29 April 2010

Dr Richard Chadwick
General Manager
Adjudication Branch
Australian Competition and Consumer Commission
GPO Box 3131
CANBERRA ACT 2601

Dear Dr Chadwick,

Re: Generic Medicines Industry Association Pty Ltd applications for authorisation of the 2nd edition of its Code of Practice

Thank you for the opportunity to provide a submission on the application of the Generic Medicines Industry Association (GMiA) to authorise its Code of Practice.

While Medicines Australia commends the GMiA for introducing a Code of Practice, it considers that the Code as currently drafted is weak. Therefore, in addition to any anti-competitive detriment that arises from the GMiA Code, a more general detriment arises, namely, that the GMiA Code gives the appearance of regulation and accountability while in reality any regulation is inadequate.

Medicines Australia therefore submits that the ACCC should decline to authorise the GMiA Code in its current form or, alternatively, should authorise the GMiA Code subject to conditions (under s 91(3) of the *Trade Practices Act 1974* (Cth)). Conditions on authorisation should principally be in respect of:

- **Transparency:** the GMiA Code does not provide for sufficient transparency as to the promotional and educational activities of GMiA members. 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.

- **Complaint handling:** the external complaints handling process in the GMiA Code must be amended so that it (a) operates effectively in practice (b) avoids conflicts of interest and (c) is sufficiently independent of the members of GMiA.

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- **Sanctions:** the sanctions imposed under the GMiA Code should be equivalent to the sanctions available under the Medicines Australia Code of Conduct for similar behaviour.

Consultation process

As you know, Medicines Australia's 16th edition of the Code of Conduct (the MA Code) received authorisation from the ACCC on 3 December 2009. In undertaking the revision of the MA Code, Medicines Australia undertook a comprehensive and extensive consultation process, including publicly calling for submissions, placing advertisements in the professional medical media, and holding workshops for consumers to maximise their contribution to the review. An Independent Auditor was also appointed to oversee and guide the Code review.

Medicines Australia is not aware of any equivalent consultation or audit process being undertaken by the GMiA in developing its Code of Practice. In fact Medicines Australia was not afforded the opportunity to review the GMiA Code prior to the first edition being issued on 1 March 2010. Whilst GMiA has invited comment from stakeholders after the Code's adoption, we consider that a more effective Code of Practice could have been developed if thorough consultation with all stakeholders including Medicines Australia had occurred during its development.

Lack of equivalent standard to MA Code

The ACCC has stated that it "considers there is significant benefit in regulating the provision of benefits by all manufacturers of therapeutic products, including manufacturers of generic drugs, prosthetics and other medical devices."[1] The ACCC has further noted that "it is open to other industry associations or groups to develop a code with similar standards of conduct and to seek authorisation from the ACCC."[2]

Medicines Australia considers that the GMiA Code does not set an equivalent standard to the MA Code for the members of GMiA and will not be as effective in regulating company behaviour as the MA Code. 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 operation 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.

Further, Medicines Australia considers that there is a general detriment where the GMiA Code gives the appearance of regulation and accountability for GMiA

[1] ACCC Determination – Medicines Australia Code of Conduct Edition 16, December 2009, page ii-iii
[2] *Ibid*, Page iii

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members while in reality any regulation is inadequate and insufficient, particularly in comparison to the MA Code.

Medicines Australia appreciates that through the authorisation process the ACCC is not able to require non-members of Medicines Australia to comply with the MA Code. However, we submit that through authorisation the ACCC can require an equivalent standard of conduct by GMiA members through its Code of Practice.

The counterfactual

GMiA has submitted that in the absence of the GMiA Code there would be no voluntary mechanism (ie no Code) within the generic medicines industry sector for industry members to enforce the standards of conduct set out in the Code.

This is not correct. Medicines Australia submits that in the absence of the GMiA Code, GMiA members would be able to voluntarily comply with the provisions of the MA Code. Such compliance would ensure that all suppliers of prescription medicines in Australia are subject to the same rules and regulations.

Therefore, while the correct counterfactual may be that absent the authorisation there will be no GMiA Code, it does not necessarily follow from this proposition that there is no regulation available to GMiA members.

The relevant market

GMiA has referred to the ACCC's statements in relation to determining the relevant market when assessing the 16th edition of the MA Code for authorisation (paragraph 5.5 in the Final Determination). Medicines Australia accepts the ACCC's explanation that a precise definition of the market was not necessary to assess the MA Code. However, we do not agree with GMiA's assertions that the relevant market in relation to its Code of Practice is different or narrower than the relevant market in which MA members operate, namely that there is an Australian market for the supply of generic medicines.

Medicines Australia members supply medicines covered by a patent as well as medicines for which the patent has expired and which are therefore subject to generic medicine competition. For patented medicines used to treat a particular medical condition, there may be alternative medicines to those, for which the patent has expired. Thus, the supplier of the patented medicine is directly competing with suppliers of the out of patent alternative medicines, which will usually include an originator and several generic medicine suppliers. It is therefore incorrect for GMiA to state "For each individual medicine sold, MA members have no direct competitors. They have exclusivity guaranteed by patent".[3]

Medicines Australia members and GMiA members are direct competitors in the prescription medicines market, whether a Medicines Australia's member's products

[3] GMiA submission to ACCC in support of applications for authorisation of the Generic Medicines Industry Association Code of Practice, 30 March 2010, page 19.

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are protected by a patent or out of patent. Indeed, clause 2.10 of the GMiA Code specifically recognises that Medicines Australia members and GMiA members are competitors where it notes that generic medicines play an important role in "introducing competition and reducing prices after the monopoly market period enjoyed by the originator Sponsor has expired".

The fact is that often a member company of Medicines Australia will compete alongside a member company of the GMiA, both supplying different brands of the same medicine to the same market and competing for the same market share in the same off-patent market.

Medicines Australia considers that it is significantly detrimental to competition in the market for prescription medicines in Australia for there to be different standards of conduct and different Codes of Conduct/Practice applying to different companies. This reduction in competition in the market will not benefit the public and may result in a public detriment because there would be the appearance of an equivalent standard of Conduct and equally effective self-regulation where this is not the case.

Acceptance of the standards set in the GMiA Code would lead to further distortionary impacts because there would then be not two, but three different ethical standards applying to the suppliers of prescription medicines in the Australian market – one for Medicines Australia members, a second for the five companies that are members of GMiA, and a third applying to those companies that are not members of either GMiA or Medicines Australia.

The following are the principal areas in which Medicines Australia considers that the GMiA Code will not be sufficiently effective in regulating the conduct of its members.

Transparency

Overview

In granting authorisation of the 16th edition of the MA Code, the ACCC stated:

> *5.138 The ACCC considers public reporting and transparency around the relationships between pharmaceutical companies and healthcare professionals is important for the Code's effectiveness. The ACCC encourages Medicines Australia, in consultation with industry, to explore further avenues for increasing transparency in other areas of the Code, such as sponsorship of healthcare professionals by pharmaceutical companies to attend educational events.*
>
> *5.139. Should changes in the way educational events are supported by pharmaceutical companies reduce the transparency achieved by the reporting requirements, it would constitute a material change in circumstances and the ACCC would review the authorisation.*

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5.140 The ACCC will continue to monitor the Code to ensure the appropriate level of transparency is maintained such that the public benefits continue to outweigh the detriments.[4]

Medicines Australia considers that transparency of the relationships between generic pharmaceutical companies and healthcare professionals under the GMiA Code should be equivalent to the transparency required under the MA Code. However, this would not be the case if the GMiA Code in its current form is authorised.

Reporting for all healthcare professionals

Whilst the GMiA Code requires members to report all educational events for healthcare professionals who *prescribe* prescription medicines (Clause 10), it does not require members to report educational events for other healthcare professionals who *dispense* medicines, such as pharmacists, or nurses. The MA Code requires educational events for all types of healthcare professionals to be publicly reported. This is a significant limitation of the GMiA Code that profoundly reduces the effectiveness of the GMiA Code in regulating the benefits provided to healthcare professionals to ensure that they are not inappropriately influenced. This therefore significantly reduces the potential public benefit of the GMiA Code.

In its submission to the ACCC in support of its application for authorisation, GMiA stated that "The reason for this approach is because the potential anticompetitive detriments arising from the provision of Educational Events only manifests itself at the prescribing level"[5] and cited the Australian Competition Tribunal's decision regarding authorisation of the 15th edition of the MA Code as the basis for this position. Medicines Australia submits that the GMiA's interpretation and application of the Tribunal's reasoning to the GMiA Code of Practice is narrow and flawed. We do not consider that the Tribunal's concern was restricted to the provision of benefits to prescribers of medicines. We also draw the ACCC's attention to the statement on page 19 of GMiA's letter of application: "The primary goal of GMiA Members is to convince the pharmacist to dispense a particular brand of a medicine, after the decision to prescribe a particular therapeutic agent has been made by the prescriber". Thus, GMiA itself explicitly states that its members' focus is on seeking to influence product choice at the pharmacist level..

Any public benefit arising from the GMiA Code's regulation of educational events is therefore limited. Further, Medicines Australia submits that there is a potential detriment to competition arising from the lack of transparency about the provision of benefits to pharmacists and nurses in association with educational events, in addition to the potential detriment in relation to prescribers. We submit that there should be transparent reporting of educational events with all types of healthcare professionals by GMiA members, equivalent to the reporting required under the MA Code. We therefore consider that it is essential that GMiA members' activities with pharmacists in providing educational events must be transparent through the reporting of these events along with the events held with prescribers.

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[4] ACCC Determination – Medicines Australia Code of Conduct Edition 16, December 2009, p 46

[5] GMiA submission to ACCC in support of applications for authorisation of the Generic Medicines Industry Association Code of Practice, 30 March 2010, p 10

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Without this amendment, Medicines Australia does not consider that any public benefit arising from some regulation by GMiA of educational events outweighs the potential anti-competitive (and other) detriments that flow from the conduct.

Entertainment

There are other aspects of the requirements for the provision of educational events for healthcare professionals that do not adequately regulate this conduct. GMiA submitted that the GMiA Code sets out a number of principles which members must follow when offering educational events to healthcare professionals.[6] Unlike the MA Code (in clauses 9.4.6 and 9.5.8), the GMiA Code does not explicitly prohibit the provision of entertainment to healthcare professionals in association with an educational event.

This reduces any possible public benefit arising from the GMiA Code. Any remaining public benefit does not then outweigh the potential anti-competitive detriment that arises from (a) the members of Medicines Australia being required to comply with more stringent requirements in relation to the prohibition of entertainment and (b) the appearance of thorough regulation being present while in reality such regulation is poor.

Payment for relatives and associates

Clause 10.2 (vi) of the GMiA Code permits a member company to pay for the meals, accommodation or travel for a healthcare professional's relative or associate "in exceptional circumstances". It is not clear from the GMiA Code what might constitute such an exceptional circumstance. The MA Code explicitly prohibits the payment for or subsidy of the hospitality, travel or other expenses of a guest, family member, companion or any other person associated with a delegate attending an educational event (clauses 9.4.8 and 9.5.7).

The acceptance in the GMiA Code that a member of GMiA may pay the costs for a partner or companion accompanying a healthcare professional to an educational meeting reduces any possible public benefit arising from the GMiA Code. Any remaining public benefit does not then outweigh the potential anti-competitive detriment that arises from (a) the members of Medicines Australia being required to not pay the costs of any partner or companion attending an educational meeting and (b) the appearance of thorough regulation being present while in reality such regulation is poor.

Educational event reports

Medicines Australia considers that the timing for submission of educational event reports from GMiA members to GMiA should be the same as under the MA Code.

Clause 10.3 of the GMiA Code allows two months for companies to submit their reports and a further two months for the events to be posted on the GMiA website. The MA Code requires companies to submit their educational event reports within

[6] GMiA submission to ACCC in support of applications for authorisation of the Generic Medicines Industry Association Code of Practice, 30 March 2010, page 10

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one month of the end of the reporting period and they must be published by Medicines Australia within three months. We submit that if there are two Codes of Conduct governing the conduct of pharmaceutical companies that supply prescription medicines in Australia, the public benefit of transparency of educational event reporting will only be realised if the same information is published and available to consumers within the same time frame.

The ACCC[7] accepted that there was a public benefit arising from greater transparency about pharmaceutical companies' relationships with health consumer organisations (HCO), through the requirement in the MA Code for a company to publish, annually, on its website a list of HCOs to which it provides financial support or significant direct or indirect non-financial support. There is no equivalent requirement in the GMiA Code. Any public benefit arising from these provisions of the GMiA Code is therefore minimal and does not outweigh the potential anti-competitive detriments associated with competitors in the industry having different reporting requirements imposed upon them.

Complaints

Medicines Australia considers that the external complaints handling system under the GMiA Code has a number of limitations which reduce the effectiveness of the Code and therefore reduce its public benefit.

Membership of Code Complaints Committee

The Code Complaints Committee (CCC) under the GMiA Code consists of eight members – four representatives that will be independent of GMiA members and four representatives from GMiA members. Thus, there is not a majority of independent members on the CCC, whereas under the MA Code the majority of members of the Code of Conduct Committee are independent of the industry. We consider that having an equal number of independent and member company representatives on the GMiA CCC weakens the independence of complaint determination and thereby significantly reduces the effectiveness of the Code.

The GMiA Code does not prescribe a quorum for either the CCC or the Appeals CCC. Therefore, it is possible that at a particular meeting of either committee there could be a majority of member company representatives. GMiA has itself identified that there is a risk of anti-competitive detriment arising from member company representatives participating in decisions to find another member in breach of the Code and applying sanctions[8]. Medicines Australia considers that the composition of the CCC and Appeal CCC under the GMiA Code actually constitutes a public detriment because the complaints mechanism is insufficiently independent of the GMiA members. Any nominal public benefit arising from the appearance of 'some' regulation does not outweigh this detriment.

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[7] ACCC Determination – Medicines Australia Code of Conduct Edition 16, December 2009, paragraph 5.138, page 46.

[8] GMiA submission to ACCC in support of applications for authorisation of the Generic Medicines Industry Association Code of Practice, 30 March 2010, page 25

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Conflicts of interest

The GMiA Code is silent on how conflicts of interest will be managed for the member company representatives on the CCC. It must be noted that GMiA comprises five member companies. A complaint will be against one of the five members; therefore the four member company representatives on the CCC must be selected from the other four member companies, most of which are likely to be direct competitors with the member company subject to the complaint. The GMiA Code does not explain whether the four member company representatives on the Committee would be each from a different company or if two or more may be from the same company. If members from the same company are permitted to be represented on the CCC or Appeal CCC, this could unfairly bias the Committee in its decisions.

The GMiA Code states, in clause 12.1.4, that alternative representatives will be nominated for the CCC if a member has a conflict of interest, but the Code does not state what would constitute a conflict of interest for either an independent or member company representative. It is also unclear whether the alternative representatives are only for the independent members or the member company representatives.

Clause 12.1.15 of the GMiA Code states that members will be appointed for a two year term. It is unclear if the member company representatives are also appointed for a two year term or are different each time the CCC (or Appeal CCC) is formed. If the member company representatives are 'permanent' for two years this would make it difficult to avoid conflicting interests with the complainant or respondent company for particular complaints. However, given the small number of GMiA member companies, if the member company representatives on the CCC are different for each CCC it also will be difficult to avoid conflicting interests. The complaints handling process can only be regarded as effective if the CCC makes an independent decision, unaffected by any conflicts of interest. The GMiA Code is unclear on how this will be achieved.

Insufficient independence

Medicines Australia is concerned that the CCC is insufficiently independent in making its final decision about a complaint and any sanction. Clauses 12.1.19 and 12.1.20 of the GMiA Code describe a process whereby the complainant and respondent may make submissions to the CCC about the decision and sanction prior to the CCC issuing its final decision. Subsequently, the respondent and complainant may also appeal the CCC final decision to the Appeal CCC. This is, in effect, two opportunities to appeal against the CCC decision, which undermines the effectiveness and independence of the CCC.

In relation to an appeal, the GMiA Code requires that the Appeal CCC will have the same composition as the CCC but with different individual representatives. Medicines Australia is concerned that the member company representatives on the Appeal CCC will most likely be from the same companies that formed the CCC, given that there would only be four member companies from which to select members (the fifth member being the respondent company). If the Appeals CCC is formed with members from the same companies that sat on the CCC, the independence of the Appeals CCC is compromised and therefore the effectiveness of the complaints handling system, and any benefit arising from it is significantly

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reduced and cannot outweigh the detriments that arise from companies considering the conduct of their competitors while giving the appearance of sufficient regulation.

Timing of dealing with complaints

The timeliness of dealing with complaints and appeals under the GMiA Code is considerably longer than the process under the MA Code. The delay between receipt of a complaint and corrective action is concerning because subject companies can continue to engage in the conduct subject to complaint during this time.

The GMiA states in its application for authorisation that the maximum time from receipt of a complaint to the CCC meeting will be 80 days, which is 80 business days or 16 weeks. If the complainant or respondent lodge an appeal, the Appeals CCC will meet up to 70 business days or 14 weeks subsequent to the CCC making its final decision, a total of up to 150 business days.

Under the MA Code, the average time for resolving a complaint is 43 working (or business) days, including complaints subject to appeal. As noted above, a GMiA member company may continue its conduct subject to complaint until the CCC decision is provided to the respondent, which may be 85 business days after the complaint is lodged with GMiA, or 17 weeks.

The long timeframe for dealing with a complaint means that there is effectively no public benefit arising from the complaint handling process while there is clear detriment arising from the appearance of sufficient regulation.

Internal complaints mechanism

The GMiA Code states that a complaint from a consumer about a Member should first be directed to the Member's internal complaints mechanism. In developing Edition 15 of its Code, Medicines Australia was cognisant that consumer complainants may find it daunting to make a complaint directly to a pharmaceutical company. Also, a direct approach to a company does not allow a consumer complainant to keep their identity confidential. Medicines Australia's Code provides for an Independent Facilitator to be appointed to assist a consumer complainant if they wish to avail themself of this service, at Medicines Australia's cost. The GMiA Code appears to require a consumer complainant to make its complaint directly to the subject company before it can submit a complaint to the CCC. Any public benefit arising from this part of the GMiA Code is therefore nominal and unable to outweigh the anti-competitive detriments arising from the conduct.

Sanctions

The financial sanctions that can be imposed by the CCC and Appeal CCC under the GMiA Code are significantly lower than the financial sanctions available under the MA Code.

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The table below provides a comparison of the financial sanctions:

Category of breach	Maximum financial penalty – GMiA Code	Maximum financial penalty – Medicines Australia Code
Minor (& technical in MA Code)	nil	$100,000
Moderate	$20,000	$150,000
Severe	$40,000	$200,000
Repeat breach	$50,000	$250,000
Serial breach	$75,000	$100,000 - $250,000

Medicines Australia considers that there is no reason for there to be lower sanctions under the GMiA Code. GMiA has offered no explanation for the lower fines in its submission. However, it has sought to argue that the market for GMiA members is different from the market for MA members.

Medicines Australia rejects this assertion and submits that there can be no reason for lower financial sanctions based on the size or revenue of GMiA members. All five GMiA member companies are in the top 30 pharmaceutical companies in Australia, ranked by local revenue. One third of Medicines Australia member companies are smaller, in terms of local sales values, than the five GMiA member companies, yet all MA members are subject to significantly higher financial sanctions if they breach the MA Code.

The ACCC has noted that appropriate sanctions under the Code will act as a deterrent to companies breaching the Code, which is important to the effectiveness of the Code. The low level of financial sanctions available under the GMiA Code significantly undermines its effectiveness. The claim that any public benefit arises from some form of sanction cannot outweigh the detriment that arises from the unequal treatment of competitor companies.

Mandatory review by independent expert of promotional material

The provision of information from GMiA members to the independent expert is limited to providing information on educational events. A review of promotional material only occurs when the independent auditor conducts on the spot audits of such material and when it receives copies of that material "in relation to particular products" on two separate occasions each year (clause 13.3 GMiA Code). In contrast, the Monitoring Committee established under the MA Code on a monthly basis receives copies of pharmaceutical company promotional material and other conduct governed by the Code, so that it can review that material and conduct for compliance with the MA Code. Any review of material by the GMiA independent expert should be of the same scope as the review conducted by Medicines Australia.

Length of authorisation

GMiA seeks authorisation for five years. Medicines Australia considers a five year period is too long and that three years would be a sufficient period for authorisation because:

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- unlike the MA Code, the GMiA Code is new and amendments will need to be made when aspects of the GMiA Code do not work; and

- the way that generic medicines are supplied in Australia is changing. A five year period would not allow for changes in the industry to be accommodated in the GMiA Code.

Transparency in publishing annual report

Unlike the MA Code, the GMiA Code does not appear to provide for publication of an annual report that is accessible to the public. Clause 16 of the GMiA Code provides that the Board will produce an annual report on the operation of the Code and that it will be "distributed to interested parties including Government, peak bodies of Healthcare Professional [sic], peak bodies of Consumer groups and the ACCC". Medicines Australia submits that this report should be publicly available via the internet so that all interested parties may easily access the report.

Other issues

In the interest of ensuring submissions on the public record are correct, Medicines Australia draws the ACCC's attention to GMiA's description of the regulatory framework in Australia. We note that it is not correct that there is a statutory requirement that advertising of registered goods to healthcare professionals must comply with the Therapeutic Goods Advertising Code (TGAC). The TGAC states (Objects, clause 1 (1)) that its object is to ensure that the marketing and advertising of therapeutic goods to consumers promotes the quality use of the goods and is socially responsible (emphasis added). Further, the term 'registered goods' under the therapeutic goods legislation encompasses prescription medicines (Schedule 4 and 8) as well as lower risk non-prescription medicines that are scheduled as pharmacist-only medicines (Schedule 3) and pharmacy medicines (Schedule 2). Thus, the TGAC does govern the advertising of some registered medicines (to consumers), but it does not regulate the advertising of prescription medicines to healthcare professionals. Finally, Section 42AA of the Therapeutic Goods Act 1989 does not prohibit the advertising of medicines directly to the general public. However, Section 42DL creates an offence for the broadcast advertising of schedule 3, 4 and 8 medicines. The combined effect of Sections 42DL and 42AA prohibits the advertising of prescription medicines to persons other than healthcare professionals.

Thank you again for the opportunity to provide a submission on the application from GMiA for authorisation of its Code of Practice.

Yours sincerely

Dr Brendan Shaw
Chief Executive

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