Consumers
Health Forum
of Australia

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 [A91218 & A91219] – interested party consultation

Thank you for your correspondence requesting a submission from the Consumers Health Forum of Australia (CHF) on the Generic Medicines Industry Association (GMiA) Code of Practice.

CHF welcomes the GMiA's decision to adopt a Code of Practice. Codes of practice or conduct for the therapeutic goods industry provide consumers with reassurance that there are certain standards that must be met, and penalties if these standards are breached. Consumers also welcome the transparency that comes from public reporting on breaches.

However, CHF has some concerns about the Code of Practice in its current form. These concerns are outlined below.

Clause 2.11 ii

Clause 2.11 ii of the Code of Practice notes:

Marketing of Generic Medicines typically seeks to change behaviour at the point of dispensing not at the point of prescribing. 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.

CHF questions the validity of some elements of this statement:

- *Change to health outcomes:* If a consumer has been taking one brand of a medication, providing them with a generic medicine has the potential to increase adverse events if appropriate supporting information is not provided. The generic product would be presented in different packaging and the shape or colour of the product could be different. This is a particular risk if a consumer is taking several different medications. Around six per cent of hospital admissions in Australia are associated with adverse

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drug events, with almost one third of admissions for older people associated with adverse events.[1] While CHF certainly does not argue that use of generic medicines will lead to adverse outcomes, there is a risk of adverse outcomes if the change is not adequately explained.

- *Financial savings*: When generic medicines are priced under the PBS co-payment, pharmacists are able to charge consumers a higher price than the price recommended by the PBS. One consumer recently reported a price difference of close to ten dollars from two different pharmacists for a generic medication priced below the PBS co-payment amount. Brand substitution will therefore not necessarily always mean a financial saving for the consumer.

Coverage

According to the GMiA's submission, GMiA members supply more than 90 per cent of generic medicines prescribed through the PBS. While this would mean that the majority of generic medicine supply would be subject to the Code of Practice, CHF remains concerned that not all suppliers of generic medicines would have to comply with the Code.

Education Event Reporting

CHF is concerned that Clause 10 of the Code of Practice only requires that Members report on Educational Events for health professionals who prescribe medicines, not those who dispense medicines. To justify this, the GMiA submission reiterates the point made in Clause 2.11 (ii):

The dispensing decision made by the Healthcare Professional 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.

CHF has outlined its concerns about these arguments above. As the decision to provide a generic medicine is often made by the dispensing health professional, rather than the prescribing health professional, CHF considers that it is essential that GMiA Members also report Educational Events for dispensing health professionals. An example of why it is important for the Code to address dispensers as well as prescribers is the recent promotional activities of some pharmaceutical companies that provide benefits and rewards to dispensers for promoting consumers with their branded product.

Internal Complaints Handling

CHF questions the need for complainants to first go through the internal complaints procedure of a GMiA Member, before their complaint can be considered by the GMiA's Code Complaints Committee (CCC). While this is a model that is suitable in other industries, such as financial services or telecommunications, the nature of the complaints that are likely to be

[1] National Prescribing Service 2009 'Medication Safety in the Community: A Review of the Literature', online at http://www.nps.org.au/research_and_evaluation/current_research/medication_safety_community, accessed 22 April 2010.

raised in relation to GMiA Members' activities would, in almost all cases, be more appropriately considered by an independent, external complaints mechanism such as the CCC. Further, requiring complainants to first go through a Member's internal complaints handling process will add additional time and complexity to the process, which could discourage complainants from continuing with their complaint.

External Complaints Handling System

CHF notes Clause 12.1.5, which requires that

In the interests of avoiding frivolous or trivial complaints, individuals or bodies making a complaint (the Complainant) are required to provide ... details of affiliation with any relevant professional, industry or consumer association.

CHF questions the need for complainants to provide details of affiliation with consumer associations, and the implication that affiliation with a consumer association would render a complaint in some way 'frivolous or trivial'.

Independent Reviewer

CHF welcomes the appointment of an Independent Reviewer under the Code, and notes clause 13.9 which states that the Independent Reviewer is to prepare a report each year on Members' compliance with Educational Event reporting obligations, description of the matters referred to the CCC, and suggested changes to the Educational Event reporting system. It is unclear from the Code whether or not this report is to be made public. CHF considers that it should be publicly available, and that the Code should specify this.

Sanctions

CHF notes that the financial penalties set out under the Code are very low in comparison to those in the Medicines Australia Code of Conduct, ranging from no financial penalty for a minor breach (in comparison to a maximum penalty of $100,000 under the Medicines Australia Code) to $75,000 for a serial breach (compared to a maximum penalty of $250,000 under the Medicines Australia Code). CHF questions whether these penalties are sufficient to discourage breaches of the Code.

A single code of conduct?

At various points (e.g. 6.9.3; 12.1.17), the GMiA Code makes reference to the need to 'have due regard' to other codes of conduct, including the Therapeutic Goods Advertising Code, Medicines Australia Code of Conduct, the Australian Self Medication Industry Code of Conduct, the Ausbiotech Code of Conduct and the Medical Technology Association of Australia Code of Practice. Many of the principles within these codes are similar; however, other aspects of the codes are inconsistent.

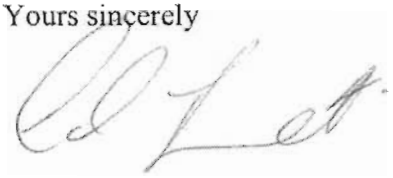
The discrepancies between the GMiA Code of Practice and other similar codes highlight the importance of the introduction of a single code of conduct for therapeutic goods, something for which CHF has advocated for some time. CHF has called for:

- A single code covering both complaints and advertising and promotional activities by industry
- A single and independent complaints mechanism with full public disclosure
- A single monitoring system
- Sanctions for non-compliance which go beyond simple retraction of claims and impose significant penalties.

CHF recognises that this is beyond the jurisdiction of the ACCC, but considers that it is worth noting when the ACCC is considering its approval of the GMiA Code and other codes of conduct for therapeutic goods in Australia.

Please do not hesitate to contact me if you would like to discuss any aspect of these comments further.

Yours sincerely



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