



The Royal Australasian
College of Physicians

Wednesday, 28 April 2010

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

Dear Dr Chadwick,

Re: Generic Medicines Industry Association (GMiA) Code of Practice 2nd Edition – application for authorisation A91218-A91219

Thank you for inviting the Royal Australasian College of Physicians (RACP) to responding to the Australian Competition & Consumer Commission's request to provide a submission on GMiA's Code of Practice.

The RACP would like to congratulate GMiA for producing the 1st Edition of their Code of Practice in March 2010 and also for making some improvements to the 2nd Edition submitted for authorisation, including adding that details of finalised complaints will now be published on the GMiA website (12.1.28).¹

The College would like to see the GMiA Code strengthen its approach to the Australian Self-Medication Industry (ASMI) Code. In particular:

1. The GMiA Code acknowledges that, "Marketing of Generic Medicines typically seeks to change behaviour at the point of dispensing not at the point of prescribing" (2.11 ii) and "the promotional activities of pharmaceutical companies can affect the way Healthcare Professionals make decisions in relation to the prescribing and dispensing of Generic Medicines" (10.1).
2. The GMiA Code only requires members to report educational events directed to prescribers, not dispensers (10.3) arguing that, "The decision to substitute a patient from one brand to another brand is unlikely to create any change to the health outcomes for the patient, and is likely to create a financial saving for the patient, potentially increasing patient compliance" (2.11 ii).

This statement does not stand up to scrutiny. Such changes can potentially have substantial negative effects. The differing size, shape and colour of different

¹ <http://www.gmia.com.au/pdf/gmia-code-of-practice-2nd-edition.pdf>

brands of the same generic medicine)² can produce patient confusion, compliance problems and negative health outcomes.³

The College would also like GMiA to reconsider this in light of the possibility of a pharmacist changing a patient's generic brands purely as a result of industry promotional activities, discounting and reward schemes. Further, if a generic medicine is priced under the PBS co-payment, pharmacists can, and do, charge a higher price than the PBS recommended price to consumers. As such, brand substitution does not necessarily result in financial savings for the patient.

Finally, given previous concern over "educational" events directed at pharmacists¹ and the set of principles for educational events outlined in the GMiA Code applicable to all healthcare professionals (10.2) it Page 2 of 3 appears most inappropriate to exclude the reporting of such events directed at pharmacists.

3. The GMiA Code asks that, "Members take all reasonable steps to ensure their behaviour does not lead to actual or potential conflicts of interest or interfere with or impede the independence of Healthcare Professionals or their professional judgment" (6.8.4).

The College would like GMiA to be more specific, for example ASMI, "Advertisements/promotions must not offer any personal incentive to a healthcare professional, pharmacy assistant, or other non-healthcare professional sales person, to recommend or supply therapeutic goods" (5.1.8).⁴

This specificity is relevant to current concerns about a Sigma Reward Scheme which has the potential to influence pharmacist to preferentially dispense and/or recommend Sigma supplied products.⁵

4. The GMiA Code states that, "Members will comply with the Medicines Australia Code of Conduct to the extent it applies to promotional material of Prescription Medicines as a condition of registration on the ARTG"(6.9.2) and that "Members will also consider other relevant Codes of Practice, including the Medicines Australia Code of Conduct, the Australian Self-Medication Industry Code of Conduct, the Ausbiotech Code of Conduct and/or the

² http://www.mja.com.au/public/issues/192_07_050410/ort10635_fm.html

³ http://www.mja.com.au/public/issues/192_07_050410/ort10635_fm.html

⁴ <http://www.asmi.com.au/documents/About/2009%20ASMI%20Code%20of%20Practice%20.pdf>

⁵ <http://www.medicalobserver.com.au/news/concerns-pharma-reward-scheme-may-breach-code>

Medical Technology Association of Australia Code of Practice to the extent that they relate to promotional material with respect to a Product" (6.9.3).

The letter of marketing approval written by the Therapeutic Goods Administration (TGA) as a condition of product registration on the ARTG states that, "promotional material... relating to the registered good must comply with the requirements of the Code of Conduct of Medicines Australia". The TGA have interpreted that statement to mean that, "There is no condition that other promotional activities must comply with the Medicines Australia Code of Conduct". The end result of this TGA interpretation (and the GMiA clauses) is a higher standard of ethical conduct expected for innovator compared with generic companies.

The College would like to suggest that clauses 6.9.2 and 6.9.3 be replaced by more specific provisions in the other Codes cited in order to create a level ethical playing field for all medicines industry associations.


5. Fines under the GMiA Code have a maximum of \$75,000 for "serial breaches", whereas "severe" and "repeat" breaches are associated with fines of \$40,000 and \$50,000, respectively. This compares unfavourably to MA's \$100,000 to \$300,000 range.

The College would like GMiA to be transparent about what they intend to do with the fines and to suggest fines are published in the Annual report and to state where the money from the fines is allocated.

6. The GMiA Code states that complaints will go first to member companies rather than an independent complaint panel. The College believe that this is an unreasonable and time-delaying imposition and we are not aware of any other Australian Medicines Code that has such a provision. The College would like to suggest that all complaints be heard in the first instance by an independent Code Complaint Committee.

The College also would like to express an interest in attending any discussions in relation to this enquiry. If you require any further clarification of the endorsement please contact Ms Mary Osborn by email on mary.osborn@racp.edu.au.

Yours sincerely



Mary Osborn
Senior Policy Officer RACP