Australian Competition & Consumer Commission

Draft Determination

Applications for authorisation

lodged by

Generic Medicines Industry Association

in respect of

the GMiA Code of Practice 2nd edition

Date: **3 August 2010**

Commissioners: Samuel
Kell
Schaper
Court
Dimasi
Walker
Willett

Authorisation nos.: A91218 & A91219

Public Register no.: C2010/347

Summary

The ACCC proposes to grant authorisation to the giving effect of the provisions of the Generic Medicines Industry Association in respect of its Code of Practice 2nd edition.

The ACCC proposes to grant authorisation for a period of three years subject to the proposed conditions:

C1: The GMiA must, on or before the date this authorisation comes into effect, amend the Code so that it extends the educational event reporting requirements in clause 10 of the Code to all Healthcare Professionals (as defined in the Code) regardless of whether a Healthcare Professional prescribes Prescription Medicines or not.

C2: The GMiA will require each of its Members to report to GMiA on all hospitality, entertainment, gifts and other non-price benefits (howsoever described) provided to pharmacists (other than more favourable trading terms) by:

a. completing the table below;

b. providing a copy of completed table for the period 1 April to 30 September and 1 October to 31 March in each year within two months of the end of each six month period; and

Company name:

General description of the benefit	Number of recipients	Value of benefit
Report under the following general descriptions: a) hospitality b) entertainment c) gifts d) other non-price incentives e) loyalty rewards programs	xx	$xx Lump sum figure of the total benefit provided to pharmacists.

c. The GMiA must place the tables provided by each Member on the GMiA website within three months of the applicable period end.

The ACCC has also decided to grant interim authorisation so that the Code Complaints Committee can convene to consider a complaint made under the Code. Interim authorisation will remain in place until the date the ACCC's final determination comes into effect or until the ACCC decides to revoke interim authorisation.

On 31 March 2010 the Generic Medicines Industry Association (GMiA) lodged applications A91218 and A91219 with the Australian Competition and Consumer Commission (ACCC) seeking authorisation of its Code of Practice 2nd edition.

The GMiA Code is a newly developed Code which seeks to formalise the commitment of GMiA members to a system of best practice self-regulation and ethical supply of generic medicines to the Australian community in compliance with applicable laws and standards. Members formally adopted the Code in March 2010.

The GMiA currently has 5 members that supply 90% of generic prescriptions dispensed in Australia.

The ACCC considers that the Code is likely to result in a public benefit. In particular, the Code provides a framework for managing potential conflicts of interest in the relationship between healthcare professionals and generic pharmaceutical companies. One way it achieves this is to provide transparency through the public reporting of hospitality and entertainment provided to prescribers of medicines at educational events. The Code does not extend this transparency to hospitality and entertainment provided at educational events for dispensers of medicines.

While the ACCC accepts that there are differences in the roles of the medical practitioner in prescribing medicines and pharmacists in dispensing medicines, nevertheless, where the pharmacist is able to provide some influence is through the advice he/she provides the patient about purchasing a generic brand and by way of the generic brand the patient receives by stocking it in the pharmacy.

The ACCC considers that transparency around the relationship between pharmacists and generic drugs manufacturers is desirable to enhance public confidence in the generic medicines sector and maintain faith in the co-regulatory system. Therefore, the ACCC proposes to impose two conditions.

The first condition extends educational event reporting to include events held for pharmacists as well as medical practitioners. This means that GMiA member companies will be required to complete a table every 6 months that requires information about the costs of hospitality such as food and beverages, entertainment, accommodation and travel associated with educational events held for medical practitioners and pharmacists.

The ACCC also proposes to impose a second condition requiring high level disclosure of the value of non-price incentives offered by members to pharmacists as a means of generating loyalty. The ACCC considers that the value of the benefits to pharmacists provided as hospitality, entertainment, gifts and other non-price incentives are less likely to be passed through to the retail level than price discounts. The ACCC considers that increasing transparency around the value of such non-price incentives offered by GMiA members to pharmacists is likely to provide greater incentives for manufacturers to offer price competition and discounting, which may then be passed through to individual consumers. Discounting is also required to be reported to government through the price disclosure requirements which may reduce the cost to government through the PBS.

This proposed condition may also address concerns by some interested parties that the offer of loyalty programs or other non-price incentives to pharmacists may undermine public confidence in the generic medicines industry. The ACCC considers that transparency around the provision of such benefits will assist in ensuring that the relationship between pharmaceutical companies and the pharmacist can withstand public and professional scrutiny. Making public the nature and

scale of such benefits conferred imposes its own constraint and the companies conferring such benefits will have to be in a position to publicly explain them.

The ACCC considers that the proposed conditions will increase the public benefits resulting from the Code.

Ultimately, the extent to which the likely public benefits from the Code are realised depends upon the extent to which the Code is complied with and effectively enforced. The ACCC considers that the Code contains a number of features which are likely to encourage compliance and go to its effective enforcement.

However, the ACCC considers the operation of the following areas are important for ensuring that the Code achieves its aims:

- close scrutiny of the provision of entertainment at educational events, especially in instances where it may undermine public confidence in the healthcare sector
- ensuring GMiA members' internal complaint processes are timely, efficient and accessible to complainants and do not create an obstacle to accessing the external complaints handling system
- the level of sanctions and whether they are sufficient in deterring breaches of the Code
- administration and enforcement of some clauses in the Code which may be open to broad interpretation, for example clauses that require members to 'not bring discredit to the industry'.

Should the GMiA wish to seek re-authorisation of its Code, the ACCC would seek further information as to how the Code has been enforced and whether the GMiA has been effective in encouraging compliance with the Code.

Concerns have also been raised that there are inconsistencies between various industry codes in the therapeutics sector. The ACCC notes that it cannot, through the authorisation process, require different sectors of the therapeutic goods industry to conform to a single code.

However the ACCC also notes the government has issued a position paper on the promotion of therapeutic goods which supports stronger self-regulation in the sector. The government's position is that the sector can seek to address inconsistencies between codes through the development of an industry framework for universal adherence to consistent industry-wide codes based on a common set of high level principles.

The ACCC proposes to grant authorisation for a period of three years. Given that the Code is newly developed, and there is currently a process to develop high level principles to be reflected in industry codes following the release of the government's position paper, the ACCC considers it appropriate to review the authorisation of the GMiA's Code after three years of operation.

Next steps

The ACCC is now seeking further submissions in relation to this draft determination, including on the proposed conditions of authorisation and the proposed duration of authorisation, prior to making its final decision. The GMiA and any interested parties may also request that a conference be held to make oral submissions on the draft determination.

Contents

List of abbreviations

ACCC	Australian Competition and Consumer Commission
AMA	Australian Medical Association
ARTG	Australian Register of Therapeutic Goods
ASMI	Australian Self-Medication Industry
CHF	Consumers Health Forum of Australia
the Code	Code of Practice 2nd edition
Complaints Committee	Code Complaints Committee
the Guild	Pharmacy Guild of Australia
GMiA	Generic Medicines Industry Association
NMP	National Medicines Policy
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PSA	Pharmaceutical Society of Australia
RACP	Royal Australasian College of Physicians
TG Act	*Therapeutic Goods Act 1989* (Cth)
TGA	Therapeutic Goods Administration
TPA	*Trade Practices Act 1974* (Cth)

1. The applications for authorisation

1.1. On 31 March 2010 the Generic Medicines Industry Association (GMiA) lodged applications A91218 and A91219 with the ACCC seeking authorisation of its Code of Practice 2nd edition (the Code). On 31 May 2010 the GMiA provided an amended version of its Code.

1.2. Authorisation is a transparent process where the ACCC may grant immunity from legal action for conduct that might otherwise breach the *Trade Practices Act* 1974 (TPA). The ACCC may 'authorise' businesses to engage in anti-competitive conduct where it is satisfied that the public benefit from the conduct outweighs any public detriment. The ACCC conducts a public consultation process when it receives an application for authorisation, inviting interested parties to lodge submissions outlining whether they support the application or not. Further information about the authorisation process is contained in Attachment A. A chronology of the significant dates in the ACCC's consideration of these applications is contained in Attachment B.

1.3. Applications A91218 and A91219 were made under sections 88(1) and 88(1A) of the TPA:

- to make and give effect to a contract, arrangement or understanding, a provision of which is or may be an exclusionary provision within the meaning of section 45 of the TPA
- to make and give effect to a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of the TPA.
- to make and give effect to a provision of a contract, arrangement or understanding, a provision of which is, or may be, a cartel provision and which is also, or may also be, an exclusionary provision within the meaning of section 45 of that TPA.
- to make and give effect to a contract or arrangement, or arrive at an understanding a provision of which would be, or might be, a cartel provision (other than a provision which would also be, or might also be, an exclusionary provision within the meaning of section 45 of the TPA).

1.4. The GMiA seeks authorisation of its Code for five years. The GMiA advises that the 2nd edition of the Code was formally adopted by GMiA members in March 2010. GMiA members agree to be bound by the Code which includes provisions for taking disciplinary action against GMiA members who breach the Code.

1.5. The GMiA advises that the Code seeks to formalise the commitment of GMiA members to a system of best practice self-regulation and ethical supply of generic medicines to the Australian community in compliance with applicable laws and standards.

1.6. The Code introduces an internal and external complaints handling system, educational event guidelines, public reporting requirements for educational events and the

establishment of a disciplinary Code Complaints Committee (Complaints Committee). A summary of the main provisions of the Code can be found at paragraphs 3.1 to 3.50.

Other parties

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

Interim authorisation

1.8. On 25 June 2010 the GMiA requested that the ACCC grant interim authorisation. Interim authorisation protects the arrangements for which authorisation is sought from legal action under the relevant provisions of the TPA while the ACCC considers and evaluates the merits of the application.

1.9. The GMiA advises it has received a complaint about the conduct of a member company under the Code. Under the Code, complaints are dealt with initially through an internal complaints handling system and then may be referred to the Complaints Committee for consideration. The GMiA advises that it is reluctant to request the Complaints Committee to convene to review the complaint without authorisation.

2. Background to the applications

The Generics Medicines Industry Association

2.1. The GMiA was established in 2001 to represent the interests of suppliers of generic medicines in Australia.

2.2. A generic medicine is a copy of a branded medicine. It is chemically equivalent to its branded counterpart meaning it contains the same active ingredient which makes the medicine work. However it may differ from the originator brand in colour, shape, size and/or taste. Before a generic drug is able to be sold in Australia the Therapeutic Goods Administration (TGA) evaluates its bioequivalence with the originator brand.

2.3. Newly developed medicines (often referred to as branded or originator medicines) are protected by a patent (which can be for a period of up to 20 years) and only when this expires can generic versions be produced.

2.4. The GMiA advises that it seeks to develop good relationships with all constituencies involved in the continued delivery of pharmaceutical care to the Australian community and to contribute to the long-term sustainability of the Pharmaceutical Benefits Scheme (PBS) through support of the principles of the National Medicines Policy (NMP).[1]

2.5. In the context of the NMP, the GMiA considers that generic medicines have a particular and important role in ensuring Australians have timely access to affordable medicines and that the PBS remains sustainable.

2.6. The GMiA currently has five members that supply over 90% of generic prescriptions dispensed. This represents approximately 33% of prescriptions on the PBS.

2.7. The table below shows the value and volume of generic medicines supplied in Australia. Sandoz and other smaller manufacturers not reflected in the table are not currently GMiA members.

[1] National Medicines Policy (NMP) has as an the overall aim to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. The NMP has four central objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Table: Supply of generic medicines in Australia year ended 30 June 2009

Manufacturer/ GMiA member	PBS script volume (million)	sales ex-manufacturer ($ million)
Alphapharm*	26.3	270.0
Sigma*	17.3	186.6
Apotex*	6.8	95.5
Sandoz	4.1	60.3
Hospira*	2.2	66.9
Ascent*	<2	

Source: GMiA submission dated 31 May 2010
*GMiA member

Prescription medicines

Regulatory overview

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

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

2.10. The TGA will test the quality, safety and efficacy of a medicine and approve it before it can be supplied in Australia.[3] The TGA carries out a range of assessment and monitoring activities to ensure that all therapeutic goods available in Australia are of an acceptable standard.[4]

2.11. All prescription medicines must be registered or listed in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. The TGA issues a marketing approval letter[5] 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.

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[2] Department of Health and Ageing Therapeutic Goods Administration website, *Regulation of therapeutic goods in Australia*, April 2005, http://www.tga.gov.au/DOCS/HTML/tga/tgaginfo.htm. Accessed 19 May 2010.
[3] Department of Health and Ageing Therapeutic Goods Administration website, *Medicines regulation and the TGA*, April 2005, http://www.tga.gov.au/docs/html/medregs.htm. TG Act, Chapter 2.
[4] TG Act, Chapter 2.
[5] 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 set out in Medicines Australia's code of conduct. Department of Health and Ageing Therapeutic Goods Administration website, *Regulation of advertising of therapeutic goods in Australia*, www.tga.gov.au/docs/pdf/advreg.pdf. Accessed 19 May 2010.

2.12. Following TGA approval drug manufacturers generally apply for listing on the Pharmaceutical Benefits Scheme (PBS). The Pharmaceutical Benefits Advisory Committee (PBAC) will consider an application for listing on the PBS and recommend whether the drug should be listed and consequently subsidised by the Australian government.

2.13. The Australian government subsidises the price of prescription medicines through the PBS. The government is responsible for approximately 85% of the total cost of the PBS with the remainder funded through patient co-payments.[6]

2.14. Once a drug has been approved to be listed on the PBS, a price is negotiated by the government with the manufacturer of the drug through the Pharmaceutical Benefits Pricing Authority (PBPA). Products that, in the judgement of the PBPA, produce similar health benefits are subsidised at the same level and each of the available brands is subsidised to the level of the lowest priced brand in the reference group. The reimbursement price set by the government includes the manufacturer price, retail mark-ups (to wholesaler and pharmacist) and dispensing fees.

2.15. Where a manufacturer applies to list the first new generic brand of a medicine already listed on the PBS, they must offer at least a 12.5% price reduction to the negotiated price listed on the PBS. This price reduction flows on to all drugs in the same reference pricing group. In this way the availability of high quality, low cost, generic medicines is important for addressing the increasing costs of the PBS.

2.16. To further reduce the pressure on the PBS, in 2007, the government introduced a price disclosure regime. Under the price disclosure regime, manufacturers are required to report to government the prices which the pharmacy pays for the products over the year. The government may then make price adjustments in the PBS schedule to reflect discounted prices paid by the pharmacy. Prices of all brands of the medicine subject to price disclosure will be reduced to the calculated Weighted Average Disclosed Price if the difference between the current PBS and the weighted average price is 10% or more. The GMiA advises that currently 119 brands are subject to the price disclosure requirements. The recently announced Commonwealth Budget includes proposals to extend the policy of price disclosure to over 1600 brands.[7]

2.17. When a PBS-listed pharmaceutical is dispensed, the patient pays a co-payment to the pharmacist (currently a maximum of $33.30 for general patients and a maximum of $5.40 for concessional patients) and any delivery and after hours fee, brand or therapeutic premium, or special patient contribution that may be applicable. The pharmacist in turn is reimbursed by the government for any difference between the patient co-payment and the reimbursement price of the pharmaceutical set by the PBPA.

2.18. The advertising of prescription medicines is subject to a number of requirements in the TG Act, as well as the TPA and other relevant laws. The TG Act prohibits the

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[6] Hans Lofren, *Generic medicines in Australia: business dynamics and recent policy reform*, Southern Med Review (2009) 2; 2:24-28.

[7] GMiA, *Applicants response to issues raised in the public consultation process concerning applications for authorisation of the GMiA Code of Practice*, 31 May 2010, p. 15; Commonwealth of Australia, Budget Paper No 2: *Budget Measures 2010-11*, 11 May 2010, pp. 248-249.

promotion of prescription medicines to the general public. Advertising of prescription only medicines to healthcare professionals is permitted by the TG Act provided that the advertising only refers to the approved uses of the product. In addition, the TPA includes general prohibitions against a variety of false or misleading representations.

Role of medical practitioners in prescribing medicines

2.19. Prescription medicines are those which require a prescription from a medical practitioner in order to access them.

2.20. The practice of pharmaceutical companies providing benefits to medical practitioners creates a risk that factors not relevant to patient welfare will be considered in the treatment options recommended. For example, medical practitioners may be influenced in terms of:

- deciding whether a prescription medicine is needed to treat the patient's condition
- where a prescription medicine is deemed necessary, deciding which particular drug is the most appropriate to treat the patient's condition.

2.21. In either case the medical practitioner is acting as the agent for the patient. The patient is reliant on the expertise of the healthcare professional to have the knowledge to diagnose and order the necessary treatment for the patient's condition. To address the concern that the medical practitioner's prescribing practices may be inappropriately influenced by the provision of benefits by pharmaceutical companies, a framework around the pharmaceutical company and medical practitioner relationship is important.

2.22. In this regard, Medicines Australia has developed a code which aims to reduce the potential for conflicts of interest by providing a self-regulatory framework for relationships between pharmaceutical companies and medical practitioners. It does so by regulating the conferral of benefits provided to medical practitioners and transparently reporting on such benefits.

2.23. Medicines Australia represents the interests of the originator medicines industry. Its members comprise more than 80% of the prescription pharmaceuticals market and are engaged in the research, development, manufacture, supply and export of prescription medicines.

2.24. In 2009 the ACCC granted authorisation to Medicines Australia for its code of conduct edition 16 for a period of five years. Edition 15 of Medicines Australia's code was previously authorised in 2006 subject to a reporting condition requiring public disclosure of hospitality provided by pharmaceutical companies to healthcare professionals at educational events. The authorisation was subject to a review by the Australian Competition Tribunal (application by Medicines Australia Inc for review of a determination by the ACCC granting authorisation to edition 15 of Medicines Australia's Code of Conduct (Medicines Australia Inc [2007] ACompT)). On 27 June 2007 the Tribunal granted conditional authorisation to Medicines Australia. The condition imposed by the Tribunal was similar to that imposed by the ACCC.

2.25. In granting authorisation to Medicines Australia in 2009, the ACCC did not impose a similar reporting condition because the reporting requirement was fully incorporated into edition 16 of the code.

Role of pharmacists in dispensing medicines

2.26. Pharmacists act as an intermediary between medical practitioners and patients to ensure the safe and effective use of prescription medicines.

2.27. Pharmacists are the dispensers of prescription medicines. At the time of dispensing a prescription and provided the prescriber has not indicated on the prescription that it cannot be substituted, a pharmacist is obliged under the Community Pharmacy Agreement to discuss with the patient substitution of a generic mediciation for the prescribed branded medicine. The pharmacist has no influence on the decision by a medical practitioner to prescribe a particular medicine.

2.28. Pharmacists provide advice about brand substitution in accordance with the Pharmaceutical Society of Australia's (PSA) Guidelines on Pharmaceutical Benefits Scheme Brand Substitution. The Guidelines provide general advice to support and assist pharmacists in their discussions with consumers about whether to substitute a branded product with a bioequivalent generic product. Under the Guidelines a patient's health should always be the prime consideration by the pharmacist in any discussion about brand substitution. Pharmacists are advised to endeavour to be consistent in the selection of brands for patients on long term therapy to avoid patient confusion. The final decision about whether to substitute brands is the patient's decision.

2.29. In this regard, the same conflict of interest issues which arise in the context of medical practitioners' prescribing practices referred to in paragraph 2.20, do not arise with respect to the pharmacist and its role in dispensing medicines. Nevertheless, where the pharmacist is able to provide some influence is through the advice he/she provides the patient about purchasing a generic brand in substitution of an originator brand, and by way of the generic brand the patient receives by stocking it in the pharmacy. The ACCC understands that typically an individual pharmacy will stock the originator brand and only one generic brand (if available) of most prescription medicines.

2.30. The GMiA advises that a pharmacy will consider many factors when determining the brand of generic medicine that is stocked, including corporate and brand awareness, product quality, certainty of supply, returns policy, trading terms, product packaging and labelling, possibility of patient confusion, substitutability, price benefit to patient, the availability of complimentary programs, and the services provided by the supplier which support the business or professional activities of the pharmacy.

2.31. Volume discounting and loyalty programs are a common way for wholesalers and manufacturers to compete in order to have their products stocked by the pharmacist.

2.32. The patient will pay up to the maximum co-payment patient price for PBS pharmaceuticals. In some cases the pharmacist will pass on volume discounts from the wholesaler to the patient and charge less than the co-payment. As noted, discounting to pharmacists on a range of products is, and will be, captured by the price disclosure regime (see paragraph 2.16).

2.33. When a pharmacist dispenses a medicine under the PBS, he/she will receive a dispensing fee and a pharmacy mark-up payment from the Australian government to cover the cost of the medicine, a retail mark-up to cover the pharmacist's costs in storing and handling medicines and a fee for the pharmacist's professional advice and services in dispensing the medicine. In addition, a $1.53 generic dispensing incentive fee is subsidised by the government to pharmacies when a PBS generic prescription is dispensed and the cost to the patient is less than the co-payment price.

3. GMiA Code of Practice 2nd edition

3.1. The GMiA seeks authorisation of its Code 2nd edition. The Code introduces new obligations upon GMiA members including the establishment of an accessible and transparent complaints handling mechanism, the establishment of a Code Complaints Committee (Complaints Committee) to consider complaints about members' conduct and impose sanctions, and the establishment of an educational event guideline and reporting system on educational events held for healthcare professionals responsible for prescribing prescription medicines.[8]

3.2. The GMiA advises that the Code is intended to be principle based providing guidance in a single document on the different legislation, regulation and guidelines with which sponsors of generic medicines listed on the ARTG must comply.[9]

3.3. Compliance with the Code is a condition of membership of the GMiA.[10] Some key provisions of the Code are set out below.

Clause 4 - Principles

3.4. The Code formalises the guiding principles which members of the GMiA comply with. The principles include, among others, supporting the long term sustainability of the PBS by ensuring the timely and cost effective provision of generic medicines to consumers, supporting the quality use of medicines, encouraging a high level of awareness and general knowledge of the safety, efficacy and appropriate interchangeability of generic medicines, enhancing accountability of members through the new complaints handling mechanism and reducing actual and potential conflicts of interest between members and healthcare professionals through educational event reporting.[11]

Clause 5 – Coverage

3.5. Members of the GMiA are bound by the Code.[12]

3.6. The Code may serve as guidance for the suppliers of generic medicines who are not members of the GMiA. Suppliers who choose to adopt and comply with the Code, without becoming a full member of the GMiA will be known as affiliate members.[13] The GMiA advises that, at present, there are no affiliate members.

Clause 6 – The GMiA Code of Practice

3.7. Members are required to comply with the Code in respect of all therapeutic goods, in addition to generic medicines, manufactured or sold by members.[14]

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[8] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition,* clause 3.1.
[9] ibid., clause 2.4.
[10] ibid., clause 2.2.
[11] ibid., clause 4.1.
[12] ibid., clause 5.1.
[13] ibid., clause 5.2. The GMiA advises it has approached six companies to become affiliate members of the Code.
[14] ibid., clause 6.1.2.

3.8. The Code requires members to support the:

- National Medicines Policy which aims to meet medication and related service needs so that both optimal health outcomes and economic objectives are achieved for Australians.[15]

- Quality Use of Medicines by selecting management options wisely, choosing suitable medicines if a medicine is considered necessary so that the best available option is selected, and using medicines safely and effectively to get the best possible results.[16]

- Australian Code of Good Manufacturing Practice for Medicinal Products and applicable occupational health and safety, and environmental laws, outlining standards for the production and testing of medicinal products.[17]

- Guidelines for the Reporting of Adverse Drug Reactions by Drug Sponsors and related pharmacovigilance documents issued by the TGA for registered prescription and registered or listed non-prescription medicines for which they are the sponsor. The Guidelines outline the administrative procedures to be followed by drug sponsors in submitting Australian reports of adverse drug reactions to the TGA.[18]

- Uniform Recall Procedures for Therapeutic Goods which define the action to be taken by health authorities and sponsors when therapeutic goods for use in humans, for reasons relating to their quality, safety or efficacy, are to be removed from supply or use, or subject to corrective action.[19]

- Guidelines for Pharmacists on PBS Brand Substitution which provide advice to support and assist pharmacists in relation to brand substitution.[20]

3.9. Further, members are required to ensure they supply, distribute and market their products according to all applicable legislative requirements including the TG Act and the TPA.[21]

Relationship with stakeholders

3.10. Members are to take all reasonable steps to ensure that they avoid actual and potential conflicts of interest with healthcare professionals. Their behaviour and relationships with stakeholders must not bring discredit to the generic medicines industry sector, must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste.[22]

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[15] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 6.2.
[16] ibid., clause 6.3.
[17] ibid., clause 6.4.
[18] ibid., clause 6.6.1.
[19] ibid., clause 6.6.3.
[20] ibid., clause 6.7.
[21] ibid., clause 6.5.1.
[22] ibid., clause 6.8.3.

Promotional and marketing activities

3.11. Members must comply with Medicines Australia's Code of Conduct to the extent that it applies to promotional material of prescription medicines as a condition of registration on the ARTG.[23]

3.12. Members will also consider other relevant codes such as the Australian Self-Medication Industry, Ausbiotech Code of Conduct, the Medical Technology Association of Australia Code of Practice, to the extent that they relate to promotional material with respect to a product.[24] To the extent that there is an inconsistency between codes, the GMiA's Code is to have priority.[25]

3.13. All claims made in promotional and marketing materials must be balanced, not misleading, and substantiated. Complaints about a member's promotional and marketing material may be made to the Complaints Committee for consideration.[26]

3.14. Members may host or sponsor educational events held with the purpose of expanding the knowledge of healthcare professionals. Such events must not bring the sector into disrepute or reduce public confidence in the industry. Members are required to report on educational events provided to healthcare professionals responsible for prescribing medicines.[27]

3.15. Members will ensure that their employees involved in promotional or marketing activities are fully trained and informed of their responsibilities under the Code and all relevant laws, guidelines and codes.[28]

Research and regulatory activities

3.16. Members will conduct all research and development activities in compliance with the TG Act, established medical guidelines, scientific principles and ethical requirements for clinical and pre-clinical experimentation and in accordance with the principles of Good Clinical Research Practice.[29]

Clause 7 – Stakeholder awareness

3.17. The GMiA and members shall raise awareness and understanding of the Code amongst stakeholders and the general public,[30] and encourage the appropriate use of generic medicines.[31]

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[23] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 6.9.2.
[24] ibid., clause 6.9.3.
[25] ibid., clause 12.1.18.
[26] ibid., clause 6.9.5.
[27] ibid., clause 6.9.6.
[28] ibid., clause 6.9.8.
[29] ibid., clause 6.11.1.
[30] ibid., clause 7.1.
[31] ibid., clause 7.2.

Clause 8 – Code awareness by members

3.18. Members are to ensure that their employees, contractors and agents fully understand their obligations under the Code and comply with the Code. Members must provide on-going training and ensure that their employees, contractors and agents avoid actual or potential conflicts of interest in their dealings with healthcare professionals.[32]

Clause 10 – Educational event reporting

3.19. Members recognise that the promotional activities of pharmaceutical companies can affect the way healthcare professionals make decisions in relation to the prescribing and dispensing of generic medicines.[33]

3.20. In the context of generic medicines, it is the prescriber who, on behalf of the patient, selects the appropriate treatment which may be a generic medicine.[34]

3.21. In relation to any educational events provided to healthcare professionals members must observe the following principles:

- The purpose of all educational events must be to provide current and relevant medical information to healthcare professionals.
- The member must be satisfied there is a genuine need for the event.
- The name of the member which is funding the event must be clearly disclosed to all potential participants in any marketing material prior to the event being held.
- The cost of the event must not be disproportionate to the value to be gained by participants from the educational content of the event.
- At least 75% of the scheduled conference time must be devoted to the provision of educational content.
- Members must not pay for meals, accommodation or travel for any relative or associate of a participant at an educational event.
- Members must take all reasonable steps to minimise the cost of educational events, for example by charging participants a registration fee, by selecting less expensive conference facilities or by conducting events in major cities rather than in remote areas.
- Delegates at educational events must not be paid for their attendance unless they have an additional role at the event such as presenting a paper or acting as MC.[35]

3.22. Members will provide a report to the GMiA on all educational events for healthcare professionals who prescribe prescription medicines which are held or sponsored by the

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[32] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 8.1.
[33] ibid., clause 10.1.
[34] ibid., clause 10.2.
[35] ibid., clause 10.2.

members by completing the table below. The table requires the costs associated with any hospitality such as food, beverages and entertainment, to be reported.

Reporting of Educational Events template

Summary of events sponsored by [insert Member name]

Reporting Period: [insert reporting period]

Description of event	Venue	Description of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of event
	Specify location	Specify professional expertise of attendees	Include food, beverages, accommodation, entertainment, travel etc			
One row per event						

3.23. Each member will be required to report twice a year for time periods 1 April to 30 September and 1 October to 31 March in each year within two months of the end of each six-month period.[36]

3.24. Reports will be forwarded to the independent reviewer who will assess each report for compliance with the Code. The independent reviewer will refer any particular event which does not comply with the guidelines to the Complaints Committee.[37]

3.25. The GMiA will publish the educational event reports on its website within four months of each period.[38]

Clause 11 – Internal complaints handling

3.26. Each member will implement an internal complaints handling system to deal with complaints from consumers and healthcare professionals which is consistent with the relevant Australian Standard[39] and which adopt the following guiding principles:

- visibility
- accessibility
- responsiveness

[36] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 10.3.
[37] ibid., clause 10.4.
[38] ibid., clause 10.5.
[39] *Consumer Satisfaction – Guidelines for complaints handling in organisations* – AS ISO 10002 -2006.

- objectivity
- cost
- confidentiality
- consumer focused approach
- accountability and
- continual improvement.[40]

3.27. If a complaint cannot be resolved through the internal complaints handling system, the member will advise the complainant of their right to complain to the Complaints Committee.[41]

3.28. The members' internal complaints handling system is intended to be the first option available to stakeholders who have a complaint. If the Complaints Committee receives a complaint which has not initially been referred to the relevant member, the GMiA will recommend to the stakeholder to utilise this system in the first instance.[42]

Clause 12 – External complaints handling system

3.29. The primary mechanism for complaints handling is through the Complaints Committee. Complaints are to be made in writing to the GMiA.[43] The name and contact details of the complainant must be provided in order to avoid frivolous complaints and to ensure that complaints are not being made on behalf of another group without the identity of that other group being disclosed. The Complaints Committee is not required to consider complaints which do not provide this information.[44]

3.30. Complaints made by consumers, healthcare professionals and government are free of charge. Complaints made by industry representatives are subject to a $5000 fee.[45]

3.31. Complaints are dealt with as follows:

- Upon receipt of a complaint, the CEO of the GMiA or delegate shall acknowledge the complaint in writing within ten business days of receipt.[46]
- The member company the subject of the complaint will be given full details of the complaint and will have 15 business days to state whether the information supporting the complaint is correct and provide a response if deemed necessary to the GMiA secretariat. The secretariat will forward the response to the complainant within ten days.[47]

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[40] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 11.1.3.
[41] ibid., clause 11.1.4.
[42] ibid., clause 12.1.2.
[43] ibid., clause 12.1.4.
[44] ibid., clause 12.1.5.
[45] ibid., clause 12.1.6.
[46] ibid., clause 12.1.7.
[47] ibid., clause 12.1.8.

- The respondent and complainant will provide the GMiA with all information necessary for the Complaints Committee to consider the complaint.[48] The Complaints Committee will be provided all information within 15 business days from the member's response to the complaint.[49]

- The Complaints Committee will endeavour to convene within 40 business days of receiving information about a complaint from the GMiA Secretariat.[50]

- The Complaints Committee will prepare a short summary of the decision reached, including reasons, and any proposed sanctions to be imposed.[51] The decision will be provided to the complainant and respondent will be notified of the decision within five business days of the Complaints Committee making its decision.[52]

- Further submissions may be made within ten business days of the decision.[53] A Final Decision will be made taking into account any further submissions.[54] The decisions made by the Complaints Committee will be forwarded to complainant, respondent and the Board of the GMiA within 15 business days.[55]

- The respondent and complainant have a right to appeal the Complaints Committee's Final Decision.[56] Any appeal will be heard by a newly formed Complaints Committee to be known as the Appeal Complaints Committee.[57] The Appeal Complaints Committee is to convene within 40 business days of the date of lodgement of the appeal and will consider the matter on a de novo basis.[58]

3.32. All information pertaining to the complaint is required to be kept confidential until the complaint is deemed finalised.[59] Decisions by the Complaints Committee to uphold a complaint will remain confidential until all appeal procedures and outcomes are exhausted.[60]

3.33. Final Decisions will be published on the GMiA website within 30 business days following the resolution of any Complaints Committee proceeding or appeal.[61]

3.34. The Complaints Committee is comprised of 8 members as follows:

- an independent chairperson who must be legally trained and have experience in trade practices law

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[48] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 12.1.10.
[49] ibid., clause 12.1.11.
[50] ibid., clause 12.1.17.
[51] ibid., clause 12.1.19.
[52] ibid., clause 12.1.20.
[53] ibid., clause 12.1.20.
[54] ibid., clause 12.1.21.
[55] ibid., clause 12.1.23.
[56] ibid., clause 12.1.24.
[57] ibid., clause 12.1.25.
[58] ibid., clause 12.1.26.
[59] ibid., clause 12.1.9.
[60] ibid., clause 12.1.28.
[61] ibid., clause 12.1.29.

- a consumer representative
- a pharmacy representative
- a medical representative
- three representatives from member companies including a representative from the GMiA Board and wherever possible including individuals providing expertise in the disciplines of marketing, science and law. Company representatives are appointed on an ad hoc basis at such times that the Complaints Committee is required to convene. Company representatives must declare any conflict of interest before their ad hoc appointment to the Complaints Committee by means of reviewing the agenda for the meeting prior to accepting the position. The GMiA will endeavour to appoint company representatives from different companies as far as possible
- an observer nominated by the TGA.[62]

3.35. A quorum of six members of the Complaints Committee or Appeals Complaints Committee is required of which at least four members have to be independent representatives.[63]

3.36. There will be alternative representatives nominated for the Complaints Committee in the event that a member of the Complaints Committee has a conflict of interest. The power to identify alternate members only applies to independent representatives and not company representatives.[64]

3.37. Members are appointed for a period of three years.[65]

3.38. In assessing a complaint, the Complaints Committee will have due regard to other industry codes. Where there is an inconsistency between codes, the GMiA's Code is to have priority.[66]

Clause 13 – Independent reviewer

3.39. The independent reviewer will be appointed by the GMiA Board to review the educational event reports submitted by each member to determine whether any events potentially breach the Code.[67] The independent reviewer must be legally trained and have experience in trade practices law.[68]

3.40. The independent reviewer will also conduct spot audits of member's marketing and promotional material to determine compliance with the Code. The independent

[62] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 12.1.13.
[63] ibid., clause 12.1.14.
[64] ibid., clause 12.1.15.
[65] ibid., clause 12.1.16.
[66] ibid., clause 12.1.18.
[67] ibid., clause 13.2.
[68] ibid., clause 13.7.

reviewer will request copies of marketing and promotional material from members in relation to particular products on two separate occasions each year.[69]

3.41. The independent reviewer may refer educational events or promotional or marketing material to the Complaints Committee. Prior to doing so, the independent reviewer is to prepare a short note outlining his/her concerns with the event or material to be provided to the Complaints Committee.[70]

3.42. The independent reviewer is also required to prepare a short report each year on:

- the level of compliance by members with the educational event reporting obligations under the Code
- a description of the matters he/she has referred to the Complaints Committee and
- any suggested changes to the educational event reporting system which may enhance its effectiveness or transparency.[71]

3.43. The report will be available on the GMiA's website and will be distributed to interested parties.[72]

Clause 14 - Sanctions

3.44. The Complaints Committee may impose sanctions where a breach of the Code is found. The Complaints Committee can direct a member to take immediate action to discontinue or modify any practice or recall and destroy any offending material which it considers is in breach of the Code or any relevant laws, guidelines or codes. The Complaints Committee may also require a member to publish corrective letters or advertising and/or require staff and contractors to undertake further training and has the power to impose fines. [73]

3.45. The Complaints Committee may impose the following fines for various breaches of the Code:[74]

Breach	Fine
Minor breach	Nil
Moderate breach	$20 000
Severe breach	$40 000
Repeat breach	$50 000
Serial breach	$75 000

[69] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 13.3.
[70] ibid., clause 13.5.
[71] ibid., clause 13.9.
[72] ibid., clause 13.10.
[73] ibid., clause 14.2.1.
[74] ibid., clause 14.2.1

Clause 15 – Code administration

3.46. The Code Administration Committee, which is comprised of an independent chairperson, the CEO of the GMiA, a representative of the Board of the GMiA and a member representative with legal expertise, will meet at least annually.[75]

3.47. It will use all reasonable endeavours to ensure the successful implementation and ongoing effectiveness of the Code[76] and it will prepare an annual report for the GMiA Board on the effectiveness of the Code which will be available on the GMiA website.[77]

Clause 16 – Annual report and ongoing review

3.48. The GMiA Board will provide an annual report on the operation of the Code containing:

- a summary of complaints and the decision in relation to each of those complaints and
- a summary of the monitoring activities conducted by the independent reviewer.[78]

3.49. The annual report will be available on the GMiA's website and will be distributed to interested parties.[79]

3.50. The GMiA Board will review the operation and effectiveness of the Code at least every five years[80] and will encourage ongoing dialogue, consultation and review of the Code during the life of the Code.[81]

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[75] Generic Medicines Industry Association, *Code of Practice March 2010 2nd edition*, clause 15.1.1.
[76] ibid., clause 15.1.3.
[77] ibid., clause 15.1.6.
[78] ibid., clause 16.1.
[79] ibid., clause 16.2.
[80] ibid., clause 16.4.
[81] ibid., clause 16.3.

4. Submissions received by the ACCC

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

4.2. The **GMiA** submits that its focus and competitive environment is very different to members of Medicines Australia, which primarily seeks to establish the comparative safety and efficacy of a new medicine within the existing treatment pathway, to maximise health outcomes. For example:

- For each individual medicine sold, GMiA members have multiple competitors selling a product that have equivalent quality and therapeutic performance characteristics.
- For each individual medicine sold, Medicines Australia members have no direct competitors for the period of the patent.
- The primary goal of GMiA members is to convince the pharmacist to dispense a particular brand of generic medicine, after the decision to prescribe a particular therapeutic agent has been made by the prescriber.
- The primary goal of Medicines Australia members is to convince the prescriber to prescribe their therapeutic agent for a particular illness or condition.
- 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.
- The primary selling point for a Medicines Australia member is the safety and efficacy of their medicine in comparison to other therapeutic choices.
- GMiA members supply medicines across the supply channel; from open schedule in retail stores, through pharmacy only to prescription medicines.
- Medicines Australia members generally only supply prescription medicines.

4.3. The ACCC sought submissions from 66 interested parties potentially affected by the applications, including industry bodies and government departments. A summary of the public submissions received from interested parties follows:

- **ACT Health** supports the principles underpinning the development of the Code.
- The **Australian Medical Association (AMA)** submits there are substantial healthcare benefits arising from the Code including from reporting expenditure on educational events, providing complaints handling mechanisms and independent review processes.

  However the AMA submits that community pharmacy has a pecuniary interest in dispensing a particular medicine and the public needs to be confident that

pharmacists are dispensing in the best interests of patients. Loyalty programs which reward pharmacies with gifts in exchange for dispensing the company's generic drugs interferes with the professional obligations of pharmacists to remain impartial about their dispensing decision.

The AMA submits the Code should be strengthened to require generic member companies to report on expenditure on educational events provided to all healthcare professionals, not just those provided to prescribers.

- The **Consumers Health Forum of Australia (CHF)** supports the development of the Code. However the CHF submits that as the decision to provide a generic medicine is often made by the dispensing healthcare professional, rather than the prescribing healthcare professional, the educational event reporting requirements should be extended to include events hosted for the dispensers of medicines.

  The CHF notes that brand substitution has the potential to increase adverse effects if appropriate supporting information is not provided.

  The CHF questions whether there is a need for an internal complaints handling process and considers that the external complaints handling system is a more appropriate forum for hearing complaints against GMiA members. The CHF also submits that the level of sanctions may be too low and may not discourage breaches of the Code.

  The CHF notes there are discrepancies between the Code and various other industry codes and suggests that a single code of conduct for therapeutic goods would address the inconsistencies.

- The **Pharmaceutical Society of Australia (PSA)** submits the Code will have minimal detriment to competition and to the public. The PSA believes it is appropriate for there to be a complementary but separate Code for the generic medicines industry sector.

- The **Pharmacy Guild of Australia (the Guild)** considers the Code will be effective in monitoring and regulating the conduct of GMiA member companies and it will result in the following public benefits:

  - commitment of GMiA members to a system of best practice self regulation
  - commitment of GMiA members to the ethical supply of generic medicines to the Australian community in compliance with applicable laws and standards
  - introduction of internal and external complaints handling systems, educational event guidelines and reporting requirements
  - establishment of an independent disciplinary Code Complaints Committee.

- The **Royal Australasian College of Physicians (RACP)** supports the development of the Code however submits there are some areas which require improvements. In particular, the RACP considers the educational event reporting requirements should be extended to include events held for pharmacists.

The RACP submits that brand substitution can have substantial negative effects as the differing size, shape and colour between brands can produce patient confusion, compliance problems and other negative health outcomes.

The RACP is concerned about the possibility that a pharmacist may change a patient's generic brand purely as a result of industry promotional activities, discounting and reward schemes.

The RACP would like the GMiA to provide more specificity regarding the operation of some of the clauses in the Code, for example clause 6.8.4 which requires 'members to take all reasonable steps to ensure their behaviour does not lead to actual or potential conflicts of interest…or impede the independence of healthcare professionals or their professional judgement.'

The RACP further submits that the level of fines should be increased and there should be greater transparency around what the GMiA intends to do with the fines collected. The RACP considers the internal complaints handling process should be removed as it will increase time delays.

- **Medicines Australia** considers that the GMiA's Code does not set an equivalent standard to the Medicines Australia code and will not be as effective in regulating company behaviour as Medicines Australia's code. Medicines Australia submits the unequal standard of ethical conduct results in a public detriment.

  Medicines Australia submits there are principal areas where the GMiA's Code will not be sufficiently effective in regulating the conduct of its members, including:

  - Inadequate transparency around the relationship between generic pharmaceutical companies and healthcare professionals. Medicines Australia submits that educational event reporting should be extended to include events hosted for healthcare professionals who dispense medicines. Further, the provision of entertainment at educational events should be prohibited. Medicines Australia also submits that the GMiA should publish its reporting tables within the same timeframe as Medicines Australia publishes its tables so that consumers have access to all the information at the same time.

  - The timing provided in the external complaints system is too long.

  - The identification of the complainant's identity in the internal complaints handling system may deter complaints being made by consumers.

  - The financial sanctions are significantly lower than the financial sanctions available under Medicines Australia's code. Medicines Australia submits the low level of fines undermines the Code's effectiveness in deterring companies from breaching the Code.

  - The material reviewed by the independent reviewer is limited in scope.

  - The GMiA's annual report should be publicly available on the internet.

- **Dr Ken Harvey** supports the development of a code regulating generic pharmaceutical companies, however considers the GMiA Code to be weaker than Medicines Australia's code and the Australian Self-Medication Industry code. Dr Harvey considers certain provisions could be strengthened, in particular extending educational events reporting to events aimed at pharmacists, increasing the level of fines and consideration as to whether an internal complaints handling process is necessary.

  Dr Harvey notes that Australia has a complex co-regulatory system for therapeutic claims and promotional practices. Dr Harvey submits an overarching, principles-based code applicable to all therapeutic claims and promotional practices will resolve this issue.

- **NSW Health** submits that while it could be argued that if the Code places restrictions on the way in which educational events are conducted it will lessen competition between members for attendance at their events, the general benefits of a code which sets high standards of behaviour and sanctions for non-compliance outweigh any significant detriment to competition.

  NSW Health also submits that the Code has the potential to provide health and financial benefits to the public through the responsible promotion of generic medicines.

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

5. ACCC evaluation

5.1. The ACCC's evaluation of the GMiA's Code is in accordance with tests found in:

- section 90(8) of the TPA which states that the ACCC shall not authorise a proposed exclusionary provision of a contract, arrangement or understanding, unless it is satisfied in all the circumstances that the proposed provision would result or be likely to result in such a benefit to the public that the proposed contract, arrangement or understanding should be authorised.

- sections 90(6) and 90(7) of the TPA which 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.

- sections 90(5A) and 90(5B) of the TPA which state 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.

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

Area of competition

5.3. The first step in assessing the effect of the conduct for which authorisation is sought is to consider the relevant area of competition affected by that conduct.

5.4. The GMiA submits that the relevant market, for the purpose of its applications for authorisation, is the market for the supply of generic medicines in Australia.

5.5. The GMiA submits there are three types of suppliers of prescription medicines following the end of patent protection on the originator brand:

1) The supplier of the originator brand who continues to market the brand of the medicine that had protection of the patent post the introduction of generic competition.

2) Companies who supply predominantly only generic medicines and do not routinely engage in the development and commercialisation of new medicines.

3) Companies who routinely engage in the development and commercialisation of new medicines and may also supply generic versions of medicines where the company did not supply the medicine when the medicine was under patent.

5.6. The GMiA represents companies that fall into the second category. The GMiA submits that its members focus on delivering a selection of products contributing to the affordability of medicines, rather than promoting an individual medicine or engaging in the development and commercialisation of new medicines. As such, the GMiA submits that its members operate in a different competitive environment to originator pharmaceutical companies.

5.7. Medicines Australia submits that the relevant market should not be narrowed to the supply of generic medicines. Medicines Australia submits that its members supply medicines covered by a patent as well as medicines for which the patent has expired. Medicines Australia submits that when the patent for a medicine has expired, the medicine is subject to competition from competing bioequivalent generic products.

5.8. The ACCC accepts that not all prescription medicines are substitutable for one another and considers there are likely to be individual product markets for different types of drugs. The ACCC recognises that some originator medicines will be covered by a patent such that GMiA members are not able to manufacture and distribute a generic version of the drug for the patented period. Once the patent has expired, both originator and generic companies may compete in each product market and there may be one or many generic alternatives of a medicine.

5.9. The price of prescription medicines are subsidised by the government. The price to which prescription products are subsidised is negotiated by the government through the PBPA. All products which have been classified as providing the same health benefits are subsidised to the same level (see paragraph 2.14). Further, the government's price disclosure policy requires manufacturers to report to government the prices which the pharmacy pays for the products. The government may use this information to make price adjustments in the PBS schedule (see paragraph 2.16).

5.10. The supply of generic prescription medicines occurs at two levels – wholesale supply to the pharmacist, and the retail supply to the patient.

5.11. The ACCC does not consider it is necessary to precisely define the relevant area of competition for the assessment of the GMiA's Code. However the ACCC notes that the Code aims to provide a set of principles underpinning the ethical supply of *generic* pharmaceuticals to the Australian community in compliance with applicable laws and standards.

5.12. The following characteristics are relevant to the consideration of the wholesale supply of generic pharmaceuticals to pharmacists:

- Generic companies operate at the market entry point when an originator drug comes off patent.
- Generic medicines must be approved by the TGA before they can be sold in Australia. The product must be demonstrated to be bioequivalent to the originator drug.
- Generic pharmaceutical companies may manufacture a suite of medicines under their brand name.
- Generic manufacturers compete to supply products to pharmacists. Pharmacists tend to stock the originator brand and one bioequivalent generic brand for most products. Generic manufacturers compete through volume discounts and loyalty schemes to have pharmacists supply their products.

5.13. The following characteristics are relevant to the consideration of the retail supply of pharmaceutical products to the patient:

- The sale of prescription medicines is dependent upon the prescribing decisions of a health practitioner. A patient cannot purchase a prescription product without a prescription and the pharmacist cannot dispense a prescription product without the prescription.
- Where generic versions of a medicine exist, the pharmacist is able to substitute the prescribed brand for a generic one as long as the medical practitioner has not indicated that brand substitution is not permitted. It is the consumer's choice about whether to purchase the generic brand.
- There is potential for price competition by pharmacists on prescriptions up to the maximum co-payment level set by government.

The counterfactual

5.14. The ACCC applies the 'future with-and-without test' established by the Australian Competition Tribunal to identify and weigh the public benefit and public detriment generated by conduct for which authorisation has been sought.[82] 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. This requires the ACCC to predict how the relevant markets will react if authorisation is not granted. This prediction is referred to as the 'counterfactual'.

5.15. The GMiA submits that in the absence of the Code there would be:

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

- no voluntary mechanism within the generic medicines industry for members to enforce the standards of conduct set out in the Code
- no requirement for the adoption of internal compliance procedures by members which complies with the relevant Australian standard
- no guidelines binding members in relation to the sponsorship of educational events
- no external regulatory system in place to constrain the conferring of benefits on healthcare professionals by members
- no mechanism for the imposition of sanctions on members for breaching the Code and
- no independent review function in relation to educational events and the marketing and promotional material of members.

5.16. Medicines Australia accepts that the counterfactual may be a situation where the GMiA Code does not exist. However, Medicines Australia submits that in the absence of the Code, GMiA members would be able to voluntarily comply with the provisions of the Medicines Australia code. In this situation Medicines Australia submits that all suppliers of prescription medicines would comply with the same set of rules and regulations on a level playing field.

5.17. The ACCC considers that in the absence of authorisation it is unlikely that the GMiA and its member companies would choose to enforce the voluntary standards in the Code due to the risks under the TPA. The ACCC also considers it unlikely that GMiA members would choose to voluntarily adopt Medicines Australia's code particularly given that, to date, no GMiA members have chosen to do so.

5.18. The ACCC notes that the Parliamentary Secretary for Health has recently issued a position paper on the promotion of therapeutic goods in which the government called on all parts of the therapeutic goods industry to work together to develop high-level principles as the basis for their codes of conduct.[83] The paper outlines the government's expectation that such principles will ensure that the relationship between healthcare professionals and the therapeutic goods industry are appropriately regulated to minimise the possibility of undue influence in the decisions of healthcare professionals to prescribe, dispense, supply or purchase products and to ensure that independent medical decision-making is maintained.

5.19. While the government supports the strengthening of self regulation, the position paper indicates that if consistent high-level principles are not realised, legislative options consistent with the government's policy objectives could be put in place in 2012.

[83] The Hon Mark Butler MP, Parliamentary Secretary for Health, *Position Paper on the promotion of therapeutic goods*, 30 June 2010.

Consistency of codes in the therapeutic goods industry

5.20. Interested parties have raised concerns that there are inconsistencies between various industry codes in the therapeutic goods sector. A number of industry participants argue that these inconsistencies result in an unequal playing field between different sectors of the industry. Indeed, Medicines Australia submits that the GMiA Code does not set an equivalent standard to Medicines Australia's code and submits this results in an unequal standard of ethical conduct set by two codes.

5.21. The CHF, Medicines Australia, Dr Harvey and the RACP have commented on the imbalance and complexity created from having a number of different industry codes applicable to the promotion of therapeutic goods. The CHF, Dr Harvey and the RACP submit that Australia's co-regulatory system is complex and convoluted and could be simplified by creating an overarching principles-based code applicable to all therapeutic claims and promotional practices.

5.22. On the other hand, the Guild submits that the GMiA's Code is a significant step forward in bringing member companies in line with the member companies of Medicines Australia.

5.23. The ACCC notes there are inconsistencies between the requirements in the GMiA's Code and those in other industry codes, in particular Medicines Australia's code. The ACCC has previously said that inconsistencies in the standards expected of different groups within an industry may distort a level playing field.

5.24. The government's position paper supporting stronger self-regulation in the therapeutic goods sector seeks to address the inconsistencies between codes through the development of an industry framework for universal adherence to consistent industry-wide codes based on a common set of high level principles.

5.25. The ACCC notes that the authorisation process is not necessarily the appropriate mechanism to redress inconsistencies between various industry codes. The ACCC assesses any code for which authorisation is sought according to the likely public benefits and detriments flowing from that particular code as required by the statutory tests for authorisation. In doing so, the ACCC may impose conditions.

Public benefit

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

> …anything of value to the community generally, any contribution to the aims pursued by society including as one of its principle elements … the achievement of the economic goals of efficiency and progress.[84]

5.27. The GMiA submits the Code will deliver public benefits, including:

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[84] *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.

- An obligation on members to follow clearly defined educational event guidelines and to report regularly on their compliance with these guidelines.

- A mechanism for the review of educational event reports by an independent reviewer.

- A mechanism for vetting members' marketing and promotional material by an independent reviewer.

- The establishment of an independent Complaints Committee with the power to examine and apply sanctions in relation to inappropriate activities by members.

- A system of co-regulation whereby the Complaints Committee can impose sanctions on members for breaches of the TPA, TG Act and other relevant guidelines and codes.

- New reporting requirements on the financial sponsorship arrangements between members and prescribing healthcare professionals.

- A requirement that members train their employees, contractors and agents about the Code and other relevant laws, guidelines and codes.

- The implementation by members of an internal complaints handling system based on the relevant Australian standard.

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

The Code provides a framework for managing potential conflicts of interest in the relationship between generic pharmaceutical companies and healthcare professionals

5.29. The GMiA advises that the Code provides an overriding obligation on members to ensure that they avoid actual and potential conflicts of interest in their interactions with stakeholders.

5.30. One of the main ways generic pharmaceutical companies and healthcare professionals have a relationship is through educational events.

5.31. The GMiA advises that the types of educational events typically held by members include:

- Medical case reviews which are presented and discussed by medical participants. Unusual or challenging medical cases are presented, evaluated and discussed as a quality improvement tool.

- Journal club meetings which are organised and run by medical practitioners undertaking advanced physician training. Relevant studies or case histories published in medical journals are analysed and discussed.

- Hospital grand rounds which are organised by senior clinicians practising in hospitals. Interesting or challenging case histories are presented and reviewed for quality improvement and educational purposes.

- Organisation and sponsorship of meetings at which senior specialist medical practitioners present on recent advantages in the diagnosis, management and treatment of disease. Presentations may be made that promote particular medicines to medical practitioners.

- Visits to pharmacies to enhance best practice generic substitution techniques, knowledge of generic medicines and bioequivalence, and over-the-counter product knowledge mainly in the field of allergy management.

5.32. The GMiA advises that much of the focus of its members' promotional activity highlights how selection of a generic product can contribute to medicine cost and affordability, rather than promoting an individual medicine.

5.33. The Code sets a framework around the relationship between member companies and healthcare professionals by:

- Providing guidelines for member companies to follow when hosting an educational event for healthcare professionals (see paragraph 3.21).

- Requiring each member company to provide a report to the GMiA disclosing the costs of all hospitality including food, beverages and entertainment provided at educational events held for healthcare professionals who prescribe medicines. The GMiA will post the reports on its website (see paragraphs 3.22 to 3.23).

- Providing for independent review of hospitality reporting. Where the independent reviewer considers an event may have breached the Code, he/she will refer the event report to the Complaints Committee for consideration (see paragraphs 3.24 to 3.25).

- Providing a catch-all provision ensuring that relationships with healthcare professionals do not bring discredit to the generic medicines industry sector. Members are required to take all reasonable steps to avoid conflicts of interest and to ensure that their behaviour does not impede the independence of healthcare professionals or their professional judgement (see paragraph 3.10).

Relationship between generic pharmaceutical companies and prescribers

5.34. An appropriate framework which governs the relationship between generic pharmaceutical companies and prescribers is important as a means to address problems in the principal-agent relationship which can occur in healthcare markets. As noted at paragraph 2.21 there is concern that a medical practitioner's prescribing practices may be inappropriately influenced by the provision of benefits by pharmaceutical companies. This creates a risk that factors not relevant to patient welfare are considered in the treatment options recommended.

5.35. In the most recent assessment of Medicines Australia's code, the ACCC considered 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 may inappropriately influence prescribing practices.

5.36. If not appropriately managed, the offer of hospitality and other forms of benefits provided by pharmaceutical companies to healthcare professionals can result in significant consumer detriment. In this regard, when considering Medicines Australia's code the Tribunal stated:

> In our opinion, unless strictly limited and audited, the provision of financial benefits directly to healthcare professionals by pharmaceutical companies, whether it be by way of hospitality, the cost of travel and accommodation at conferences, sitting fees for advisory committees and other forms of benefits that have been described in the evidence, risks distortion of the medical decision-making processes of healthcare professionals. It may also include the opinion leaders in the field. It is difficult to accept that pharmaceutical companies would go to the effort of providing such benefits if they did not think there was likely to be a positive return.[85]

5.37. The ACCC considered that the reporting requirements in Medicines Australia's code provided transparency around the provision of hospitality to healthcare professionals and served as a disincentive for inappropriate behaviour.

5.38. Consistent with Medicines Australia's code, the GMiA Code requires members to report twice per year on the educational events sponsored by members and the hospitality provided by completing the table which will be submitted to the GMiA for review and placed on the GMiA's website.

5.39. In assessing the GMiA's Code, the ACCC is satisfied that the public reporting of hospitality and entertainment provided by members at educational events for the prescribers of prescription medicines will provide transparency around the relationship. As noted by the AMA, this will provide a degree of comfort that generic medicine companies are not trying to unduly influence healthcare professionals to prescribe, supply or administer a generic medicine. The ACCC considers the reporting requirements constitute a public benefit.

5.40. As noted by Medicines Australia, unlike the Medicines Australia code, the GMiA Code does not explicitly prohibit the provision of entertainment to healthcare professionals at educational events.

5.41. The provision of entertainment for medical practitioners as part of an educational event has been and remains a matter of community concern and the ACCC considers it is difficult to see how such entertainment would not bring the industry into disrepute. However, the ACCC notes that the nature of educational events held by generic pharmaceutical companies for medical practitioners and the venue for such events (see paragraph 5.31) are less likely to involve the provision of entertainment.

5.42. While the GMiA requires the nature and cost of entertainment to be reported under its educational event reporting requirements, the ACCC considers that this type of conduct needs to be closely scrutinised especially in instances where it may undermine public confidence in the healthcare sector. The ACCC would expect that entertainment which is not consistent with the Code, for example by bringing the generic industry into disrepute or reducing public confidence in the industry, would be sanctioned by the GMiA. Should the GMiA seek re-authorisation of the Code, the ACCC would closely

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

scrutinise the types of entertainment reported and how complaints relating to entertainment have been dealt with under the Code.

Relationship between generic pharmaceutical companies and dispensers

5.43. The Code does not impose the same reporting requirements on the provision of hospitality and entertainment at educational events directed at pharmacists by members as those required for educational events held for medical practitioners.

5.44. The GMiA submits that the reason for not extending the reporting requirements to include events held for dispensers is because of the difference in the roles of the medical practitioner in prescribing medicines and the pharmacist in dispensing medicines. This difference is outlined at paragraphs 2.19 to 2.33.

5.45. The CHF, Dr Harvey and the RACP submit that brand substitution can have adverse effects for a patient if not properly explained and confusion can result from the different sizes, shapes and colours that the patient may not be used to.

5.46. A number of interested parties submit that the educational event reporting requirements should be extended to include hospitality at events held for pharmacists as it is the pharmacist who ultimately makes the final decision (by way of electing which generic brand is stocked) about which brand of generic medicine the patient purchases.

5.47. The ACCC accepts that the substitution of a bioequivalent generic drug following appropriate consideration and explanation by a medical practitioner and/or pharmacist is unlikely to create adverse health outcomes for the majority of patients. The ACCC also accepts that the same conflict of interest issues do not arise in the context of pharmacists and their role in dispensing prescription medicines as arises with medical practitioners. Nevertheless, where the pharmacist is able to exercise some influence is through the advice he/she provides the patient about purchasing a generic brand in substitution of an originator brand.

5.48. The ACCC is of the view that transparency around the provision of hospitality to pharmacists at educational events would maintain public confidence that such relationships are able to withstand professional and public scrutiny. This is one of the aims of the Code.

5.49. While the GMiA accepts that greater transparency about the relationship between generic manufacturers and pharmacists would result in a small public benefit from enhancing public confidence that such relationships do not go unscrutinised, the GMiA submits that hospitality reports would not provide any meaningful information to the public about the true nature of the relationship.

5.50. Further, the GMiA considers that extending the reporting requirements to events held for pharmacists will result in significant administrative and cost burden for members which would need to be passed on to patients through increased prices of generic medicines.

5.51. The ACCC accepts that while there may be some administrative burden for members, it is likely to be small given the types of educational events held for pharmacists and the hospitality provided. The ACCC understands that education for pharmacists is usually

carried out as in-store training during business hours, possibly with the provision of light refreshments. Even if the information reported is limited, this is still relevant information as it shows the nature of the relationship and facilitates public confidence in the relationship.

5.52. Therefore the ACCC proposes to impose a condition that the Code be amended to extend the requirement that hospitality provided at educational events for pharmacists be included in the reporting table.

5.53. In the most recent consideration of Medicines Australia's code, the issue regarding the lack of transparency around the sponsorship of pharmaceutical companies to healthcare professionals to attend educational events, including international events, was raised. At the time of granting authorisation to Medicines Australia, the ACCC encouraged the industry to consider these issues with respect to the disclosure and transparency of such sponsorship.

5.54. While the issue of sponsorship of healthcare professionals has not arisen during the ACCC's consideration of the GMiA's Code, the ACCC considers that this is an important issue and is seeking further information about whether generic pharmaceutical companies sponsor healthcare professionals to attend events, how such sponsorship may be regulated under the Code, whether transparency in this area would provide a benefit and how such disclosure might be achieved.

Loyalty schemes and other non-price incentives by generic manufacturers to pharmacists

5.55. Generic drug manufacturers offer a range of discounts, favourable trading terms or other non-price incentives to pharmacists to build loyalty and encourage pharmacists to stock their products. Generating loyalty amongst pharmacists is an important consideration for generic drug manufacturers as pharmacists tend to stock the originator brand and one generic brand (if available). Pharmacists are generally reluctant to change suppliers on a short term basis, particularly as consistency in the selection of brands for patients on long term therapy avoids patient confusion, and efficiencies can be realised from rationalising ordering and delivery arrangements.

5.56. Where generic drug manufacturers compete at the wholesale level through discounts offered to pharmacists it is more likely that these savings will be reflected in the retail price charged by pharmacists to consumers. For example, there are discount pharmacies that advertise themselves as providing significant discounts on certain prescriptions.

5.57. The ACCC also notes that discounts to the pharmacist will be reported to government through the price disclosure requirements which may reduce the cost to government through the PBS (see paragraph 2.16).

5.58. However, the ACCC notes that some generic drug manufacturers offer reward programs and other non-price incentives to generate loyalty among pharmacists. For example, since March 2000, Sigma Pharmaceuticals has offered a rewards program whereby members accumulate points for every dollar spent with the wholesaler. In 2008-09 Sigma Rewards members accrued over 1.3 billion points. These points may be

later redeemed for a range of products or services, including holidays, electronic equipment and tickets to sporting events.[86]

5.59. The ACCC considers that the value of the benefits to pharmacists provided as hospitality, entertainment, gifts and other non-price incentives are less likely to be passed through to the retail level than price discounts. The ACCC considers that increasing transparency around the value of such non-price incentives offered by GMiA members to pharmacists may provide greater incentives for manufacturers to offer price competition and discounting.

5.60. The ACCC proposes to impose a condition requiring the GMiA to require its members to publicly disclose the total value of hospitality, entertainment, gifts and other non-price incentives provided to pharmacists as an incentive for the pharmacist to stock the member's brand of products.

5.61. The proposed condition may also address the potential for loyalty programs to undermine public confidence in the generic medicines industry due to such programs being unregulated and not transparent. Recently, press articles have raised concern about the perception that incentives offered to pharmacists who participate in rewards programs could affect their impartiality and professionalism.[87]

5.62. Further, the RACP, Dr Harvey and the AMA, note concern that industry promotional activities that reward pharmacists for dispensing a company's product interferes with the professional obligations of pharmacists to act in the best interest of patients.

5.63. On the other hand, the GMiA considers that the decisions of pharmacists to stock a particular generic brand do not impact the health outcome for the patient. Further, the decision by a pharmacist to stock a particular brand is a business decision based upon a number of factors, for example, reliability of product supply, patient preferences for particular generic suppliers and the availability of complimentary programs and services for the pharmacy such as the INFORM Medical Information service.

5.64. The ACCC notes that while the GMiA's Code does not specifically refer to loyalty programs, it requires members to take all reasonable steps to avoid actual and potential conflicts of interest with healthcare professionals and that their behaviour and relationships with stakeholders do not bring discredit to the generic medicines industry and must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.

5.65. Whether loyalty programs offered by generic pharmaceutical manufacturers to pharmacists are likely to undermine public confidence in the health sector and bring discredit to the industry in breach of the Code is an issue which should be considered thoroughly by the GMiA.

5.66. Increasing transparency will also assist in maintaining public confidence in the generic medicines sector. Making public the nature and scale of such benefits conferred

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[86] Sigma Rewards website, http://www.sigmarewards.com/Tour/. Accessed 5 July 2010.
[87] E Connors and K Mercer, *ATO targets Sigma chemist rewards*, Australian Financial Review, 19 April 2010, p. 1; G Lekakis, *Concern over drug company 'reward scheme'*, The Daily Telegraph, 24 March 2010; S McKenzie, *Concerns pharma reward scheme may breach code*, Medicine Observer, 16 April 2010.

imposes its own constraint and the companies conferring such benefits will have to be in a position to publicly explain them.

5.67. The proposed condition is designed to capture those non-price incentives such as hospitality, entertainment, gifts and loyalty programs (other than more favourable trading terms such as payment periods and financing), which are not provided in conjunction with the provision of education as these will be reported under the educational event reporting requirements. It is aimed to provide high level information and not specific information about the provision of individual benefits to individual pharmacists.

5.68. The ACCC notes there may be some compliance costs associated with the condition. However as the ACCC proposes to require the disclosure of high level total cost information, it does not consider the compliance costs are likely to be prohibitive. The ACCC welcomes submissions on the disclosure requirements and how compliance costs can be minimised while achieving transparency.

5.69. The proposed condition requires the GMiA to place the material on its website within three months of the end of the reporting period.

The Code sets standards for member companies' promotional and marketing activities

5.70. The Code requires its members to meet certain standards of conduct. The Code:

- requires compliance by generic companies with Australia's National Medicines Policy and Quality Use of Medicines in the development of generic products
- regulates the manufacturing practices of products and the supply and distribution of generic medicines
- requires the establishment of systems and processes to ensure the therapeutic safety of generic medicines
- requires compliance with the PSA's Guidelines for Pharmacists on PBS Brand Substitution
- regulates the promotional and marketing activities of member companies
- requires compliance with product supply guarantee requirements and
- requires compliance with the TG Act in all research and regulatory activities.

5.71. More specifically, clause 6.9 of the Code places obligations on members in relation to the promotion and marketing of generic medicines prohibiting promotional material that does not comply with relevant legislation such as the TG Act, the TG Advertising Code and other legislation, for example the TPA.

5.72. The Code also requires compliance with Medicines Australia's code to the extent that it applies to promotional material as part of the product's marketing approval. Members should consider other industry codes to the extent that they relate to promotional material.

5.73. The GMiA submits that the system of co-regulation established by the Code results in a public benefit as members may be sanctioned by the Complaints Committee for contraventions of the Code, and the Complaints Committee may further sanction member companies for conduct that contravenes the TPA and the TG Act and other relevant legislation, guidelines and codes to demonstrate that the GMiA also condemns such conduct.

5.74. While many of the standards, guidelines and general legislative prohibitions against misleading and deceptive conduct exist with or without the Code, the ACCC notes that having the standards set out in the Code, together with enforcement provisions for contraventions of the Code, reinforces the need for compliance with the Code. The ACCC accepts that public benefit results from having these specific provisions within a self regulatory code.

5.75. As found by the Tribunal in relation to Medicines Australia's code, there are also likely to be transaction costs savings experienced by regulatory agencies associated with investigations and other administrative and judicial processes necessary for the enforcement of statutory regulation, by having an industry body deal with such issues. In this respect, there are benefits from the co-regulatory system.

The Code requires its representatives to be appropriately trained

5.76. The Code places obligations on member companies to ensure that their employees, contractors and agents receive ongoing training on compliance with the provisions of the Code, including standards for high ethical conduct and professionalism.

5.77. The GMiA submits the Code results in a public benefit as, absent the Code, there would be no obligation on members to provide extensive and regular training to their employees, contractors and agents on their obligations under the TPA and TG Act.

5.78. The ACCC considers that internal training 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.

Effectiveness of the Code

5.79. The ACCC considers that the extent to which these public benefits are likely to result depends upon the extent to which the Code regulates the behaviour of member companies through effective enforcement mechanisms.

5.80. As the Code is a newly developed industry Code the ACCC does not have information to determine whether or not it is being effectively enforced. At this point in time, the ACCC can only look to the factors which may assist in its operation and effectiveness.

5.81. The ACCC's consideration of the features which go to the effective enforcement of the Code are discussed below.

5.82. Should the GMiA seek re-authorisation of its Code, the ACCC would seek information as to how the Code has been enforced and whether the GMiA has been effective in regulating the behaviour of its members.

The Code provides complaints processes and enforcement mechanisms

Internal complaints handling system

5.83. The GMiA submits that the implementation by members of an internal complaints handling system, based on the relevant Australian standard, delivers significant public benefit. The GMiA submits the system has been designed to provide appropriate and timely responses to consumer complaints.

5.84. The internal complaints handling system is the first option for stakeholders to make a complaint about a member's conduct. If the complaint cannot be resolved at this level, the complainant may forward the complaint to the Complaints Committee.

5.85. The CHF, RACP and Dr Harvey question the need for complainants to first go through the internal complaints procedure, submitting that the types of complaints being made should more appropriately be dealt with by an external and independent committee. Further, they submit the process will add additional time and complexity to the process which may discourage complainants from continuing with their complaint.

5.86. Similarly, Medicines Australia submits that a consumer may find it daunting to make a complaint directly to a pharmaceutical company. A direct approach to a company does not allow a consumer complainant to keep their identity confidential. Medicines Australia notes that it appoints an independent facilitator to assist consumer complainants.

5.87. The ACCC notes it is not uncommon for an industry code to contain a procedure for complaints to first be considered by the business involved. The ACCC notes that where the complaint is not dealt with to the satisfaction of the complainant there is an opportunity for the matter to be referred to the GMiA.

5.88. However, the ACCC notes that it is important for an internal complaints process to be timely, efficient and accessible to ensure that it does not create an obstacle to raising complaints or accessing the external complaints handling system.

External complaints handling system

5.89. The GMiA submits the establishment of an external complaints handling system will provide consumers, healthcare professionals and other stakeholders with an effective means for addressing complaints against a member with regard to potential breaches of the Code.

5.90. A number of interested parties questioned the independence of the Complaints Committee which consisted of an equal number of independent and member company representatives on the committee. Subsequently, the GMiA amended its Code reducing the number of company representatives and specifying quorum that must be convened before the Complaints Committee can perform its duties.

5.91. The GMiA advises that committee representatives incorporate a range of skills while keeping its size manageable. The GMiA advises that the TGA has nominated a representative to act as an observer on the Complaints Committee. Further, the GMiA has clarified that only independent representatives are able to appoint alternate representatives.

5.92. Medicines Australia was concerned that given there are only five member companies, conflicts of interest may readily arise when dealing with complaints. The GMiA has amended the Code to require company representatives to declare any conflict of interest before their appointment to the committee by reviewing the agenda. The ACCC considers that a conflict of interest would arise where a company representative was appointed to the Complaints Committee where its company was the subject of the complaint.

5.93. Medicines Australia further submits that the delay between receipt of a complaint and corrective action is concerning because subject companies can continue to engage in the conduct which is the subject of the complaint during this time. The GMiA responded that the two-step process – that is providing the opportunity for the complainant and respondent to make submissions following a draft decision before the final decision is made – creates an administrative efficiency in the consideration of complaints. The GMiA advises that it is envisaged that in initial submissions the complainant and respondent can focus their submissions on liability and further submissions can focus on the question of an appropriate sanction.

5.94. The Complaints Committee is able to impose sanctions where a breach has been found including:

- immediate action to discontinue or modify a practice
- requirement to recall and destroy any offending material
- corrective letters and advertising
- requirement for employees, contractors or agents to undertake a course of study or further training on their obligations under the Code, relevant laws, guidelines or codes
- fines.

5.95. A number of interested parties submit that the level of fines are too low and will not deter inappropriate behaviour under the Code. Medicines Australia notes that the GMiA's sanctions are considerably lower than those available under its code (for example, a maximum of $150 000 for a moderate breach, $200 000 for a severe breach and $250 000 for a repeat breach).

5.96. The GMiA advises that the financial sanctions have been set relative to the amount its members spend annually on hospitality. This amount is considerably less than that spent by Medicines Australia members. The GMiA submits the level of fines are aligned with those of other sectors of suppliers of therapeutic goods, for example the Code of the Medical Technology Association of Australia. Further, the GMiA submits that Medicines Australia only increased the level of its fines after the ACCC found that

its code was not being effectively enforced. The GMiA submits that the level of sanctions will be reassessed to ensure that the sanctions are an effective deterrent in future revisions of the Code. The GMiA submits that should the Code be found to be ineffective, it may consider increasing the level of fines.

5.97. The ACCC considers that appropriate sanctions are important for ensuring that a code will act as a deterrent to companies breaching the code. The ACCC notes that the level of fines range from a maximum $20 000 for a moderate breach, $40 000 for a severe breach and $75 000 for a repeat breach. The ACCC notes that the transparency provided by the event reporting requirement will provide information to enable an assessment of the level of fines relative to the amount GMiA members spend annually on hospitality. The ACCC would welcome further information about whether these levels are likely to be sufficient to act as a deterrent to breaching the Code.

5.98. Further, the ACCC considers that negative publicity surrounding the imposition of a fine and other sanctions through public reporting is likely to act as a significant deterrent to breaching the Code. Negative publicity may act as even more of a deterrent than the fine itself.

5.99. The ACCC also notes that some of the clauses in the Code may be open to broad interpretation and the effect of these clauses depends upon how they are administered in practice. For example clauses that require members to 'not bring discredit to the generic medicines industry' or 'conform to professional and community standards of ethics and good taste' are subjective. The GMiA advises these clauses provide a broad power to be used to impose an additional sanction where the member has been found to breach a particular law.

5.100. The ACCC notes that the RACP and Dr Harvey seek further clarification of the operation of such clauses. The ACCC understands that while, at present, it is difficult to anticipate all the types of conduct that might fall under such clauses, over time, the GMiA should be able to provide more guidance as to what types of conduct fall under such clauses.

5.101. The ACCC considers that the composition of the Complaints Committee addresses the potential for misuse of the complaints process. Further, sanctions and fines imposed will be publicly reported providing transparency around the analysis of complaints and the activities of the Complaints Committee. This transparency and public reporting around the imposition of fines and other sanctions helps to ensure that the Complaints Committee is imposing effective and appropriate sanctions.

Independent reviewer

5.102. The independent reviewer (see paragraphs 3.39 to 3.43) will review member reports on their educational events and may refer any event to the Complaints Committee where it considers the event is not consistent with the educational event guidelines. The independent reviewer may also conduct on-the-spot audits of promotional material and will request copies of marketing and promotional material from members in relation to particular products on two separate occasions each year.

5.103. Medicines Australia submits that the material reviewed by the independent reviewer is too narrow and its scope should be increased.

5.104. The GMiA considers that a lesser degree of monitoring of promotional material is appropriate in the generic sector as there is much less scope for making false and misleading claims about generic versions of medicines which have been available and promoted in the market for more than 20 years.

5.105. The independent reviewer will report annually on educational events and the operation of the Code which will be made publicly available on the GMiA's website.

5.106. The ACCC considers the appointment of an independent third party to actively review educational event materials and to conduct on-the-spot audits of member's marketing and promotional materials is likely to assist encouraging compliance with the Code. Where a member is found not to be complying with the Code, the independent reviewer is able to refer the matter as a complaint to the Complaints Committee.

Public reporting

5.107. The GMiA will prepare an annual report on the operation of the Code which will include:

- the Code Administration Committee's report regarding the effectiveness of the code and any recommendations for amendment
- the independent reviewer's report regarding the level of compliance by members with the educational event reporting requirements including a summary of matters referred to the Complaints Committee
- a summary of the complaints received by the Complaints Committee and outcomes of such complaints.

5.108. The annual report will be provided to interested parties and placed on the GMiA's website. This transparency will highlight how the various functions of the Code are operating.

The Code is to be regularly updated after wide-ranging and extensive consultation

5.109. The Code will be reviewed at regular intervals of not more than every five years. The review will include dialogue with industry participants and other stakeholders such as government departments, consumers and healthcare professionals.

5.110. The GMiA will also encourage ongoing dialogue, consultation and review of the Code during the life of the Code.

5.111. The ACCC considers that regular reviews of a code are an effective way to ensure it remains current and up to date with changes in the industry and provides an opportunity for stakeholders to give feedback on its operation. However, the ACCC considers that as the Code is new it is preferable for it to be reviewed earlier than five years (see paragraphs 5.141 to 5.145).

ACCC conclusion on public benefits

5.112. The Code provides a framework for managing potential conflicts of interest in the relationship between healthcare professionals and generic pharmaceutical companies. The Code requires public reporting of all hospitality and entertainment provided to the prescribers of prescription products. The ACCC considers the transparency provided by the reporting requirements will result in a public benefit.

5.113. The Code does not impose similar reporting requirements for hospitality provided at educational events by members to the dispensers of prescription products. The ACCC considers that while the same conflict of interest issues may not arise in relation to pharmacists in their role in dispensing medicines, the pharmacist is able to exercise some influence through the advice he/she provides the patient about purchasing a generic brand in substitution of an originator brand.

5.114. Transparency around the relationship between pharmacists and generic drug manufacturers is therefore desirable to enhance public confidence in the generic medicines sector and maintain faith in the co-regulatory system. Therefore, the ACCC proposes to impose a condition extending educational event reporting to include events for pharmacists as well as medical practitioners.

5.115. The ACCC also considers that increasing transparency around the value of non-price incentives offered by GMiA members to pharmacists as an incentive for the pharmacist to stock the member's brand of products will increase the public benefit from the Code,

5.116. The ACCC considers that increasing transparency around the value of such non-price incentives offered by GMiA members to pharmacists is likely to provide greater incentives for manufacturers to offer price competition and discounting, which may then be passed through to individual consumers. Discounting is also required to be reported to government through the price disclosure requirements which may reduce the cost to government through the PBS.

5.117. Further, making public the nature and scale of such benefits conferred imposes its own constraint and the companies conferring such benefits will have to be in a position to publicly explain them.

5.118. Therefore, the ACCC proposes to impose a condition requiring the GMiA to require its members to publicly disclose the total value of hospitality, entertainment, gifts and other non-price incentives provided to pharmacists.

5.119. The ACCC accepts that public benefits are likely to result from:

- providing a framework for the relationship between generic pharmaceutical companies and healthcare professionals
- setting standards of conduct for member companies' promotional and marketing activities
- requiring appropriate training of company representatives.

5.120. The extent to which these public benefits are realised depends upon the extent to which the Code is complied with and effectively enforced. As the Code is a newly developed code, the ACCC does not have information to determine whether it is being effectively enforced. The ACCC can, however, look to features of the Code which will go to its effective enforcement. These include:

- The establishment of internal and external complaints handling process and an ability for the Complaints Committee to impose sanctions including fines for breaches of the Code
- the establishment of the independent reviewer to review educational event reports
- public reporting of the activities of the Code Administration Committee, independent reviewer and Complaints Committee
- regular Code reviews to ensure the Code keeps up to date with changes in the industry.

5.121. Should the GMiA wish to seek re-authorisation of its Code, the ACCC would seek further information as to how the Code has been enforced and whether the GMiA has been effective in encouraging compliance with the Code.

Public detriment including any anti-competitive detriment

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

> …any impairment to the community generally, any harm or damage to the aims pursued by the society including as one of its principal elements the achievement of the goal of economic efficiency.[88]

5.123. The GMiA considers there is potential for anti-competitive detriment to result from the:

- educational event guidelines which place restrictions on the way in which educational events are conducted by member companies and
- operation of the Complaints Committee which will involve representatives from member companies participating in decisions to impose sanctions against other members.

5.124. Other than in these areas, the GMiA submits that generic pharmaceutical companies compete vigorously.

5.125. The ACCC notes that the Code restricts the ability of GMiA members to compete through the advertising and promotion of their products to healthcare professionals. although, as noted these restrictions in the Code are a means to address concerns that arise from an unregulated relationship between pharmaceutical manufacturers and healthcare providers (see paragraphs 5.29 to 5.54).

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

5.126. The ACCC also notes that the composition of the Complaints Committee addresses the potential for anti-competitive conduct through the misuse of the complaints process by competitors.

5.127. More broadly, while non-price incentives provided by generic pharmaceutical companies to pharmacists may soften price competition, as discussed at paragraphs 5.55 to 5.69, the ACCC considers that the Code itself is unlikely to give rise to significant anti-competitive detriment in the wholesale supply of prescription products to pharmacists.

ACCC conclusion on public detriments

5.128. The ACCC considers that the Code is unlikely to result in significant anti-competitive detriment.

Balance of public benefit and detriment

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

5.130. In the context of applying the net public benefit test in section 90(8)[89] of the TPA, the Tribunal commented that:

> … something more than a negligible benefit is required before the power to grant authorisation can be exercised.[90]

5.131. The ACCC considers the public benefits likely to result from the conduct are:

- providing a framework for the relationship between generic pharmaceutical companies and healthcare professionals
- setting standards of conduct for member companies' promotional and marketing activities
- requiring appropriate training of company representatives.

5.132. The ACCC is satisfied that the Code contains a number of features which are likely to contribute to the effectiveness of the Code and ensure that the public benefits are likely to eventuate.

5.133. The ACCC considers that the Code is unlikely to result in significant anti-competitive detriment as the restrictions in the Code are unlikely to influence the price and supply of generic drugs.

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[89] 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.
[90] *Re Application by Michael Jools, President of the NSW Taxi Drivers Association* [2006] ACompT 5 at paragraph 22.

5.134. Accordingly, the ACCC considers the public benefit that is likely to result from the conduct is likely to outweigh the public detriment. The ACCC is therefore satisfied that the tests in sections 90(6), 90(7), 90(5A), 90(5B) and 90(8) of the TPA are met.

5.135. The TPA allows the ACCC to grant authorisation subject to conditions.[91] Generally, the ACCC may impose conditions to ensure that the net public benefit test is met or continues to be met over the proposed period of authorisation.

5.136. As discussed at paragraphs 5.43 to 5.54, the educational event reporting requirements under the Code require only events for the prescribers of prescription medicines to be reported. The ACCC considers that transparency around the provision of hospitality and entertainment at educational events for pharmacists will assist in maintaining public confidence in the health sector.

5.137. The ACCC considers that the value of the benefits to pharmacists provided as hospitality, entertainment, gifts and other non-price incentives are less likely to be passed through to the retail level than price discounts. The ACCC considers that increasing transparency around the value of such non-price incentives offered by GMiA members to pharmacists may provide greater incentives for manufacturers to offer price competition and discounting, which may then be passed through to individual consumers. Discounting is also required to be reported to government through the price disclosure requirements which may reduce the cost to government through the PBS.

5.138. Further, transparency around the provision of such incentives will assist in maintaining public confidence in the generic medicines sector.

5.139. Therefore, the ACCC proposes to impose the following conditions to increase the likely public benefit from the Code:

> **C1: The GMiA must, on or before the date this authorisation comes into effect, amend the Code so that it extends the educational event reporting requirements in clause 10 of the Code to all Healthcare Professionals (as defined in the Code) regardless of whether a Healthcare Professional prescribes Prescription Medicines or not.**
>
> **C2: The GMiA will require each of its Members to report to GMiA on all hospitality, entertainment, gifts and other non-price benefits (howsoever described) provided to pharmacists (other than more favourable trading terms) by:**
>
> **a. completing the table below;**
>
> **b. providing a copy of completed table for the period 1 April to 30 September and 1 October to 31 March in each year within two months of the end of each six month period; and**

[91] Section 91(3).

Company name:

General description of the benefit	Number of recipients	Value of benefit
Report under the following general descriptions: a) hospitality b) entertainment c) gifts d) other non-price incentives e) loyalty rewards programs	xx	$xx Lump sum figure of the total benefit provided to pharmacists.

c. The GMiA must place the tables provided by each Member on the GMiA website within three months of the applicable period end.

5.140. It is for the GMiA to ensure that it complies with these conditions.

Length of authorisation

5.141. The TPA allows the ACCC to grant authorisation for a limited period of time.[92] The ACCC generally considers it appropriate to grant authorisation for a limited period of time, so as to allow an authorisation to be reviewed in the light of any changed circumstances.

5.142. In this instance, the GMiA seeks authorisation for a period of five years. The GMiA submits that the implementation of the Code for a period of five years will allow the GMiA to collect sufficient data about complaints, referrals made by the independent reviewer and the decisions made by the Complaints Committee in a meaningful way to assess the effectiveness of the Code. Further, the GMiA Board will review the Code at least every five years.

5.143. Medicines Australia submits authorisation should be granted for only three years because:

- the GMiA Code is new and amendments will need to be made when aspects of it do not work and
- the way that generic medicines are supplied in Australia is changing.

[92] Section 91(1).

5.144. The ACCC proposes to grant authorisation for a period of three years. Given that the Code is newly developed, and the broader therapeutic goods industry is currently developing high level principles to be reflected in industry codes following the release of the government's position paper, the ACCC considers it appropriate to review the authorisation of the GMiA's Code after three years of operation.

5.145. Therefore, the ACCC proposes to grant authorisation for a period of three years subject to the condition outlined above. The ACCC considers this period will still give the GMiA sufficient time to analyse how the Code is working and determine whether amendments should be made.

Variations to the Code

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

Interim authorisation

5.147. Section 91 of the TPA allows the ACCC to grant interim authorisation without making a decision on the merits of the application.

5.148. The ACCC will only grant interim authorisation in appropriate circumstances. In many circumstances it is not appropriate to do so because interim authorisation allows an applicant, for a limited period, to engage in conduct before the ACCC has been able to fully assess whether the conduct satisfies the authorisation test.

5.149. On 25 June 2010, the GMiA requested interim authorisation to enable it to deal with a complaint about the conduct of a member company under the Code. Under the Code, complaints are dealt with initially through an internal complaints handling system and then may be referred to the Complaints Committee for consideration. The GMiA advises that it is reluctant to request members of the Complaints Committee to convene to review the complaint without authorisation.

5.150. The CHF and Medicines Australia question the validity of any decision made by the Complaints Committee under an interim authorisation, especially in the event that any final grant of authorisation is subject to conditions, for example where the ACCC concludes the level of fines are too low.

5.151. The National Health and Medical Research Council and ACT Health do not object to the request for interim authorisation. The PSA and Alphapharm support the grant of interim authorisation submitting that the ability for the GMiA to deal with the complaint in a timely manner may result in increased consumer confidence in the self-regulation of generic medicines industry.

5.152. In assessing the request for interim authorisation, the ACCC considers that the Code is likely to result in a public benefit. Interim authorisation will enable the Complaints Committee to convene to commence consideration of the complaint. The ACCC notes that the Code imposes timeframes for dealing with complaints and interim authorisation will enable it to carry out this function while the ACCC is considering the substantive applications. As such the ACCC has decided to grant interim authorisation.

5.153. Interim authorisation will remain in place until the date the ACCC's final determination comes into effect or until the ACCC decides to revoke interim authorisation. The ACCC's decision in relation to interim authorisation should not be taken to be indicative of whether or not final authorisation will be granted.

5.154. The ACCC notes that the proposed condition is not necessary for the grant of interim authorisation as interim authorisation is sought to provide protection so that the Complaints Committee can convene to consider a complaint.

6. Draft determination

The applications

6.1. On 31 March 2010 the Generic Medicines Industry Association (GMiA) lodged applications A91218 and A91219 with the ACCC seeking authorisation of its Code of Practice 2nd edition (Code). On 31 May 2010 the GMiA provided an amended version of its Code.

6.2. Application A91218 was made using Form A Schedule 1, of the Trade Practices Regulations 1974. The application was made under:

- section 88(1A) of the TPA to make and give effect to a contract or arrangement, or arrive at an understanding a provision of which would be, or might be, a cartel provision (other than a provision which would also be, or might also be, an exclusionary provision within the meaning of section 45 of that TPA)

- section 88(1) of the TPA to make and give effect to a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45 of the TPA.

6.3. Application A91219 was made using Form B Schedule 1, of the Trade Practices Regulations 1974. The application was made under:

- section 88(1A) of the TPA to make and give effect to a provision of a contact, arrangement or understanding, a provision of which is, or may be, a cartel provision and which is also, or may also be, an exclusionary provision within the meaning of section 45 of that TPA

- section 88(1) of the TPA to make and give effect to a contract, arrangement or understanding, a provision of which is or may be an exclusionary provision within the meaning of section 45 of the TPA.

6.4. In particular, the GMiA seeks authorisation for its Code of Practice 2nd edition which formalises the commitment of GMiA members to a system of best practice self-regulation and ethical supply of generic medicines to the Australian community in compliance with applicable laws and standards.

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

The net public benefit test

6.6. For the reasons outlined in Chapter 5 of this draft determination, and subject to the condition below the ACCC considers that in all the circumstances the conduct for which authorisation is sought are 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.

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

6.8. The ACCC therefore **proposes to grant** authorisation to applications A91218 and A91219 **on condition that:**

C1: The GMiA must, on or before the date this authorisation comes into effect, amend the Code so that it extends the educational event reporting requirements in clause 10 of the Code to all Healthcare Professionals (as defined in the Code) regardless of whether a Healthcare Professional prescribes Prescription Medicines or not.

C2: The GMiA will require each of its Members to report to GMiA on all hospitality, entertainment, gifts and other non-price benefits (howsoever described) provided to pharmacists (other than more favourable trading terms) by:

a. completing the table below;

b. providing a copy of completed table for the period 1 April to 30 September and 1 October to 31 March in each year within two months of the end of each six month period; and

Company name:

General description of the benefit	**Number of recipients**	**Value of benefit**
Report under the following general descriptions: a) hospitality b) entertainment c) gifts d) other non-price incentives e) loyalty rewards programs	xx	$xx Lump sum figure of the total benefit provided to pharmacists.

c. The GMiA must place the tables provided by each Member on the GMiA website within three months of the applicable period end.

Conduct for which the ACCC proposes to grant authorisation

6.9. The ACCC proposes to grant authorisation to the giving effect to the provisions of the GMiA's Code of Practice 2nd edition for a period of three years.

6.10. Further, the proposed authorisation is in respect 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.

6.11. This draft determination is made on 3 August 2010.

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

Interim authorisation

6.13. On 25 June 2010, the GMiA requested interim authorisation so that the Complaints Committee could convene to consider a complaint made under the Code.

6.14. The ACCC grants interim authorisation to give effect to the provisions of the Code so that the Complaints Committee can convene to consider the complaint made under the Code.

6.15. Interim authorisation will remain in place until the date the ACCC's final determination comes into effect or until the ACCC decides to revoke interim authorisation.

Further submissions

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

Attachment A — the authorisation process

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

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

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

The ACCC conducts a public consultation process when it receives an application for authorisation. The ACCC invites interested parties to lodge submissions outlining whether they support the application or not, and their reasons for this.

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

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

The ACCC then reconsiders the application taking into account the comments made at the conference (if one is requested) and any further submissions received and issues a final determination. Should the public benefit outweigh the public detriment, the ACCC may grant authorisation. If not, authorisation may be denied. However, in some cases it may still be possible to grant authorisation where conditions can be imposed which sufficiently increase the benefit to the public or reduce the public detriment.

Attachment B — chronology of ACCC assessment for applications A91218-A91219

The following table provides a chronology of significant dates in the consideration of the applications by the GMiA.

DATE	ACTION
31 March 2010	Applications for authorisation lodged with the ACCC.
29 April 2010	Closing date for submissions from interested parties in relation to the substantive applications for authorisation.
31 May 2010	Submission received from the GMiA in response to interested party submissions. The GMiA provides amended version of the Code.
25 June 2010	The GMiA requests interim authorisation.
6 July 2010	Closing date for submissions from interested parties in relation to the request for interim authorisation.
16 July 2010	Submission received from the GMiA in response to interested party submissions on the request for interim authorisation.
3 August 2010	ACCC decision regarding interim authorisation and draft determination.

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

Trade Practices Act 1974

Section 90—Determination of applications for authorisations

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

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

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

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

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

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

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

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

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

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

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

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

(ii) the provision were given effect to.

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

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

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

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

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

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

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

(c) the proposed conduct were engaged in;

as the case may be.

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

(8) The Commission shall not:

(a) make a determination granting:

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

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

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

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

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

(b) make a determination granting an authorization under subsection 88(1) in respect of a provision of a contract, arrangement or understanding that is or may be an exclusionary provision unless it is satisfied in all the circumstances that the provision has resulted, or is likely to result, in such a benefit to the public that the contract, arrangement or understanding should be allowed to be given effect to.

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

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

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

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

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

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

Variation in the language of the tests

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

The Australian Competition Tribunal (the Tribunal) has found that the tests are not precisely the same. The Tribunal has stated that the test under section 90(6) is limited to a consideration of those detriments arising from a lessening of competition but the test under section 90(8) is not so limited.[93]

However, the Tribunal has previously stated that regarding the test under section 90(6):

[the] fact that the only public detriment to be taken into account is lessening of competition does not mean that other detriments are not to be weighed in the balance when a judgment is being made. Something relied upon as a benefit may have a beneficial, and also a detrimental, effect on society. Such detrimental effect as it has must be considered in order to determine the extent of its beneficial effect.[94]

Consequently, when applying either test, the ACCC can take most, if not all, public detriments likely to result from the relevant conduct into account either by looking at the detriment side of the equation or when assessing the extent of the benefits.

Given the similarity in wording between sections 90(6) and 90(7), the ACCC considers the approach described above in relation to section 90(6) is also applicable to section 90(7). Further, as the wording in sections 90(5A) and 90(5B) is similar, this approach will also be applied in the test for conduct that may be a cartel provision.

Conditions

The Act allows the ACCC to grant authorisation subject to conditions.[95]

Future and other parties

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

- persons who become party to the contract, arrangement or understanding at some time in the future[96]

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

94 *Re Association of Consulting Engineers, Australia* (1981) ATPR 40-2-2 at 42788. See also: *Media Council case* (1978) ATPR 40-058 at 17606; and *Application of Southern Cross Beverages Pty. Ltd., Cadbury Schweppes Pty Ltd and Amatil Ltd for review* (1981) ATPR 40-200 at 42,763, 42766.

95 Section 91(3).

- persons named in the authorisation as being a party or a proposed party to the contract, arrangement or understanding.[97]

Six- month time limit

A six-month time limit applies to the ACCC's consideration of new applications for authorisation[98]. It does not apply to applications for revocation, revocation and substitution, or minor variation. The six-month period can be extended by up to a further six months in certain circumstances.

Minor variation

A person to whom an authorisation has been granted (or a person on their behalf) may apply to the ACCC for a minor variation to the authorisation.[99] The Act limits applications for minor variation to applications for:

> … a single variation that does not involve a material change in the effect of the authorisation.[100]

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

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

Revocation; revocation and substitution

A person to whom an authorisation has been granted may request that the ACCC revoke the authorisation.[101] The ACCC may also review an authorisation with a view to revoking it in certain circumstances.[102]

The holder of an authorisation may apply to the ACCC to revoke the authorisation and substitute a new authorisation in its place.[103] The ACCC may also review an authorisation with a view to revoking it and substituting a new authorisation in its place in certain circumstances.[104]

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96 Section 88(10).
97 Section 88(6).
98 Section 90(10A)
99 Subsection 91A(1)
100 Subsection 87ZD(1).
101 Subsection 91B(1)
102 Subsection 91B(3)
103 Subsection 91C(1)
104 Subsection 91C(3)