20 April 2010

LA TROBE UNIVERSITY

School of Public Health
Faculty of Health Sciences

Dr 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

I am responding to Monica Burke's request to provide a submission on this matter.

First, GMiA deserve congratulation for eventually 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 GMiA Code removes some anomalies between the ethical standards expected of members of Medicines Australia (MA) and GMiA with respect to education events, highlighted in 2009 by controversy over a Sigma "educational" cruise offered to both pharmacists and medical practitioners.[2]

However, the GMiA Code is considerable weaker (and less specific) than the MA Code and others, such as 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).

   Despite this, 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).

   I dispute this reasoning. First, if pharmacists switch patient's generic brands purely as a result of industry promotional activities such as cruises, discounting and reward schemes this is likely to produce patient confusion, compliance problems and impaired health outcomes (because of the differing size, shape and colour of different brands of the same generic medicine).[3] Second, 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 pharmacists[1] and the set of principles for educational events outlined in the GMiA Code applicable to all healthcare professionals (10.2) it

[1] http://www.gmia.com.au/pdf/gmia-code-of-practice-2nd-edition.pdf
[2] http://www.news.com.au/doctors-offered-cruise-to-prescribe-sigma/story-0-1225747127980
[3] http://www.mja.com.au/public/issues/192_07_050410/ort10635_fm.html

appears most inappropriate to exclude the reporting of such events directed at pharmacists.

2. 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).

   Other Codes are much 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]

3. 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 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". [6]

   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.

   My own view is clause 6.9.4 is meaningless and both clause 6.9.2 and 6.9.3 should 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.

4. 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.

5. Finally, the GMiA Code expects complaints to go first to member companies rather than an independent complaint panel. I believe that this is an unreasonable and time-delaying imposition and I am not aware of any other Australian Medicines Code that has such a provision. It is my view that all complaints should be heard in the first instance by an independent Code Complaint Committee.

In summary, while the GMiA Code is clearly better than the absence of any Code that preceded it, it is still weaker than several other Medicines Codes of longer standing. In addition, it will not apply to the 10% of generic companies who are not members of GMiA.

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[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

[6] Email from Kay.McNiece@health.gov.au, Re: Sigma Mediterranean Conference for GPs and Pharmacists [No Protective Marking] [SEC=UNCLASSIFIED] Date: Tue, 14 Jul 2009 11:15:32 +1000

This highlights a general problem I have raised before. Australia currently has a variety of complex and convoluted co-regulatory systems for therapeutic claims and promotional practices depending upon the type of product (innovator and generic prescription, over-the-counter and complementary medicines, therapeutic devices, food and cosmetics) and the media in which claims are made.

The various Codes and their monitoring and complaint systems are inconsistent, especially with respect to timeliness, transparency, sanctions and effectiveness. As a result, claims of efficacy for some products (especially complementary medicines) are out of all proportion to the underlying evidence, adverse-effects and drug-drug interactions are rarely mentioned and consumers (and health professionals) have difficulty selecting evidence-based products. This is a particular problem with sponsors who are not members of industry associations.

The Consumers Health Forum and others have suggested that the current situation could be simplified and unified by creating one overarching principles-based Code applicable to all therapeutic claims and promotional practices. This should be supported by one monitoring process, one complaint (and appeal) process and one set of effective sanctions, including corrective advertising orders and a sliding scale of fines.

The system should be funded and monitored by government and administered transparently by an independent expert committee representing the therapeutic goods sector, the advertising industry, consumers, healthcare professionals and government. Specific panels could deal with promotional activities targeting health professionals and consumers. Product registration or listing on the Australian Register of Therapeutic Goods should be conditional upon compliance with the system. A legislative base in the Therapeutic Goods Act &/or regulations is required to ensure enforcement.

I accept that the ACCC has no jurisdiction about such matters. Because of this I have copied this submission to the relevant Parliamentary Secretary for Health, the Hon Mark Butler MP.

Yours sincerely,

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