public health institution;
- prohibiting conducting PFPs for controlled drugs due to the requirements of State and Territory legislation;

- providing that no personal details of patients or individual patient data may be collected in a PFP;

- noting that when justified by clinical need, two or more starter packs may be combined in a package with patient education documents which explain that the product is provided under a PFP for a fixed period, after which it may only be available on a private prescription if not reimbursed under the PBS.

145. The DHA notes that the Code requires that a company make available the rationale for a PFP without delay but in any event in no longer than ten working days. The DHA submits that it is unclear what event triggers the ten working days.

146. Dr Vitry submits that there is evidence that information provided by the pharmaceutical industry is often unbalanced and biased. Dr Vitry cites the example of a PFP currently being run by Boeringer Ingelheim, the manufacturer of dabigatran (Pradaxa). Dr Vitry submits that specialists and GPs in Australia have been proposed to enrol up to ten patients each in this PFP.

147. Dr Vitry submits that this PFP is misleading and dangerous as, according to the National Prescribing Service "safety and efficacy warnings were seriously understated by the manufacturer", " the majority of hospitals were unaware and ill equipped to manage patients presenting who were receiving this treatment", and that "most prescribing and dispensing systems carried inaccurate information".

148. Dr Vitry further submits that PFPs can have disastrous consequences in terms of public health and increased numbers of severe and fatal adverse reactions. Dr Vitry notes that they can lead to a very rapid intake of new drugs whose safety is still very uncertain and aim to induce swapping from older drugs without medical need but with potential safety issues.

149. Dr Vitry submits that in the absence of any demonstrated advantage of PFPs for patients and with evidence of harm, PFPs should be banned.

150. The CHF submits that it should be a requirement that any information regarding adverse events which occur during PFPs be made available to the regulator and to clinicians. The CHF submits that sponsors should be required to proactively engage with clinicians and the regulator regarding safety concerns during PFPs rather than relying on the spontaneous reporting of adverse events.

151. Medicines Australia in response to interested party submissions submits that edition 17 of the Code has been amended to introduce additional specificity as to when a PFP can be used and these amendments further strengthen the Code's effectiveness. Medicines Australia further submits that it does not consider that the Code requires additional amendments at this stage.

152. Medicines Australia submits that it will confirm in the Code of Conduct Guidelines that the rationale for a PFP must be provided to a party within ten working days from the date a copy of the rationale is requested.

153. The ACCC notes the concerns of interested parties about the impacts of PFPs. However, the ACCC accepts that absent the Code, pharmaceutical companies would be free to interact with healthcare professionals and patients through PFPs without any form of regulation. As a consequence, the ACCC accepts that there are some public benefits arising from the regulation of PFPs under the Code. The ACCC encourages Medicines Australia to assess the use of PFPs during the next review of the Code.

ACCC conclusion on relationships between pharmaceutical companies and healthcare professionals

154. Ultimately, the ACCC considers that providing a framework for appropriate relationships between pharmaceutical companies and healthcare professionals helps to address the principal-agent problem and the scope for the prescribing practices of healthcare 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.

155. However, as noted above, the ACCC is concerned that the Code reflect community expectations about the level of transparency provided under the Code and looks forward to receipt of Medicines Australia's further work on this.

The requirement that pharmaceutical companies have an internal compliance procedure promoting compliance by all company employees

156. Medicines Australia submits the Code specifically provides for member companies to implement internal training and compliance procedures to ensure compliance with the Code and to make sure their staff are appropriately trained.

157. Medicines Australia submits that edition 17 of the Code strengthens these internal compliance procedures by:

- requiring all medical representatives entering the Australian prescription pharmaceutical industry for the first time to enrol in the Code of Conduct component of the endorsed Medicines Australia education program within their first six months of employment. Medicines Australia submits that field based medical personnel must comply with those provisions;

- reinforcing the recommendation that compliance with the Code form part of the overall performance assessment of company representatives by moving this recommendation from the Explanatory Notes into the body of section 5.2.

158. 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 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.

Effectiveness of the Code

159. In its review of previous editions of the Code, the ACCC has noted that any public benefits will only arise to the extent that the Code is effective in its operation.

160. In relation to edition 17 of the Code, interested parties have raised particular concerns about:

- the level of fines, with some interested parties submitting that they should be increased further;
- the format of current reporting measures not allowing for sufficient scrutiny; and
- how the Code could be more effective if it included a consumer and a health professional representative on the governing body that conducts the review of the Code every three years.

Effectiveness of sanctions under the Code

161. The maximum fine under the Code for severe or repeated breaches is up to $250,000. Edition 16 of the Code made several amendments to the fines available, including increasing the maximum fines from $200,000 to $250,000. The maximum fines were more than doubled between each of editions 12, 13 and 14.

162. Medicines Australia supports the current level of fines under the Code. In response to submissions calling for larger monetary sanctions (detailed below), Medicines Australia points to the high level of fines under the Code compared to other codes (e.g. the GMiA Code of Practice). Medicines Australia also notes the significant increase in the maximum possible fine in the last iteration of the Code.

163. In support of the effectiveness of the current sanctions system, Medicines Australia notes that the Code allows for non-monetary penalties, such as orders to discontinue a certain conduct, or to publish corrective statements. Medicines Australia suggests these sanctions are taken seriously by member companies.

164. Medicines Australia also suggests that compliance with the Code has been increasing, which demonstrates the effectiveness of existing sanctions.

165. A number of submissions commented on the level of existing sanctions. These submissions generally criticise the effectiveness of the sanction regime, submitting that the maximum available fine is small relative to the annual profits of the companies involved. The submissions also note that the maximum fine of $250,000 is rarely used, and instead the average fine is

around $50,000. The submissions question the deterrence effect of small fines when the companies involved are so large.

166. Broadly, two amendments were suggested by the submissions:

- Increase the maximum available fine. The figure of $1 million was mentioned by a number of submissions.

- Enact a similar system to the US, where large fines are available and there are incentives for investigators to undertake significant investigations into conduct in breach of the regulations (investigators receive a percentage of any subsequent financial penalties). Similarly, whistleblowers are incentivised to come forward by offering them a percentage of any sanctions imposed on companies from the whistleblower's information.

167. Choice also called for breaches of the Code to be classified as a criminal act, and to use the potential for jail terms for individuals as a deterrent.

168. The ACCC notes that it is difficult to determine whether the existing level of fines is appropriate. It is clear that the fines available under the Code would not be substantial enough by themselves to deter a very profitable breach. The ACCC would be concerned if it was provided with specific evidence of systemic efficient breaches[26] of the Code. If evidence of such breaches were found this would undermine the effectiveness of the Code. To date the ACCC has not received any submissions which detail specific evidence of systemic efficient breaches of the Code.

169. The ACCC notes that financial sanctions are part of a package of disciplinary measures. Further, under the Code, member companies are required to cease any activities that are deemed to breach the Code. Member companies found to have breached the Code may also be required to publish corrective statements. Member companies are likely to be further disciplined in some way by the threat of a legislative response by government if breaches were to become systemic.

170. Medicines Australia submits that breaches of the Code do not appear to be common, nor is there evidence of repeated breaching by member companies. Further, the ACCC has not been provided with any specific evidence of systemic non-reporting or non-investigation of potential breaches by Medicines Australia. The ACCC would be concerned if it was provided with such evidence.

171. Medicines Australia submits that the number of complaints received by the Code Committee has progressively decreased from 83 in 2007/08 to 14 in 2010/11 (see below). The number of complaints referred to the Code Committee by the Monitoring Committee has also decreased from eight in 2009/10 to two in 2010/11. It is not clear whether this is directly related to the effectiveness of the monetary fines, but it suggests the disciplinary measures available under the Code, and the threat of the introduction of regulation, are having some effect.

[26] An efficient breach refers to a situation where a member company breaches the Code because it considers that the payment of a fine would be of greater economic benefit than adherence to the Code.

Figure 1: Sanctions imposed by the Code and Appeals Committees on companies with complaints found in breach and finalised in 2010-11 (source: Medicines Australia Code of Conduct Annual Report 2010-2011)

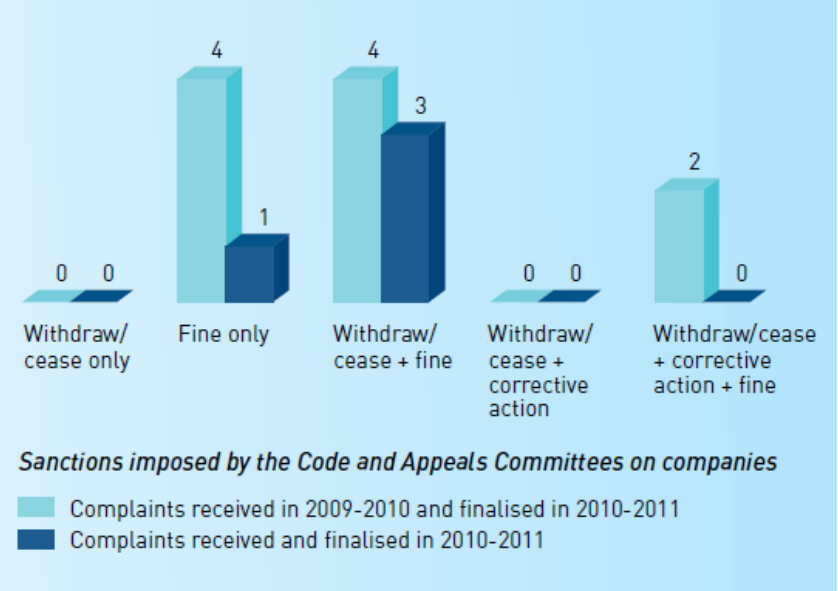

Figure 2: Fines imposed by the Code and Appeals Committees on companies with complaints found in breach and finalised in 2010-11 (source: Medicines Australia Code of Conduct Annual Report 2010-2011)

172. The ACCC accepts the submissions of interested parties that the fines must be kept at an effective level and encourages Medicines Australia to maintain fines at a level such that the fines and their enforcement prevent any efficient breaches of the Code.

173. Given the apparent level of compliance with the Code reported by Medicines Australia, the ACCC considers that the monetary and non-monetary sanctions currently available under the Code likely provide an effective deterrence against breaches of the Code by member companies. In particular, the potential for public criticism surrounding the imposition of a fine may increase

the effectiveness of the fine itself. The threat of the introduction of regulation is also likely to deter companies from breaching the voluntary code.

174. The ACCC notes that the decline in the number of breaches of the Code reported by Medicines Australia relies on Medicines Australia becoming aware of any breaches. The ACCC encourages Medicines Australia to look at ways to ensure the Monitoring Committee effectively identifies breaches (discussed below).

175. The ACCC also invites submissions from interested parties about specific breaches of the Code that may not have come to the attention of Medicines Australia or that were not included in reporting.

The effectiveness of the Monitoring Committee

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

177. Medicines Australia submits that the Monitoring Committee has seen an increased level of compliance with the Code by member companies in recent years. The activities of the Monitoring Committee are shown below.

Figure 3: Summary of materials and activities reviewed by the Monitoring Committee in 2010-11 (source: Medicines Australia supporting submission)

Therapeutic Class	Types of material subject to review	Number of companies	Number of items	Number of meetings to undertake review
Endocrine and Metabolic Disorders	Advertisements	11	110	1
Musculoskeletal	Competitions	5	18	1
Skin	Printed Advertisements	2	4	0.5
All therapeutic classes	General Company Websites	29	29	1.5
All therapeutic classes	Market Research with healthcare professionals	26	150	2
Analgesia	Printed promotional material	8	30	1
Neoplastic	Advertisements	9	25	1
All therapeutic classes	Prescribing Software	5	5	1
Contraceptive Agents	Printed promotional material	3	20	1
Nose and Oropharynx & eye	Printed promotional material	6	31	1
TOTAL		n/a	402	11

178. The FSM submits that the Code should provide for random monitoring and reporting of drug representative compliance with the Code in interactions with health professionals.

179. The ACCC has not received any submissions which indicate that the effectiveness of the Monitoring Committee has declined since the ACCC authorised edition 16 of the Code. On that basis, the ACCC considers that the effectiveness of the Monitoring Committee is not having a significant detrimental effect on the effectiveness of the Code. Any measures that Medicines Australia takes to ensure that the Monitoring Committee effectively identifies breaches of the Code will further reduce any risk of detriment arising.

180. The ACCC notes that a number of interested parties suggested that the addition of a consumer and a health professional to the governing body that conducts the review of the Code every three years would increase the effectiveness of monitoring. Medicines Australia notes in response that there are three ongoing Code committees: the Monitoring Committee, the Code Committee and the Appeals Committee and that each of these committees includes permanent healthcare professional members. Medicines Australia notes that consumer representatives nominated by the CHF are appointed to the Monitoring Committee, Code Committee and Appeals Committee for three years and that the Monitoring Committee requires a consumer representative to be present. Medicines Australia submits that it actively promotes understanding of the Code and this promotion is successful in reducing non-compliance. The ACCC has previously considered 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.

181. The ACCC has previously accepted that promotion of the Code by Medicines Australia through both formal and informal measures increases the effectiveness of the Code. The ACCC has not received any submissions which indicate that this has changed since the ACCC authorised edition 16 of the Code.

Reporting under the Code

182. As discussed earlier, Medicines Australia has strengthened reporting requirements under edition 17 of the Code.

183. The ACCC notes that 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.[27]

184. 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 influences 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

[27] 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.

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.[28]

185. A number of interested parties argued that the present reporting format adopted by Medicines Australia prevents analysis of the data by third parties. Interested parties such as Choice note that the provision of this data in a more accessible form, such as an excel format, would facilitate an analysis of the average complaints, average fines and assist in determining whether or not Code compliance for a specific company was improving.

186. 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. The ACCC notes that this could be further strengthened through the provision of data in more accessible formats and will be liaising further with Medicines Australia about this issue.

Complaints process

187. The ACCC has previously expressed concerns, in authorising previous editions of the Code, that an onerous complaints process may decrease the effectiveness of the Code.

188. Medicines Australia submits that there is an effective and appropriate complaints procedure that is easily accessible to stakeholders. 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.

189. Medicines Australia also submits that the complaints process is accessible to complainants, the power of the Code Committee to impose sanctions is a public benefit and that information on the complaints process is publicly available.

190. A participant in the pharmaceutical industry submits that pharmaceutical companies will not bring a complaint against other pharmaceutical companies as it may affect their relationship with healthcare professionals.

191. Another interested party raised concerns about the complaints process on the basis that it required significant input from complainants. The interested party noted that, as a complainant, Medicines Australia required them to present their case and that it required 120 hours of work to have the complaint heard.

192. The interested party also notes that transcripts of Medicines Australia decisions, or the written submissions of the pharmaceutical company, are not made available unless a complainant indicates that they wish to appeal a decision. The interested party notes that during this time the pharmaceutical company has access to the full complaint made by the complainant.

[28] ibid, at ¶315.

193. The interested party also notes that complaints hearings only take place in Sydney, and that no video facilities are provided for complainants in other states to take part in the process.

194. Medicines Australia notes in response to interested party submissions that the complaints process is identical for both industry and non-industry complainants. Medicines Australia notes that its guidelines in relation to complaints provide that:

- non-industry complainants may choose to contact the pharmaceutical company to discuss their concerns before lodging a complaint and to seek an explanation;
- following a complaint, a copy of the complaint and the company's response to the complaint will be provided directly to the Code Committee; and
- if an appeal is lodged, the complainant receives a copy of the company's response and each party has an opportunity to review all relevant documents.

195. The ACCC notes that there may be significant differences in resources between industry and non-industry complainants, and that a homogeneous complaints policy does not take this into account. The existing complaints process may not be appropriate to facilitate individuals making complaints under the Code. The ACCC notes that there has been consistently low participation of the general public and academics in the complaints process having made only 11 complaints in the past four reporting periods (healthcare professionals have made 28 complaints and 'organisations' have made 11 complains in this time) (see below).

Figure 4: Complaints received by the Code Committee from 2007/08 to 2010/11 (source: Medicines Australia supporting submission)

Source/ Year	2007/2008	2008/2009	2009/2010	2010/2011	Total
Healthcare professionals	5	11	8	4	28
Organisations (e.g. TGA, College/Society, Consumer Organisations)	4	6	1	0	11
Other (general public and academics)	1	2	6	2	11
Monitoring Committee	53	26	14	2	95
Pharmaceutical Companies (member and non-member companies)	20	14	10	6	50
Total	83	59	39	14	195

196. If the complaint procedures were shown to be ineffective this would be of significant concern to the ACCC. The ACCC considers that Medicines Australia should review its complaints procedures so that they are not overly onerous on complainants, and that procedural fairness is afforded to all complainants. The ACCC notes that the ability for the public to make complaints is an important feature of increasing the transparency around the

relationship of the pharmaceutical industry with healthcare professionals. The ACCC will be liaising further with Medicines Australia about this issue.

Conclusion on the effectiveness of the Code

197. The ACCC notes Medicines Australia's submission that the number of breaches of the Code has been decreasing relative to previous editions of the Code.

198. The ACCC notes that the effectiveness of the Code may be further strengthened by reporting data in more accessible formats and by reviewing its complaints and Monitoring Committee procedures. The ACCC will be liaising further with Medicines Australia about this issue, as discussed above.

ACCC conclusion on public benefits

199. The ACCC accepts that the following public benefits are likely to result from edition 17 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 health consumer organisations;
- outlining the boundaries for appropriate relationships between pharmaceutical companies and healthcare professionals to limit the potential for conflicts of interest; and
- requiring pharmaceutical companies to have an internal compliance procedure promoting compliance by all company employees.

200. The ACCC has noted in the discussion above a number of areas where the ACCC will seek further information from Medicines Australia.

201. The ACCC also encourages Medicines Australia to consider further the potential for patient support programs to be viewed as promotional rather than educational and assess the use of both patient support programs and PFPs during the next review of its Code.

Public detriment

202. Public detriment is also not defined in the Act 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.[29]

203. 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.

204. The GMiA raised particular concerns about the anticompetitive effects of the total prohibition of brand name reminders.

205. The ACCC's assessment of the likely public detriments from the proposed conduct follows.

Anti-competitive detriment

206. The ACCC notes that the Code regulates how Medicines Australia's members compete through the advertising and promotion of their products to healthcare professionals. However, 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.

207. 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.

Reduced competition from prohibiting brand name reminders

208. Edition 17 of the Code has introduced a complete prohibition on brand name reminders. Medicines Australia defines brand name reminders as an item of low monetary value which is intended to remind healthcare professionals of the existence of a product. This may include medical items such as tongue depressors, anatomical models, surgical gloves or peak flow meters. It may also refer to non-medical items such as stationery items, pens, sticky notepads, mugs or clocks.

209. As noted at paragraph 24, the promotion of all prescription medicines, including by non-members, must comply with the requirements in the relevant sections of the Code.

210. The GMiA submits that the total prohibition on brand name reminders will result in public detriments in the form of a lessening of competition. The GMiA

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

submits that brand name reminders are not an inducement to prescribe; rather they are a standard method of advertising and promotion to keep brand awareness of medicines top of mind. The GMiA submits that the brand name reminders are generally low cost items that are used as part of practicing medicine and that by being able to maintain product awareness of older and/or cheaper products, the prescriber is more likely to consider less expensive alternatives as part of their decision making process.

211. The GMiA submits that new medicines released in Australia are often supported by significant financial resources to promote that medicine. The GMiA submits that generic medicines are unable to afford these forms of advertising as their costs cannot be covered within the cost margins of generic medicines.

212. The GMiA submits that a brand name reminder is a low cost means by which a healthcare professional can be reminded that there are competing substitutable products available. The GMiA submits that the effect of removing brand name reminders will be to reduce competition.

213. Medicines Australia submits that while brand name reminders are no longer permitted, medical education items which enhance patient care can be provided. Further, Medicines Australia submits that member companies are not prohibited from promoting their products to healthcare professionals generally, such as via the supply of printed promotional materials, healthcare professional journals, audiovisual material and the internet. Consequently, Medicines Australia considers that the ban on brand name reminders will not reduce competition between pharmaceutical companies, including manufacturers of generic pharmaceuticals.

214. The ACCC notes that a doctor may prescribe a branded medication, but in most circumstances the patient can be provided with another brand without authority from their doctor. Brand substitution by pharmacists is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is not prohibited under legislation of the relevant State or Territory.

215. The ACCC notes that the "Guidelines for Pharmacists on PBS Brand Substitution" published by the Pharmaceutical Society of Australia provide general advice to support and assist pharmacists in exercising their professional judgement when offering brand switching. The Pharmaceutical Society of Australia brand switching policy states:

- Generic brands will be offered to all consumers presenting PBS prescriptions for which there are bioequivalent preparations available, unless the prescriber has ticked the "brand substitution not permitted"

box, or the pharmacist has recorded in the consumer's profile switching should not take place.

- Brand switching will not occur without the consent of the consumer.
- When the consumer consents to brand switching this is noted on the prescription and recorded in the consumer's medication profile.
- All care is exercised to continue to supply the same brand while the consumer continues to frequent the pharmacy and to be prescribed that medication. If there is a need to switch brands, all care is taken to ensure the consumer agrees to the further brand switching.

216. The ACCC considers that the ability of pharmacists to substitute generic medicines at the point of dispensing prevents any detriments associated with the prohibition of brand name reminders to prescribers, such as medical practitioners.

217. However, the ACCC has previously noted in authorising the GMiA Code of Conduct, that a pharmacist can influence patient choice through the advice he/she provides the patient about purchasing a generic brand in substitution for an originator brand, and by way of the generic brand the pharmacist elects to stock in his/her pharmacy.

218. Given that pharmacists may substitute branded medicines for generic medicines at the point of dispensing, the ACCC has examined the incentives of pharmacists to dispense generic medications.

219. When a manufacturer successfully applies to have its drug listed on the PBS Schedule, it negotiates a 'chemist list price' with the Pharmaceutical Benefits Pricing Authority. This is the maximum price that a manufacturer can charge pharmacies for the drug.

220. The chemist list price forms the basis for the 'dispensed price' which is the amount the government reimburses pharmacies for dispensing the product, negotiated between the government and the Pharmacy Guild. The dispensed price includes the chemist list price, the wholesaler's mark-up, the pharmacists' mark-up (to cover the costs of storage and handling), a dispensing fee and other fees (such as a dangerous drug fee).

221. Manufacturers compete to have their products dispensed by pharmacies. In many cases, manufacturers supply generic medicines to pharmacies at discounts from the chemist list price. This benefits pharmacists because they still receive reimbursement from the government based on the full chemist list price, and so retain the margin.

222. The ACCC considers that the level of discounting will differ based on a number of factors, including the number of competitors which are able to supply a particular generic drug. The ACCC notes that these discounts can be up to 90% of the chemist list price.[30]

[30] Medical Observer, *Pharmacy Guild fears heavy discounts threaten industry*, 26 June 2012, http://www.medicalobserver.com.au/news/pharmacy-guild-fears-heavy-discounts-threaten-industry. Accessed 4 October 2012.

223. The GMiA has previously submitted to the ACCC, in the context of the GMiA Code of Conduct authorisation, that the primary selling point for a GMiA member is the price to the pharmacist of their brand of generic medicines, in comparison to other equivalent brands.

224. The GMiA has also previously advised the ACCC that there are a number of non-price benefits currently provided by generic manufacturers to pharmacists, including:

- stock replacement for expired items;
- quality use of medicines programmes;
- access to programs and software tools designed to increase generic substitution;
- training and educational events for pharmacists/pharmacy assistants;
- pharmacy aids e.g. prescription holders, patient information sheets;
- co-operative merchandising e.g. signage, calendars, mail-outs, T-shirts;
- conference sponsorship;
- dinner/lunch/breakfast meetings;
- small value coupons/vouchers/movie tickets.

225. The ACCC considers that pharmacists have strong financial and other incentives to stock and dispense generic medications, and that absent brand name reminders will continue to do so. The ACCC notes that the prohibition on brand name reminders applies equally to all manufacturers of both generic and branded medicines. It is not clear that the prohibition of brand name reminders will have a material effect on the competitive process, when compared to factors such as competition on price. The ACCC also considers that there are a range of other mechanisms generic manufacturers may utilise to maintain product awareness of their products. The ACCC therefore considers that the prohibition of brand name reminders is unlikely to result in significant competitive detriments.

ACCC conclusion on public detriments

226. The ACCC considers that any anti-competitive detriment resulting from the Code will be minimal. While the Code restricts to some degree the promotional activities of Medicines Australia members and non-members, the ACCC accepts that the Code does this to address potential market failures which may arise. The ACCC considers that there may be minimal detriments which may arise as a result of the total prohibition on brand name reminders.

Balance of public benefit and detriment

227. In general, the ACCC may only grant authorisation if it is satisfied that, in all the circumstances, edition 17 of the Code is likely to result in a public benefit, and that public benefit will outweigh any likely public detriment.

228. In the context of applying the net public benefit test in section 90(8)[31] of the Act, the Tribunal commented that:

> … something more than a negligible benefit is required before the power to grant authorisation can be exercised.[32]

229. For the reasons outlined in this draft determination at this time the ACCC is satisfied that the likely benefit to the public would outweigh the detriment to the public including the detriment constituted by any lessening of competition that would be likely to result.

230. Accordingly, the ACCC is satisfied that the relevant net public benefit tests are met.

Length of authorisation

231. The Act allows the ACCC to grant authorisation for a limited period of time.[33] 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.

232. In this instance, Medicines Australia seeks authorisation for a period of five years. Medicines Australia submits that this is consistent with the term of authorisation granted in relation to edition 16 of the Code.

233. No interested party commented on the appropriate length of authorisation.

234. 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.

235. As already noted, the ACCC considers that it is important that the Code continue to reflect community expectations about the level of transparency on relationships between the pharmaceutical industry and healthcare professionals. The ACCC raised the issue of disclosing payments to individual healthcare professionals in its consideration of edition 16 of the Code in 2009. The ACCC notes that Medicines Australia has since convened a transparency working group, inviting participation from consumer, healthcare professional and the pharmaceutical industry groups, and which will look into ways that

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31 The test at 90(8) of the Act is in essence that conduct is likely to result in such a benefit to the public that it should be allowed to take place.

32 *Re Application by Michael Jools, President of the NSW Taxi Drivers Association* [2006] ACompT 5 at paragraph 22.

33 Section 91(1).

payments at an individual level can be disclosed appropriately. Medicines Australia advises that this working group will report by December 2013.

236. In order to ensure that the Code continues to meet community expectations the ACCC proposes to grant authorisation for only three years rather than the five years sought by Medicines Australia. During this authorisation period, Medicines Australia will be able to complete the work it has already commenced on the level of transparency provided by the Code and make any necessary changes to the Code. Scope of the authorisation more broadly

237. The ACCC notes that a number of interested parties consider that the Code or similar provisions of the Code should apply more broadly in the industry including to also cover pharmaceutical companies who are not members of Medicines Australia.

238. Choice submits that the therapeutic industry is regulated by a variety of self-regulatory codes with varying regulations, monitoring, complaint procedures and transparency. Choice submits that this creates an uneven playing field.

239. Choice considers that this is highlighted by recent actions of Ranbaxy Australia whereby it offered pharmacists $14,648 of generic atorvastatin free of charge. However, as Ranbaxy Australia is not a member of Medicines Australia or the GMiA, Choice submits that the complaint regarding this promotion could not be considered by Medicines Australia.

240. 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 Act. The ACCC notes that few complaints against non-member companies are referred to the ACCC for investigation as a potential breach of the Act.

241. 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.

242. 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 armslength 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.

243. 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, as the GMiA has done to increase transparency in the generic pharmaceutical industry.

244. The ACCC notes that the authorisation process is not necessarily the appropriate mechanism to redress inconsistencies between various industry codes. The ACCC is required to assess any code for which authorisation is sought on a case by case basis according to the likely public benefits and detriments flowing from that particular code as required by the statutory tests for authorisation. 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.

245. In this respect, the ACCC notes the DHA Working Group on the Promotion of Therapeutic Products made a number of recommendations for industry, government and healthcare professionals in 2011.[34] The report includes a set of high level principles as the basis for strengthening and aligning industry codes of conduct. The Australian Government has stated that its preference is to maintain an emphasis on self-regulation and strongly supports industry's initiative to harmonise their codes of conduct.

Draft determination

The applications

246. On 4 July 2012 Medicines Australia lodged applications for revocation of an authorisation and substitution of a new authorisation A91316-A91320 with the ACCC. Applications A91316-A91320 were made using Form FC Schedule 1, of the *Competition and Consumer Regulations 2010.* The applications were made under subsection 91C(1) of the Act for edition 17 of its Code of Conduct (the Code) which sets the standards for the marketing and promotion of prescription pharmaceutical products in Australia.

247. Section 90A(1) requires that before determining an application for authorisation the ACCC shall prepare a draft determination.

The net public benefit test

248. For the reasons outlined in this draft determination, the ACCC considers that in all the circumstances the conduct for which authorisation is sought 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 conduct.

[34] Working Group on Promotion of Therapeutic Products, *Report to Parliamentary Secretary Catherine King*, 18 March 2011, http://www.health.gov.au/internet/main/publishing.nsf/Content/37D9B56C888EF27ECA2577D600081DDD/$File/Report%20of%20the%20Working%20Group%20on%20Promotion%20of%20Therapeutic%20Products.pdf, Accessed 6 October 2012.

249. The ACCC is satisfied that the conduct for which authorisation is sought is likely to result in such a benefit to the public that the conduct should be allowed to take place.

250. The ACCC therefore **proposes to grant** authorisation to applications A91316-A91320.

Conduct for which the ACCC proposes to grant authorisation

251. The ACCC proposes to grant authorisation to Medicines Australia for edition 17 of its Code which sets the standards for the marketing and promotion of prescription pharmaceutical products in Australia for three years.

252. Further, the proposed authorisation is in respect of edition 17 of the Code as it stands at the time authorisation is granted. Any changes to the Code during the term of the proposed authorisation would not be covered by the proposed authorisation.

253. Authorisation does not represent ACCC endorsement of a group or scheme. Rather, it provides statutory protection from legal action for conduct that might otherwise raise concerns under the competition provisions of the *Competition and Consumer Act 2010*.

254. This draft determination is made on 26 October 2012.

Further submissions

255. 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 Act.

Attachment A - Summary of relevant statutory tests

Sections 90(5A) and 90(5B) provide that the ACCC shall not authorise a provision of a proposed contract, arrangement or understanding that is or may be a cartel provision, unless it is satisfied in all the circumstances that:

- the provision, in the case of section 90(5A) would result, or be likely to result, or in the case of section 90(5B) has resulted or is likely to result, in a benefit to the public; and

- that benefit, in the case of section 90(5A) would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if the proposed contract or arrangement were made or given effect to, or in the case of section 90(5B) 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.

Sections 90(6) and 90(7) state that the ACCC shall not authorise a provision of a proposed contract, arrangement or understanding, other than an exclusionary provision, unless it is satisfied in all the circumstances that:

- the provision of the proposed contract, arrangement or understanding in the case of section 90(6) would result, or be likely to result, or in the case of section 90(7) has resulted or is likely to result, in a benefit to the public; and

- that benefit, in the case of section 90(6) would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if the proposed contract or arrangement was made and the provision was given effect to, or in the case of section 90(7) has resulted or is likely to result from giving effect to the provision.

Section 90(8) states that the ACCC shall not:

- 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

- 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.