GMiA

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Generic Medicines Industry Association

Applicants response to issues raised in the public consultation process concerning Applications for Authorisation of the Generic Medicines Industry Association Code of Practice

31 May 2010

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A. Introduction

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

This submission, prepared by GMiA, provides further information on the below points as suggested by the ACCC and responds to issues raised in submissions made by interested parties.

Areas where further information would be helpful to the ACCC:

- the healthcare professionals that member companies direct educational events to
- the role of general practitioners in prescribing generic medicines
  the role of pharmacists in dispensing generic medicines
- how the Code addresses:
  - non-compliance by affiliate members
  - actions that 'bring the generic medicines industry into disrepute' (clause 6.9.6)
  - the extent to which members must 'consider other relevant Codes' (clause 6.9.3)
  - ensuring the independence of members on the Code Complaints Committee.

GMiA also refers to the meeting between representatives of the ACCC and GMiA on 25 May 2010. At that meeting, the ACCC asked GMiA to address some additional issues including

- whether a public benefit would arise from an obligation in the GMiA Code of Conduct on members to report on the educational events provided to pharmacists;
- level of sanctions;
- market conditions for generic medicines.

GMiA would like to thank the interested parties who made submissions to the ACCC concerning the GMiA Code of Practice.

The GMiA Code of Practice was developed under the guidance of a Code Development Committee chaired by the CEO of the GMiA. The committee comprised a balance of independent experts with physician, pharmacy and consumer representatives and representatives from member companies with medical and legal expertise.

The GMiA Code of Practice has been circulated to a broad number of stakeholders including direct distribution by GMiA to 40 stakeholders and by the ACCC to 70 stakeholders.

1. Educational events to healthcare professionals

Members of GMiA may provide educational events to community pharmacists, dispensary assistants and pharmacy assistants, general practitioners, cardiologists, geriatricians, allergists, immunologists, physician trainees, small numbers of nurse practitioners and specialist pharmacists. Educational

events may only be directed to non pharmacy staff given the authorisation of the pharmacist in charge.

Members of GMiA typically provide further education to healthcare professionals focused on providing a high level of skill and expertise to safely and effectively switch a patient from one brand to another brand.

Educational programs provided by members of GMiA typically provide training and support to enhance healthcare professionals in best practice generic substitution techniques, knowledge of generic medicines and bioequivalence, and over the counter product knowledge, mainly in the field of allergy management.

Members may also provide other sponsored educational events that may include the provision of hospitality:

- Medical case reviews, which are presented and discussed by the 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 practicing 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 made that promote particular medicines to medical practitioners.
- Provision of travel costs to healthcare professionals to attend relevant ongoing professional education.

2. Role of general practitioners in prescribing generic medicines

Substitution of a different brand of the same medicine by the pharmacist, with consent by the patient, was introduced in Australia on 1 December 1994. This policy has provided significant benefits to the Australian public by making medicines more affordable.

General practitioners are well aware of the long standing policy of brand substitution by the pharmacist. General practitioners are able to tick a box on the prescription in the event that there are medical grounds that the patient should not be switched brands. If the 'no substitution box' is ticked on the prescription, the pharmacist may not switch brands.

3. Role of pharmacists in dispensing generic medicines

The Pharmaceutical Society of Australia produced "Guidelines for Pharmacists on PBS brand substitution" in July 2004. Members of GMiA recognise and advocate the adherence to these Guidelines. A copy of the Guidelines is re-produced in Appendix 1.

For medicines listed on the Pharmaceutical Benefits Schedule, pharmacists may supply an alternative brand of a benefit without reference to the prescriber, providing the patient agrees and the alternative brand is bioequivalent to the brand to be substituted. A generic brand may attract a lower patient co-payment than the originator brand.

The pharmacist is responsible for ensuring that the patient provides consent for the pharmacist to switch brands of a medicine. In the event that the pharmacist and the patient determine that it is appropriate to switch brand, the pharmacist is responsible for ensuring that the patient receives thorough advice about the new brand, including a discussion about the safety and suitability of the new brand.

Consequently, it is the pharmacist to whom GMiA member companies focus their business activities in order to have their generic brands considered as the medicine of choice if substitution at the patient level is to occur.

The nature of the business relation is based on reliability of product supply, patient preferences for particular generic suppliers, the availability of complimentary programs and services (such as INFORM, Medical Information service) and trading terms. The Commonwealth Government policy of price disclosure (see Appendix 2) requires sponsors of generic medicines to disclose the terms of trade to the Government. All relationships recognise the professional standing of pharmacy and their duty of care to the patient.

The following lists the main factors which determine the brand of generic medicine that the pharmacist stocks: 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, additional programs and services provided by the supplier which support the business or professional activities of the pharmacy.

Different pharmacists/pharmacies will place different levels of importance on each of these factors, depending on their business focus. For example, a pharmacist which has greater focus on professional care and service to his patients would value product quality, labelling and packaging, avoiding patient confusion and additional services more highly than more commercial factors.

It is our observation that an individual pharmacy will stock the originator brand and one generic brand (if available) of each medicine. In some instances, a pharmacy may stock two generic brands, but this is becoming less common as the number of patent-expired medicines increase, and as the number of generic medicines expands.

4. Affiliate members

Clause 5.2 of the second edition of the GMiA Code of Practice provides a level of membership to GMiA (known as affiliate membership) for the suppliers of generic medicines to adopt and comply with the Code. This class of membership is designed for suppliers of generic medicines who choose not to be full members of GMiA.

Both full and affiliate members of the GMiA are bound by the Code. As at March 2010 there were five full members of the GMiA, which supply more than 90% of Generic Medicines prescribed through the PBS. There are currently no affiliate members.

GMiA has extended an invitation of full membership or affiliate membership to all other known suppliers of generic medicines in the Australian market, being Sandoz, Ranbaxy, Generic Health, Spirit, PFK, Actavis and Pharmacor. These companies are currently considering the option of joining GMiA either in the capacity of full or affiliate members.

5. Actions that 'bring the generic medicines industry into disrepute'

Clause 6.9.6 is designed to provide the Code Complaint Committee a broad power to impose sanctions against members who engage in seriously illegal or unethical conduct. For example, this provision may be used to impose sanctions on a member which was found to have engaged in corrupt conduct or have entered into an illegal cartel with a competitor.

While such conduct would usually be illegal under other Commonwealth and State legislation, the CCC would have the power under the Code to impose a further sanction to demonstrate that the GMiA also condemns such conduct.

6. Extent to which members must 'consider other relevant Codes'

In discharging its functions under the Code, under Clause 6.9.3 the Code Complaints Committee may consider the terms of any other Codes which it believes are relevant to the conduct under consideration. The Codes which are likely to be considered relevant have been listed in the Code. However, in the event that there is an inconsistency between the terms of the Code and any other relevant Code, the Code is to have priority.

GMiA proposes to include the following sentence at the end of clause 12.1.18 in the Code,

"In the event that there is an inconsistency between the terms of the Code and any other relevant Code, the Code is to have priority".

7. Independence of members on the Code Complaints Committee

In constructing the composition of the members of the Code Complaints Committee (CCC), the Code Development Committee considered the range of skills that would be desirable on such a committee. There is a range of perspectives and disciplines that the CCC may be required to draw on and it was considered important to seek to equip the committee with this range of skill base. A balance of independent committee members was also a key consideration in the designing the committee. Further, it was important to ensure that the size of the committee was manageable.

When the committee was constructed the key representation required was considered to be:

- An independent chairman who must be legally trained and have experience in trade practices law to provide the committee with clear administrative process;
- Representation by key stakeholders considered to be physicians, pharmacists and consumers;
- Technical expertise covering the key disciplines of supplying generic medicines being corporate governance from the Board, marketing, scientific and legal skills drawn from individuals employed within member companies.

The above approach yielded a balance of four independent members and four member company representative members.

GMiA has invited the TGA to nominate a representative on the CCC. The TGA advises that its practice is to nominate observers to industry code complaint committees. The TGA has nominated a representative to act as observer on the GMiA CCC.

It has been suggested that the composition of the committee should favour independent members. GMiA proposes to reduce the number of member representatives from four representatives to three representatives. GMiA proposes to amend clause 12.1.13 as follows

The CCC will consist of eight (8) members:

i. an independent chairperson who must be legally trained and have experience in trade practices law,
ii. a Consumer representative,
iii. a Pharmacy representative,
iv. a Medical representative,
v. ~~a~~three representatives from member companies including a representative from the GMiA Board~~,~~ and wherever possible including individuals providing expertise in the disciplines of marketing, scientific and legal. Company representatives are appointed on an ad hoc basis at such times that the CCC is required to convene. Company representatives must declare any conflict of interest before their ad hoc appointment to the CCC by means of reviewing the agenda for the CCC meeting prior to accepting the position.

GMiA will endeavour to appoint company representatives from different companies as far as possible.

~~vi. a representative from a member company with marketing expertise,~~

~~vii. a representative from a member company with legal expertise, and~~

vi. ~~a representative from a member company with scientific expertise~~

~~viii.~~vii. an observer nominated by the Therapeutic Goods Administration.

It has been suggested that there may be practical implementation difficulties in appointing four member representatives when the membership of GMiA currently comprises five members. GMiA has reduced the number of company representatives on the CCC and GMiA anticipates that its membership may increase in the near future. This will increase the membership base from which GMiA can draw member company representatives for the CCC.

It has been suggested that there should be a specified quorum that must be convened before the CCC can perform its duties. GMiA proposes to include the following clause in the Code,

"A quorum of six members of the CCC or Appeal CCC is required of which at least four members have to be independent representatives".

It has been suggested that it is unclear whether a company representatives can have alternative representatives. GMiA proposes to include the following clause in the Code,

"The power to identify alternative members only applies to independent representatives and not company representatives".

8. Public benefit from reporting educational events to pharmacists

At a meeting between representatives of the ACCC and representatives of GMiA on 25 May 2010, the ACCC asked GMiA to address the issue of whether a public benefit would arise from an obligation in the GMiA Code of Conduct on members to report on the educational events provided to pharmacists.

GMiA believes that, while such reporting would result in a small public benefit, it would also generate a significant public detriment.

The main public benefit which would arise from reporting details of the educational events provided by members of GMiA to pharmacists is that it would provide greater transparency about the relationships which exist between these two groups. To use the words of the Tribunal:

> *355 ...The existence of Code provisions restricting the provision of such (educational event) benefits and the existence of an enforcement mechanism through which complaints can be and are made, is a public benefit in two respects:*

1. *It is likely to give rise to a degree of restraint in the conferral of benefits upon healthcare professionals and, to that extent, to mitigate the detriment or potential for detriment associated with the provision of such benefits.*

2. *It will enhance a degree of public confidence that such conduct does not go unscrutinised and that there is a mechanism by which it can be reviewed.*

Therefore it may be argued that reporting of educational events to pharmacists will confer a public benefit because it will enhance public confidence that such relationships do not do go unscrutinised.

However, the main flaw in this argument is that the reporting of educational events to pharmacists does not tell the public anything meaningful about the true nature of the relationship between generic suppliers and the pharmacists. GMiA believes that pharmacists do not recommend a particular generic medicine to a patient solely because of the provision of an educational event, but rather the decision to select a particular brand is influenced by a range of factors.

The main reasons why a pharmacist will recommend a particular generic medicine to a patient are 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, additional programs and services provided by the supplier which support the business or professional activities of the pharmacy.

Therefore, a broad obligation on generic suppliers to report on educational events to pharmacists will not provide the public with an accurate picture of why pharmacists recommend a particular generic medicine to a patient. The public may gain the erroneous impression from educational event reporting that a particular educational event may have influenced a pharmacist to recommend a particular generic medicine, when in actual fact there were a range of other factors which contributed to that decision.

By contrast, GMiA believes that reporting of educational events for prescribers of medicines does provide a more complete picture of the relationship between pharmaceutical companies and doctors. This is because the role of the doctor is limited to prescribing a medicine and not to the dispensing of that medicine.

GMiA also notes the significant administrative and cost burden that event reporting of educational activities provided to pharmacists would place on its members. The cost of collecting this information would need to be passed onto patients by way of increased prices of generic medicines.

In conclusion, GMiA believes that the provision of incomplete information to the public about the relationship between generic suppliers and pharmacists, in the form of educational event reports, would be misleading and constitute a significant public detriment. GMiA believes that this public detriment would outweigh the limited public benefit which would arise from the reporting of educational events to pharmacists.

9. Sanctions

A number of submissions argue that the proposed sanctions under the GMiA Code of Conduct are too low when compared to the sanctions which currently apply under the MA Code of Conduct. GMiA believes that the sanctions in the GMiA Code should not be compared with the sanctions in the MA Code for two reasons.

First, GMiA has set these proposed financial sanctions by reference to the amount GMiA members spend annually on hospitality. This approach appears to be consistent with the approach which the ACCC applied in the MA Authorisation when discussing the appropriate sanctions:

> 5.110. *The ACCC considers that appropriate sanctions will act as a deterrent to companies breaching the Code. The ACCC notes that the level of the fines have been increased in edition 16 of the Code. Whether these higher levels will act as a deterrent is yet to be tested. The ACCC notes that while the maximum level of fines have increased, fines may still be small relative to the money spent on hospitality by pharmaceutical companies. For example, between January and June 2009, $15.6 million was spent by Medicines Australia members on food and beverages, accommodation and travel expenses associated with educational events.*

GMiA believes that the proposed sanctions in the GMiA Code of Conduct are appropriate when considered in the light of the total amounts spent by GMiA Members on hospitality, as the activity and monies spent by members of GMiA is on a considerably smaller scale as compared to the members of MA.

It is also important to consider the profitability of patented medicines as compared to medicines subject to market competition. The mark up per pack of medicine sold is considerably lower for a generic medicine as compared to a patented medicine, necessarily resulting in considerably lower operating margins for the businesses of members of GMiA.

Second, GMiA believes that the sanctions in the MA Code of Conduct were increased from a lower base due largely to MA's ineffective enforcement of their Code. As stated by the Tribunal:

> ***360*** ***...In our opinion the existing enforcement mechanism (in the MA Code) so far as it relates to these provisions, is weak. It is also open to lenient interpretation. There is little in the way of any real deterrent to contravention or incentive to compliance. There seems to be little incentive or enthusiasm for companies to complain about one another in this area.***

GMiA does not believe that the financial sanctions under its Code should be increased to the same level as those in the MA Code of Conduct simply because the enforcement of the MA Code of Conduct was found to be ineffective in the past. If, after a period of operation, the ACCC finds that the enforcement of the GMiA Code of Conduct has been ineffective, then there would be an argument to increase the level of the financial sanctions under the Code.

10. Market conditions for generic medicines

The Australian market comprises three types of suppliers of generic medicines:

1) The supplier of the originator brand typically continues to market the brand of the medicine that enjoyed the 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; and

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.

GMiA represents companies that supply predominantly only generic medicines and do not routinely engage in the development and commercialisation of new medicines, that is category (2). In addition to introducing market competition upon expiry of valid medicine patents, the presence of a viable generic medicines market provides many further important balances in the market that are not delivered by other suppliers of generic medicines, including:

- An opportunity for Government to set the subsidised price of medicines at a level reflecting the health outcome delivered by that medicine, a fundamental tenet of equal public cost for equal health outcomes.
- A role in ensuring that new technology continues to offer true improvements by delivering better health outcomes.
- A role in discouraging patients from being switched to new and more expensive medicines if they do not deliver an improved health outcome.
- A stimulant to further drug discovery and innovation more generally. Extended or permanent monopolies on pharmaceutical products remove the incentive to discover new medicines and the benefit of patents to the producer of the intellectual property must be carefully weighed against the cost to the public of patents.
- Keeping in check potential activity by sponsors of originator medicines that may inappropriately apply patents on undeserving technology or extend the patent life of their products.

Suppliers of generic medicines compete fiercely. By definition, at market entry of a new generic molecule, all patients will be on the originator brand. Early market entry by the suppliers of a generic medicine is an important predictor of commercial success.

In Australia there are six main suppliers of generic medicines. Table 10.1 presents the market shares of the main suppliers of generic medicines on the Pharmaceutical Benefits Scheme by $ value and volume. There are also a number of smaller companies, data on these companies are not published in the Government publication.

Table 10.1: Main suppliers of generic medicines in the Australian market

Manufacturer	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	Not reported	

Source: Pharmaceutical Benefits Pricing Authority Annual Report for year ended 30 June 2009

Suppliers of generic medicine will provide discounts to the pharmacy sector. The terms of discounting are reportable to the Commonwealth Government. Under the policy of price disclosure the Government will reduce the price listed in the Pharmaceutical Benefits Scheme to a weighted average market price at fixed time intervals. This policy is designed to ensure that benefits of market competition flows to the public. Appendix 2 provides more detail on the price disclosure policy.

11. Additional amendments responding to specific issues raised in the public submissions

Members of GMiA have reviewed the public submissions and felt that there were some worthwhile suggestions that would enhance the Code. As result of the review of public submissions, GMiA proposes to include the following amendments to the Code,

Clause 10.2 (vi): remove the words "in exceptional circumstances" in relation to payments to the relatives or associates of healthcare professional who attend an educational event.

Clause 13.10: "The Independent Reviewer report will be available on the GMiA website and will be distributed to interested parties including Government, peak bodies of Healthcare Professional, peak bodies of Consumer groups and the ACCC".

Clause 16.2: "The annual report will be available on the GMiA website and distributed to interested parties including Government, peak bodies of Healthcare Professional, peak bodies of Consumer groups and the ACCC".

Clause 16.3: "GMiA will encourage ongoing dialogue, consultation and review of the Code with stakeholders during the life of the Code."

12. Application of authorisation to future Members of GMiA Code

GMiA wishes to clarify that it intended the authorisation of the Code of Conduct to extend to parties which may choose to become signatories to the Code of Conduct in the future, but which are not presently identified. These future Members will be companies which are currently engaged, or which may become engaged, in the manufacture and/or supply of generic medicines.

13. Balance of public benefit and detriment

GMiA is submitting a Code of Practice to ACCC for authorisation that seeks an independent review of this Code to achieve the appropriate balance of regulation in the generic medicines sector and the creation of an effective competitive environment. Any additional regulation of the sector may carry an adverse outcome of reduced competition. Thus, any additional regulation must be carefully considered in the context of the overall public benefit and detriment.

Appendix 1: Guidelines for Pharmacists on PBS Brand Substitution

Pharmaceutical Society of Australia

July 2004

Guidelines for Pharmacists on PBS Brand Substitution

These guidelines represent general advice to support and assist pharmacists. It is expected that professional judgement will be exercised in adapting these guidelines to specific presenting circumstances.

Background

Generic medicines

- 'Generic medicines' refer to products which are equivalent to originator brands or innovator products which are no longer protected by patent. 'Generics' may or may not be less expensive than an equivalent product.
- An application for registration of a generic product in Australia generally includes a bioequivalence study versus the originator brand obtained in Australia. A bioequivalence study has the aim of establishing whether two (or more) formulations of the same drug are equivalent in terms of the rate and extent of absorption of the drug (or active moiety) into the systemic circulation.

Pharmaceutical Benefits Scheme

- In 1994, changes were made to legislation to permit pharmacists to substitute generic products for original brand pharmaceuticals if they are listed in the *Schedule of Pharmaceutical Benefits* (the '*Schedule*') as being bioequivalent and able to be substituted, even where the prescription specifies a particular brand. Under the legislation, substitution must not occur if the prescriber has indicated that substitution is not permitted.
- When writing prescriptions under the Pharmaceutical Benefits Scheme (PBS), approved prescribers should indicate on the prescription where brand substitution is not permitted. PBS prescriptions must not be prepared using a default which would result in all prescriptions being indicated as 'brand substitution not permitted'.
- Pharmacists dispensing PBS prescriptions must be familiar with the definitions that apply to brand equivalence under the *Schedule*. Briefly, brands flagged 'a' are bioequivalent or therapeutically equivalent and may be interchanged without differences in clinical effect. Brands flagged 'b' are also equivalent but indicate that it is not known if there is equivalence between brands marked 'a' and those marked 'b'. Note that even if brands are not 'flagged' it cannot be assumed that they are 'not equivalent' since sponsors can request that an indication of equivalence not be shown. Pharmacists should refer to the current edition of the *Schedule* for further information.

Guidelines

- Pharmacy staff should be trained to assist the pharmacist in informing and educating consumers about brand substitution choices. Pharmacists should have systems in place to ensure that all patients (or their carer) have the opportunity to request a generic equivalent before dispensing occurs and that they have access to relevant information about generic medicines and/or brand substitution.
- Brand substitution may only occur after consultation with and agreement of the patient (or the carer), and if the prescriber has not indicated on the prescription, "no substitution", or equivalent.
- Where substitution is allowed and the patient is offered or enquires about alternate brands, the pharmacist and the patient should discuss the safety and suitability of alternate brands for that patient.
- The patient's health should always be the pharmacist's prime consideration in any brand substitution decision. Decisions to substitute one brand for another should not place patients at risk.
- Pharmacists should endeavour to be consistent in the selection of brands for patients on long-term therapy in order to avoid patient confusion. If this is not possible then the patient should be consulted.
- In some circumstances substitution may be 'unavoidable', for example, due to an inability to source a particular brand which is out of stock at the suppliers. Where substitution is allowed, the pharmacist must provide thorough advice (including for example, differences in product presentation) whenever substitution occurs under such circumstances. If, however, substitution has been disallowed by the prescriber, the pharmacist must discuss the matter with him/her.
- Where the prescriber disallows substitution and the patient requests substitution, pharmacists should either discuss the matter with the prescriber or refer the patient back to the prescriber.
- Pharmacists should encourage (or offer to assist) patients to have their medication regularly reviewed to check for duplication of different brands of the same medicine.
- Pharmacists should discuss brand substitution issues with their local prescribers to maintain and improve professional relationships and minimise the chances of any conflict or misunderstanding.

Endorsed by National Council July 2004
(v.1 March 1997; v.2 July 2003)

Resources

1. Commonwealth Department of Health and Ageing. Schedule of Pharmaceutical Benefits — for Approved Pharmacists and Medical Practitioners. *Note:* An electronic version can be accessed at http://www1.health.gov.au/pbs/index.htm
2. Pharmaceutical Society of Australia. Essential CPE: Bioequivalence. Dec 2000.
3. Pharmaceutical Society of Australia. Essential CPE Satellite Lecture Series: Generics — the issues, the debate. Jun 2003.
4. Pharmaceutical Society of Australia. Generic medicines. inPHARMation. Jun 2003.
5. Pharmaceutical Society of Australia. Generic medicines. Pharmacy Self Care Fact Card. Jun 2003.
6. Birkett DJ. Generics – equal or not? Aust Prescr 2003; 26: 85–7.

Appendix 2: Commonwealth policy of price disclosure

In recognition of the discounting occurring between Sponsors and the pharmacy sector, recent amendments to the NH Act legislate that any discounting by Sponsors on products listed on the F2A formulary from 1 August 2007 must be disclosed by the Sponsor to the Government under the price disclosure regime.

Prices of all brands of the medicine subject to price disclosure will be reduced to the calculated Weighted Average Disclosed Price (WADP), if the difference between the current PBS ex-manufacturer price and the WADP is 10% or more. As at 1 August 2009 a total of 119 brands were subject to the price disclosure requirements, however not all brands are required to disclose. For some brands disclosure is at the discretion of the Sponsor.

The recently announced Commonwealth Budget includes proposals to expand the policy of price disclosure to cover approximately 1,600 brands.

Discounts over the year are reported to Government. These data are analysed by Government and any applicable price discounts are reflected as price adjustments in the PBS schedule.

Since the introduction of the price disclosure policy, there have been three rounds of disclosure. Table A.1 sets out the items subject to the price disclosure policy and the resultant price reduction after the first year of the regime. Products denoted with an asterix reflect sponsor voluntary price reductions implemented 1 December 2009; meloxicam denoted with a hash has to date had no price reduction as a possible price reduction initially calculated at 22.46% and subsequently revised to 14.57% remains under discussion; products denoted with a '^' were implemented 1 April 2010.

Price reductions stemming from the price disclosure policy, based on the level of market discounting, is variable and can be significant up to 71.8%.

Table A.1: Items subject to price disclosure policy and resultant price reduction after 1st year of review

Round 1		Round 2		Round 3	
Doxorubicin IV *	63.54%	Fluconazole ^	55.26%	Carvedilol ^	27.29%
Mitozantrone *	34.42%	Vancomycin ^	71.80%	Sumatriptan	0%
Ondansetron *	15.37%	Alendronic	0%	Enalapril	0%
Meloxicam#	0%	Ceftriaxone	0%	Irinotecan	0%
Amisulpride	0%	Naltrexone	0%		
Fosinopril	0%	Octreotide	0%		
Oxybutiynin	0%				
Perindopril	0%				
Valproic	0%				

Appendix 3: Specific issues raised by Medicines Australia

The Medicines Australia (MA) submission to the ACCC in relation to the GMiA Code of Conduct (Code), dated 29 April 2010, directly compares the provisions of the MA code and the provisions of the GMiA Code . GMiA suggests that this approach is erroneous.

The MA code of conduct has been drafted to address issues specific to the introduction of new medicines where there is limited market knowledge of the product. It is entirely appropriate that the new medicines and generic medicines sectors adhere to different codes of practice reflecting the different market conditions including different levels of market understanding of products and different levels of commercial return.

MA's overall approach

A flaw in the approach taken by the MA in its submission to the ACCC is its failure to fully understand the test which the ACCC has to apply in deciding whether to grant an authorisation. MA seems to be under the impression that all Codes of Conduct in the health area must closely resemble its own Code, irrespective of the public detriment which the particular Code is seeking to address. GMiA does not believe that this is the correct approach.

Appearance of regulation and accountability

MA states in its submission that, in its opinion, the GMiA Code as currently drafted is weak. MA then states that the "GMiA Code gives the appearance of regulation and accountability while in reality any regulation is inadequate".

GMiA disagrees with the MA's characterisation of the GMiA Code as giving the "false" appearance of accountability and regulation. It is erroneous to suggest that the GMiA Code does not provide sensible and effective regulation of the conduct of GMiA members in a number of areas, particularly in relation to educational event reporting. The GMiA Code establishes a clear set of educational event reporting guidelines, a Code Complaints Committee and an Independent Reviewer. Each of these mechanisms provides a great deal of accountability and regulation where none existed previously.

While the Code does not duplicate exactly the mechanisms of regulation and accountability which exist under the MA Code, this does not make the Code any less effective.

The GMiA carefully considered the level of public detriment which the GMiA Code was seeking to address, which it considered to be significantly less than the public detriment being addressed under the MA Code.

Transparency

MA complains that the Code is not transparent. In particular, MA states:

> *Specifically, the reporting requirements imposed on GMiA members should be equal to those imposed on members of Medicines Australia, especially in relation to the reporting of educational events for all healthcare professionals, those that prescribe prescription medicines and those that dispense those medicines.*

MA simply states that the reporting requirements of GMiA members and MA members should be the same but provides no reasons for this view. Notably, MA does not refer to the public detriments which the respective Codes are seeking to address.

Further, MA does not provide any explanation of why the decision was made to apply the reporting obligations on its members under their Code extending to all healthcare professionals.

MA seems to be of the opinion that because their Code requires members to report educational events provided to all health care professionals, that other Codes should also impose such a requirement. MA appears to base this view on their reading of the Tribunal's decision. In their submission, MA states:

> *GMiA's interpretation and application of the Tribunal's reasoning to the GMiA Code of Practice is narrow and flawed. (MA) do not consider that the Tribunal's concern was restricted to the provision of benefits to prescribers of medicines.*

GMiA has carefully reviewed the Tribunal's decision and can find no evidence to support the MA's contention that the Tribunal's concerns about public detriment extended beyond the provision of benefits to prescribers of medicines. Of particular relevance are the following observations by the Tribunal (emphasis added):

> *315 In our opinion there is a significant detriment associated with the unrestricted development of non-arms length relationships between pharmaceutical companies and healthcare professionals and particularly those relationships which involve the receipt of benefits by healthcare professionals. The detriment lies in the effect that such conduct may have upon the **prescribing practices** of healthcare professionals directly influenced by it or by the views of professional opinion leaders who have links to particular companies. If the **prescribing practices** of healthcare professionals are influenced directly or indirectly by sympathies for particular products because of benefits derived from or links to the manufacturer or distributor of those products, patient care may be compromised. Patients in need of treatment will not necessarily be provided with that which is best for them. In an indirect sense there is also an anti-competitive detriment to the extent that key decisions in the relevant market may be affected by factors extraneous to the quality of the product and its cost...*
>
> *343 ...It is not controversial to say that the influence on **prescribing practices** which results from the provision of benefits by pharmaceutical companies will not necessarily result in injury to consumers. As already discussed, however, it is difficult to see how the provision*

of benefits to a healthcare professional by a pharmaceutical company can ever be a legitimate consideration or influence in patient decision-making by that professional. Any irrelevant consideration or influence of that kind affecting such decision-making has the potential to result in positive harm or, more likely, less than optimal treatment choices.

361 *The practice of pharmaceutical companies conferring benefits upon healthcare professionals carries with it a risk that* ***prescribing decisions*** *may be affected or influenced by considerations not relevant to patient welfare. It also carries with it a risk of reduced public confidence in the industry and the profession. So far as such practices may affect* ***prescribing decisions*** *there is a species of market failure because such influences are unrelated to product quality or patient welfare.*

It is apparent from these extracts, that the main public detriment which the Tribunal identified concerning the provision of hospitality by pharmaceutical companies to health care professionals was the potential for negative impacts on patient welfare from incorrect prescribing decisions. As stated by the Tribunal, such hospitality may result in:

- patient care being compromised;
- patients in need of treatment not necessarily being provided with that which is best for them;
- positive harm or, more likely, less than optimal treatment choices; and
- prescribing decisions being affected or influenced by considerations not relevant to patient welfare.

These detriments would only arise from the actions of the healthcare professional with responsibility for prescribing particular medicines to patients, and not from decisions by pharmacists to dispense particular generic medicines to patients.

Consultation Process

MA states in its submission that it is not aware of GMiA undertaking a comprehensive consultation or audit process prior to release of its Code. GMiA undertook a level of consultation as was practical for the association and is unaware that it is under any responsibility to undertake the same level of consultation as was performed by MA. GMiA suggests that MA's comments in relation to this issue are irrelevant to the authorisation process.

Lack of equivalent standard to the MA Code

MA complains that the GMiA Code does not set equivalent standards to the MA Code. They also make the following statement:

There is therefore a detriment to competition arising from the unequal standard of ethical conduct set by the two Codes which relate to direct competitors in the market for prescription medicines. This anti-competitive detriment outweighs any potential public benefit arising from

some level of self-regulation being exercised by GMiA members. Moreover, the different ethical standards applying to originator and generic suppliers distorts the operations of a competitive level playing field. This leads to a detriment to competition by providing unfair competitive advantage to one group of companies competing in the same market as another group of companies.

These statements appear to be made without a clear understanding of the authorisation process as well as the historical factors which have lead to the current appellation of the MA Code.

First, the elements of any authorised Code are determined by the public detriment and/or anticompetitive detriment which the Code is seeking to address. Where a Code is seeking to address minimal levels of public or anticompetitive detriment, the standards imposed under the Code will be less onerous. Therefore, the reason the GMiA Code establishes lesser, but nevertheless appropriate, standards than the MA Code, is because the level of detriment which the GMiA Code is seeking to address is minimal and clearly less than the detriment which the MA Code needed to address.

Second, a number of the more onerous obligations included in the MA Code arose as a consequent of the adverse findings reached by the Tribunal in 2007. The Tribunal carefully considered the operation of MA Code and concluded that it was not being enforced effectively. As stated by the Tribunal (emphasis added):

> ***361*** *The Tribunal considers that this is a case in which it is appropriate, if the authorisations are to be granted, to impose conditions to provide an incentive to compliance with the Code provisions relating to the conferring of benefits on doctors. That incentive is best secured by a combination of internal review and evaluation of such benefits and their accessibility to public scrutiny.* ***In our opinion the existing enforcement mechanism, so far as it relates to these provisions, is weak. It is also open to lenient interpretation. There is little in the way of any real deterrent to contravention or incentive to compliance. There seems to be little incentive or enthusiasm for companies to complain about one another in this area.***

In other words, the Tribunal decided to impose conditions on the grant of the authorisation of the MA Code of Conduct because the existing enforcement mechanisms were weak, subject to lenient interpretation and the Code lacked any real deterrent effect.

The GMiA should not be forced to include the more onerous MA Code standards in its Code, simply because the enforcement and application of the MA Code has been found to be ineffective by the Tribunal in the past.

GMiA also rejects MA's claims that different ethical standards will result in anti-competitive detriment by creating an uneven playing field. First, the differences between the two Codes are highly unlikely to have the effect of distorting competition between originators and generic suppliers in any meaningful way.

Secondly, MA members supply generic medicines on an unlevel playing field as the originator medicine has the advantage of a brand name that has been entrenched in the market place for many years. By definition at day one of market entry of the first generic medicine, 100% of patients will be on the branded medicines, and suppliers of generic medicines must provide the market with a reason to switch brands.

The MA submission notes that old medicines may be substituted for old medicines. This can only occur by the physician at the point of prescribing and would only be done in instances where the physician is assured that there will be a better or equivalent health outcome. These instances are likely to be rare as new medicines are typically supported by more marketing and promotional activities by the supplier of the medicine.

Thirdly, it does not make sense to claim that the imposition of new ethical standards on suppliers of generic medicines, where no such standards existed previously, could result in increased anticompetitive detriment. Rather, as a matter of logic, the imposition of these new ethical standards must have the effect making the uneven playing field which MA must believe already exists, more level in the future.

The fundamental issue which MA must acknowledge is that is has made a decision in the past to introduce a number of onerous and possibly unnecessary obligations into its Code. For example, the MA Code creates an obligation on members to report on educational events provided to pharmacists. This obligation was introduced into the MA Code without any explanation of why such reporting was necessary in terms of reducing an existing public detriment. No argument has been put forward to demonstrate that such educational events would result in pharmacists engaging in conduct which would result in patient care being compromised.

Counterfactual

GMiA suggests that MA has misunderstood the purpose of the counterfactual. The test is not to consider what GMiA members "would be able to do" in the absence of the GMiA Code, but rather what is likely to occur in the future. GMiA understands that the balancing test involves the ACCC comparing the public benefit and public detriment generated by arrangements in the future if the authorisation is granted with those generated if the authorisation is not granted.

Members of GMiA would not have put forward the GMiA Code if adoption of the MA Code had presented a sensible alternative.

Insufficient independence of the CCC

MA suggests that the Code Complaint Committee (CCC) is insufficiently independent because the complainant and respondent may make submissions to the CCC about the decision and sanction prior to the CCC issuing its final decision. MA's concern in this regard is not valid.

By creating a two-step process, the GMiA Code simply creates an administrative efficiency in the consideration of complaints. Under the process set out in the GMiA Code, the complainant and respondent are able focus their initial submissions to the CCC on liability and do have to spend additional time addressing the question of the appropriate sanction. This process will make the task preparing, responding to and considering a complaint much less complicated and time-consuming than is currently the case under the MA Code.

GMiA believes that it has addressed other concerns surrounding the independence of the CCC raised by MA via proposed amendments to the Code outlined in section 7 of this submission.

Sanctions

MA argue that the sanctions in the GMiA Code are inappropriate because they are much lower than the sanctions in the MA Code. MA adds that there can be no reason for lower sanctions based on the size or revenue of GMiA Members.

GMiA has not set the proposed level of sanctions with reference to the size or revenue of the GMiA Members. Rather GMiA has set these sanctions by reference to the amount GMiA members spend annually on hospitality and profitability margins. This approach appears to be consistent with the approach which the ACCC applied in the MA Authorisation in considering the appropriate sanctions:

> *5.110. The ACCC considers that appropriate sanctions will act as a deterrent to companies breaching the Code. The ACCC notes that the level of the fines have been increased in edition 16 of the Code. Whether these higher levels will act as a deterrent is yet to be tested. The ACCC notes that while the maximum level of fines have increased, fines may still be small relative to the money spent on hospitality by pharmaceutical companies. For example, between January and June 2009, $15.6 million was spent by Medicines Australia members on food and beverages, accommodation and travel expenses associated with educational events.*

GMiA believes that the proposed sanctions are appropriate when considered in the light of the total amounts spent by GMiA Members on hospitality.

Mandatory review by independent expert of promotional material

MA suggests that the scope of the independent expert's review of promotional material should be the same as the scope of this review under the MA Code. GMiA is of the opinion 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.