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Generic Medicines Industry Association

Applicants response to issues raised in the ACCC draft determination

Applications for Authorisation

of the Generic Medicines Industry Association

Code of Practice

September 2010

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Introduction

A new Generic Medicines Industry Association (GMiA) Code of Practice, formalising the high standards of behaviour adhered to by members of GMiA, was released on 1 March 2010. On 31 March 2010 the GMiA applied for authorisation of its Code of Practice (2nd edition).

Generic Medicines industry Association (GMiA) welcomes the ACCC's proposal to grant authorisation to the Generic Medicines Industry Association's Code of Practice.

This submission, prepared by GMiA, responds to the ACCC draft determination released on 3 August 2010.

The ACCC draft determination is subject to a number of conditions that are designed to increase the transparency around the provision of non-price benefits, such as hospitality, entertainment, gifts and loyalty programs, by pharmaceutical companies will ensure these arrangements are subject to public and professional scrutiny.

Members of GMiA welcome any initiatives that increase public confidence in generic medicines and the activities of the generic medicines sector. Members of GMiA believe that the provisions in the 2nd edition of the Code of Practice are sufficient and the proposed draft conditions should not be imposed.

The proposed additional conditions entail significant compliance costs generating significant additional administrative burden on members of GMiA. In contrast, the public benefit derived from the reporting of non-price benefits is trivial and non-existent. It is inappropriate to add administrative burden to industry in the absence of a clear net benefit.

Members of GMiA request the ACCC to grant authorisation of the GMiA Code of Practice (2nd edition) as submitted on 31 March 2010, including the amendments submitted on 31 May 2010. Members of GMiA request the ACCC **NOT** to impose any conditions, including the proposed draft conditions of 3 August 2010 or any other conditions.

GMiA's primary concern

GMiA's primary concern with the ACCC's Draft Determination is that it does not properly apply the relevant statutory tests under section 90 of the *Trade Practices Act* 1974 (TPA).

At paragraph 5.1 of the Draft Determination, the ACCC quotes the relevant statutory tests. In order to grant authorisation the ACCC must be satisfied that the public benefit arising from the GMiA Code of Conduct (GMiA Code) is likely to outweigh the public detriment. Furthermore, the ACCC can only impose conditions where it believes this is necessary to ensure that the net public benefit test is met. In other words, conditions should only be imposed where the ACCC believes the net public benefit test has not been met (para 4.34 of ACCC's *Guide to Authorisation*).

Para 4.34 of ACCC's *Guide to Authorisation*:

"The ACCC issues a written draft determination stating whether it proposes to grant authorisation. In practice, the draft determination comprises:

- *The reasons for the ACCC's proposed decision. This part usually consists of a series of chapters which:*
  - *detail the conduct for which authorisation is sought;*
  - *outline the applicant's submission(s) in support of the application;*
  - *outline interested parties' submissions;*
  - *outline the relevant authorisation test;*
  - *provide an evaluation of the public benefit and public detriment that the ACCC considers flow from the conduct, and set out the ACCC's conclusion on whether the authorisation test was met (and if not, whether any conditions can be imposed to ensure that the test is met)."*

GMiA submits that the level of public benefit created by the GMiA Code as originally drafted and submitted to the ACCC was significant. These public benefits were consistent with the types of public benefits found by the ACCC in the past in relation to the Medicines Australia Code of Conduct (MA Code) and the Australian Competition Tribunal in *Re Medicines Australia Inc* [2007] ACompT 4 (27 June 2007).

Indeed, the ACCC has found in the Draft Determination that the Code contains a number of features which result in either "public benefit" or "substantial public benefit".

The ACCC also concluded that the Code "is unlikely to result in significant anticompetitive detriment" – para. 5.128 of the draft determination.

Therefore, it is the opinion of the GMiA, there was no basis for the ACCC to seek to impose additional conditions, given its finding on the net public benefit. It is clear that the level of public benefit arising from the Code without the conditions greatly exceeded the public detriments.

It was also incumbent on the ACCC to conclude that the Code did not pass the net public benefit test prior to turning its mind as to whether additional conditions should be imposed. Nowhere in the ACCC decision does it state that the net public benefit test was not met prior to the ACCC's decision on the imposition of conditions.

Additional areas of concern

1. Misrepresenting tribunal decision in relation to the Medicines Australia case

The ACCC draft determination misrepresents the findings of the Tribunal in the Medicine's Australia case. The ACCC quotes, at para. 5.36, the following broad observation by the Tribunal in the MA case:

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 benefit that have been described in the evidence, risks distortion of the medical decision-making processes of healthcare professionals. It may also influence the views of 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.

The above quote suggests that the Tribunal was concerned that the provision of financial benefits to health care professionals may result in "distortion of the medical decision-making process". However, this quote does not reflect how the Tribunal believed that the medical decision-making process may be distorted by financial benefits.

The following quotes from the Tribunal decision provide a much clearer explanation of what the Tribunal was specifically concerned about (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.

The ACCC in its Draft Determination fails to consider the detriment which the Tribunal said may arise from pharmaceutical companies providing various benefits to healthcare professionals – namely the risk that healthcare professionals may prescribe a medicine to a patient which is not appropriate or optimal.

There is no reference in the Tribunal's decision to a concern that the supply of a generic medicine to a patient by a pharmacist could conceivably result in any similar type of detriment. The reasons for this are quite apparent – the generic product is bioequivalent to the prescribed product and therefore, cannot have adverse health consequences.

The promotional activity by suppliers of generic medicines is targeted to pharmacists seeking to switch use from one brand of a medicine to another brand of the same medicine. The choice of brand of medicine has no impact on the health outcome of the patient nor on the PBS budget.

This is in stark contrast to the reporting requirements specified under the Medicines Australia Code. Promotional activity by members of Medicines Australia will influence the choice of medicine prescribed by a doctor and this has a direct impact on the health outcome of the patient. Promotional activity by members of Medicines Australia also has the potential to result in the over use of medicines by doctors that can cause a huge blow out of PBS costs.

The ACCC, in its Draft Determination, avoids a full and frank discussion of the Tribunal's findings in relation to detriment, particularly as the above arguments formed a central part of the GMiA's arguments for limiting the scope of educational event reporting to prescribers. The ACCC had an obligation in terms of fairness and transparency to include GMiA's arguments in relation to this issue in the Draft Determination and then to objectively discuss these arguments.

2. Proposed conditions will not achieve desired outcome

The ACCC proposes the inclusion of two conditions in the Code on the grounds that increased transparency around the relationship between pharmacists and the suppliers of generic medicines is desirable. GMiA refers to section 8 of its submission from May 2010 where it is highlighted that the reporting of events provided by suppliers of generic medicines 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 or other non-price benefits, 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 and other non-price benefits 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 the proposed reporting conditions that a particular educational event or non-price benefit 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.

The ACCC erroneously considers that the conferring of non-price benefits to pharmacists are less likely to be passed onto the consumer as compared to price discounts that may be passed through to individual consumers. This perspective does not recognise the Commonwealth Government subsidy received by the consumer. Over eighty per cent of PBS prescriptions are subsidised at the concessionary rate, such that the concessionary consumer pays only $5.40 per prescription. There is little scope for the pharmacist to pass on a price discount where the consumer is making a payment of $5.40 only.

There is considerable information asymmetry present in the pharmaceutical market. It is not well understood by consumers that generic medicines are more affordable because the sponsor does not need to fund the original research and development for the medicine. Instead, the discounting of pharmaceuticals can be associated with poorer quality of product and poorer delivery of service. This creates another barrier to the pharmacist to pass on price discounts to the patient, as pharmacists may be reluctant to pass on price discounts to the patient for fear that the patient may associate a cheaper medicine as an inferior medicine.

GMiA notes that under section 99ADC of the National Health Act (Cwlth) 1953 the type and value of any benefit (whether monetary or otherwise) is reportable under price disclosure requirements. Thus, the value of non-price benefits is passed on to the consumer via price adjustments under the price disclosure policy.

GMiA again notes the significant administrative and cost burden that event reporting of educational activities provided to pharmacists would place on its members. It is inappropriate to add administrative burden to industry in the absence of a clear net benefit. 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 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.

3. Introduction of second condition

GMiA believes that it is inappropriate for the ACCC to impose the second condition in the Draft Determination; namely:

> *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).*

This condition is unrelated to the subject matter of the application. In GMiA's opinion, it is not appropriate for the ACCC to seek to impose a condition in a Draft Determination which is unrelated to the subject matter of the application. GMiA proposed to introduce educational event guidelines and educational event reporting. GMiA acknowledged that these initiatives might result in a small anticompetitive detriment. However, GMiA also argued that the public benefits arising from both the educational event guidelines and educational event reporting would greatly exceed any anticompetitive and other detriments.

A further concern which GMiA has about this condition is that it was totally unaware that such a condition was being contemplated by the ACCC. The ACCC never foreshadowed that it might introduce such a condition nor did it ever ask for submissions from GMiA about the appropriateness of imposing such a condition before issuing its Draft Determination. The ACCC should not surprise applicants for authorisation with conditions which have never been the subject of any discussion with the applicant prior to the issue of the Draft Determination.

4. ACCC engaging in industry restructuring

GMiA suggests that through the Draft Determination the ACCC is seeking to engage in industry restructuring. In the Summary to the Draft Determination (page iii), the ACCC makes the following comment about the second condition:

> 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.

It appears from the above statement, that the ACCC prefers generic medicine manufacturers to engage in price competition with pharmacists rather than focusing on non-price competition. It is clear also from the above quote, that one aim of the ACCC's second condition is to drive non-price competition out of the market which, in the ACCC's view, would in turn result in greater price competition.

This is outside the essence of the authorisation process that is primarily to permit parties which wish to pursue some form of collective action to do so if their conduct can be shown to result in a public benefit.

5. Sponsorship of healthcare professionals to attend educational events

The ACCC has asked GMiA and interested parties for comments on the issue of the sponsorship of healthcare professionals to attend educational events and whether generic pharmaceutical companies sponsor healthcare professionals to attend events.

The implication of this question appears to be that the ACCC wishes to ascertain whether such sponsorship agreements may raise a public detriment. In the event that the ACCC forms the view that such agreements do result in a public detriment, it would appear that the ACCC may decide to impose a further condition.

In GMiA's view, such an approach to considering an authorisation application by the ACCC is flawed. The ACCC's role is to ascertain whether the proposals put forward by the parties seeking authorisation have sufficient public benefit so as to allow the proposals to be authorised. The ACCC's task is not to seek to remedy any perceived public detriment in the market, which does not relate to the proposal put to them for authorisation.

Accordingly, GMiA believes that it is inappropriate for the ACCC to be canvassing opinion in this way, in circumstances where it has already clearly determined that the public benefit outweighs the public detriment. As stated above, it is GMiA's opinion that the public benefits arising from the GMiA Code so far outweigh the public detriments that it is simply inappropriate for the ACCC to contemplate imposing any further conditions.

6. Compliance costs associated with the conditions

The ACCC has also asked GMiA and interested parties for their views on the likely compliance costs associated with the conditions.

GMiA has already advised the ACCC that the compliance costs associated with recording and reporting educational events for pharmacists is likely to be considerable.

The compliance costs associated with the additional condition will be very significant. GMiA members will have to collect information about every form of non-price benefit that may be passed onto pharmacists, including hospitality, entertainment, gifts and loyalty points. This will require members to keep records of every non-price benefit provided to a pharmacy throughout Australia and then to place a financial value on each of those non-price benefits. GMiA members will be required to report this information twice a year.

In GMiA's view, the information which members will be required to record and publish in order to comply with the second condition will be of limited value to consumers. This is because the relevant data will state no more than that a particular member company provided non-price benefits of a certain value to a certain number of pharmacists in a six-month period.

In GMiA's view, it is not appropriate to impose such a significant compliance costs on members of GMiA for a public benefit of limited value.

7. GMiA members will have higher reporting requirements

A significant implication of the conditions which the ACCC seeks to impose on members of GMiA in the Draft Determination is that the conditions will result in members of GMiA having to comply with more extensive and onerous reporting requirements than other suppliers of prescription medicines.

For example, members of GMiA will have more extensive and more onerous reporting requirements than members of Medicines Australia. Under the Medicines Australia Code, members are not required to report the non-price benefits which they may provide to pharmacists or other healthcare professionals.

It is inappropriate for the ACCC to seek to impose more onerous conditions on members of GMiA in relation to the reporting of non-price benefits to pharmacists without also requiring such a condition be imposed on members of Medicines Australia. As a matter of logic, the detriment which the ACCC believes arises from the provision of non-price benefits to pharmacists must be the same whether the non-price benefits are being provided to pharmacists by members of GMiA or Medicines Australia.

A further concern about the ACCC's approach is that it did not impose a condition on the members of Medicines Australia that they report non-price benefits to pharmacists. GMiA assumes that the reason why the ACCC did not impose such a condition in the Medicines Australia Code was because it did not believe that the imposition of such a condition was required in order to satisfy the net public benefit test. GMiA believes it is also very apparent that the imposition of the conditions in the GMiA Code is not required in order to satisfy the net public benefit test.

Medicines Australia in its submissions to the ACCC in relation to the GMiA Code argued that if the obligations on GMiA members under the GMiA Code were not equivalent to the obligations on Medicines Australia members under the MA Code, then this inconsistency would create an uneven playing field.

GMiA in its submissions to the ACCC rejected this argument primarily on the basis that the obligations on members of GMiA under the GMiA Code should only be determined on the basis of the public detriment which needed to be addressed. In other words, because there was very little public detriment arising under the GMiA Code, it is appropriate that members of GMiA commit to a smaller number of what may be described as "public benefit" obligations.

Unfortunately, a consequence of the proposed conditions in the ACCC's Draft Determination is that a very onerous set of conditions may be imposed on members of GMiA despite the absence in the GMiA Code of any significant public detriment. At the same time, the ACCC has imposed a much less onerous set of conditions on members of Medicines Australia despite the existence of much more serious potential public detriment, namely that health practitioners may prescribe an incorrect or sub-optimal medicine to patients.

Such inconsistency in the ACCC's approach is wrong and brings the entire authorisation process into disrepute. Parties which approach the ACCC for authorisation should be confident that the ACCC will apply the net public benefit test correctly and consistently. In GMiA's view, the conditions being proposed by the ACCC in the Draft Determination have the potential to seriously undermine business confidence in the authorisation process.