Generic Medicines Industry Association Pty Ltd

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Generic Medicines Industry Association

Code Administration Committee Report

Operation of GMiA Code of Practice

October 2011

For further details
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1. Introduction

The GMiA Code Administration Committee (CAC) met on 14 September 2011 to complete its responsibilities under section 15 of the GMiA Code of Practice (Code). The attached report is the annual report prepared by the CAC for the GMiA Board regarding the effectiveness of the Code.

2. Scope of report

This report considers the operation of the Generic Medicines Industry Association (GMiA) Code of Practice (Code) over the period 1 March 2010 – 30 September 2011.

3. Report on administration and implementation process of Code

The Code is administered by the GMiA secretariat.

The first edition of the Code was adopted by Members of GMiA and introduced on 1 March 2010. GMiA submitted the second edition of the Code to the ACCC for authorisation on 30 March 2010. Authorisation was granted on 3 November 2010.

The process of review for authorisation provided an important opportunity to raise stakeholder awareness and scrutiny of the Code.

The Code is posted on the GMiA website and its existence has been published via GMiA news releases; presentations at public seminars; and direct communication with stakeholders including but not limited to the Consumer Health Forum, Choice, the Therapeutic Goods Administration (TGA), National Medicines Policy Committee, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the National Pharmacy Services Association, the Australian Medical Association, Medicines Australia, Ausbiotech and the Australian Self Medication Industry.

The CEO has represented Members of GMiA on key Government reviews and this has provided another avenue to advocate the existence of the Code. The CEO of GMiA was a member of the working group convened by the Parliamentary Secretary for Health to review the promotion of therapeutic goods. This working group reported to the Parliamentary Secretary on 18 March 2011.

The CEO of GMiA was appointed by the Parliamentary Secretary for Health and Ageing to the panel tasked to review the transparency of TGA. This panel reported to the Parliamentary Secretary on 30 June 2011 and the report was released by the Parliamentary Secretary on 20 July 2011. The report can be found at http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm

GMiA conducted workshops on 18 February and 29 April 2011 for Members of GMiA to raise awareness with Members of their commitments under the Code. The workshop presentation and notes were also distributed to all Members.

4. Report on effectiveness of Code

The Code has been effective in formalising the high standards of conduct adhered to by Members.

The effectiveness of the Code is reviewed against the objectives of the Code (as they are set out in section 3.1 of the Code):

i. *Formalise the commitment of the Members to a system of best practice self-regulation and ethical supply of Products to the Australian community, in compliance with applicable laws and standards.*

   The adoption by Members of the first and second editions of the Code in 2010 has formalised the commitment by Members to a system of best practice self-regulation and ethical supply of generic medicines to the Australian community. Under the Code, Members agree to act in compliance with applicable laws and standards.

ii. *Increase awareness of and confidence in the quality, safety and cost effectiveness of Generic Medicines by Consumers, Healthcare Professionals and Government.*

   Members of GMiA promote awareness of generic medicines. ACCC authorisation of the Code has increased the awareness of the Code and the voluntary efforts of the Members of the GMiA in regulating the generic medicines industry to promote best practices (including quality, safety and the effectiveness of generic medicines). The invitation of the GMiA for comment at a parliamentary level, along with the participation of the CEO of GMiA in the review processes of the Department of Health and Ageing, points to the confidence of Government in the GMiA and their recognition of the importance of generic medicines generally.

iii. *Promote timely access for all consumers to safe and cost effective Generic Medicines.*

   Members of GMiA promote timely access to safe and cost-effective generic medicines through their continued efforts to market those medicines subject to the objectives and framework of the Code.

iv. *Identify the unique objectives of the Generic Medicines industry sector in its relationships with Consumers, Healthcare Professionals and Government and provide guidance as to how this relationship can be developed consistent with appropriate industry, professional and ethical standards.*

   GMiA represents Members at a number of forums with consumers, healthcare professionals and government. The CEO of GMiA was appointed by the Commonwealth Parliamentary Secretary for Health to be a member of the Working Group on Promotion of Therapeutic Products and the TGA Transparency Review Panel. Both these fora provided GMiA with important opportunities to express the objectives and principles of Members of GMiA with working group and panel members comprising consumer

representatives, healthcare professionals and government. Conversely, the views and perspectives of other stakeholders were also heard by GMiA.

The GMiA CEO represents Members at the biannual TGA/ Industry Consultative Council which also includes consumer representatives.

v. *Assist Members to promote and maintain a culture of ethical supply of Generic Medicines.*

GMiA conducted workshops on 18 February and 29 April 2011 for Members of GMiA to raise awareness with Members of their commitments under the Code. The workshop presentation and notes were also distributed to all Members. The ongoing promotion of the ethical supply of generic medicines by GMiA to its Members is further assured through its ongoing review process. The GMiA CAC is required to convene at least once each year and endeavour to ensure the successful implementation and ongoing effectiveness of the Code. In the event that the Code may be improved in order to better promote the ethical supply of Generic Medicines, the CAC may make recommendations to the GMiA Board that the Code by amended accordingly.

vi. *Promote ethical and professional conduct by all Members and their employees in the manufacture, supply and marketing of Generic Medicines and in their dealings with Consumers, Healthcare Professionals and Government.*

Members of GMiA are encouraged to adhere to the above principles, by virtue of their voluntary membership of the GMiA and consequently their voluntary regulation by the Code which promotes their ethical and professional conduct in the manufacture, supply and marketing of generic medicines and their dealings with consumers, healthcare professionals and Government.

vii. *Provide a mechanism for collaboration and dialogue with other Stakeholders to ensure that the Code continues to reflect high standards of conduct, consistent with established community and professional expectations.*

Consultation during the ACCC authorisation over 2010 process provided an important opportunity to raise stakeholder awareness and scrutiny of the Code.

On 7 September 2011 GMiA circulated an email to a broad range of stakeholders to extend an invitation to provide feedback and comments to GMiA to be included in the annual review of the administration of the GMiA Code of Practice. A copy of this email can be found in appendix 1 to this document.

viii. *To establish an accessible and transparent complaints handling mechanism which Consumers, Healthcare Professionals and other Stakeholders can utilise to make complaints about the conduct of Members.*

An accessible and transparent external complaints handling process has been established. This is described in full in section 12 of the Code. Stakeholders can make complaints about the activities of Members to the GMiA via post, email or the GMiA website.

ix. To establish a Code Complaints Committee to consider complaints about Members and impose sanctions in appropriate cases.

The Code Complaints Committee was established 2010. GMiA has exchanged contracts with an independent Committee Chairman, an independent pharmacy representative, an independent medically qualified representative and a consumer representative. A TGA representative has also been appointed as an observer to the Code Complaint Committee.

x. To establish an educational event reporting procedure that requires Members to report on the Educational Events run by Members for Healthcare Professionals responsible for prescribing and dispensing prescription medicines.

With the adoption of the Code, event reporting is now a routine component of Members' activities.

Event reporting

The Code has introduced the requirement for public reporting of information by Members to help ensure that the prescribing behaviours and specifically the selection of medicines by healthcare professionals is not unduly influenced by Members and is able to withstand public and professional scrutiny.

Members of GMiA have been reporting on educational events provided to prescribing healthcare professionals since 1 April 2010. Since 1 December 2010, Members have been reporting on educational events provided to all healthcare professionals AND on non-price benefits extended to pharmacists.

The educational event report template is identical to the educational event report template completed by suppliers of initial brand medicines who are members of the Medicines Australia industry association. GMiA adopted the template from the Medicines Australia Code of Conduct in the interests of publically delivering the same information as suppliers of the initial brand of medicines. GMiA understands that the educational event report template was originally designed by the ACCC and the adoption of this reporting template was a condition of ACCC authorisation of the Medicines Australia Code of Conduct.

The template under which Members report on non-price benefits extended to pharmacists was designed by the ACCC and the adoption of this reporting framework was also a condition of ACCC authorisation.

The first set of reports was posted on the GMiA website on 10 January 2011. These reports tabled educational events extended to prescribing healthcare professionals between 1 April 2010 - 30 September 2010. The next set of reports tabling educational events extended to prescribing healthcare professionals between 1 October 2010 - 31 March 2011 are also posted on the GMiA website.

Reports summarising non-price benefits extended to pharmacists during the 2010 calendar year are posted on the GMiA website.

Independent reviewer

As set out in section 13 of the Code, an independent reviewer has been appointed by GMiA. The independent reviewer has reviewed the reports tabling educational events extended to prescribing healthcare professionals between 1 April 2010 and 31 March 2011. The independent reviewer has also conducted spot audits of Members' marketing and promotional material to determine compliance with the Code. Spot audits occurs twice yearly at around the same time as the educational event reports are reviewed.

The independent reviewer has reviewed the reports summarising non-price benefits extended to pharmacists over the 2010 calendar year. The independent reviewer completed a short report, as required under section 13.9 of the Code, in September 2011.

5. Documentation of any material correspondence received from stakeholders pertaining to the Code

Beyond the events discussed in this report, including the ACCC authorisation and the review of promotion of therapeutic goods convened by the Parliamentary Secretary for Health, GMiA has not received any material correspondence from stakeholders pertaining to the Code over the period 1 March 2010 to 30 September 2011.

6. Report on the effectiveness of the complaints process including the number of complaints, the types of complaint, how the complaint was resolved, the time taken to deal with the complaint and the type of sanction imposed

During the period 1 March 2010 – 30 September 2011 the Association received two complaints.

Details of complaint #1 received by GMiA

A complaint was received by GMiA on 21 April 2010. The complaint was referred to the Independent Chairman of the Code Complaint Committee. The Chairman determined that the Code Complaint Committee would not adjudicate on the complaint in light of a corporate restructure that was announced by the Member after receipt of the complaint but before the Code Complaint Committee could be convened. The corporate

restructure rendered the activity subject to the complaint outside the jurisdiction of the Code Complaint Committee.

The complaint pertained to an activity of a Member company that was unique to that Member and not representative of the generic medicines sector as a whole. After the corporate restructure, the activity subject to the complaint was not an activity performed by the corporate entity that retained membership of GMiA.
That is, the activity subject to the complaint was being performed by a division of the Member company that was separate to the division of the company that performed the activity relevant to the membership of GMiA, that is, the manufacture and sale of generic medicines to the Australian market. After the corporate restructure, the activity was no longer the business activity of a GMiA Member.

The complainant was notified of the outcome on 30 September 2010. The complainant did not raise any further concerns.

Details of complaint #2 received by GMiA
On 18 April 2011 Medicines Australia wrote to GMiA advising that the Medicines Australia Monitoring Review Committee had reviewed all sponsor pop-up communications relating to or associated with prescription medicines in the February 2011 *Medical Director* prescribing software.

The communication from Medicines Australia is not a complaint as defined under the GMiA Code of Practice. Nevertheless, GMiA is reporting on the incident under this section of the CAC report for the purposes of full and transparent reporting of relevant events.

The Committee had noted concerns in the prescribing software pop-up about the statement, "*Expanded PBS listing*", in relation to the product Epipen sponsored by Alphapharm, a Member of GMiA. The Committee also noted that the pop-up included a website address to the Epipen Club.

GMiA contacted Medicines Australia to ascertain the process that Medicines Australia adopts when their monitoring review committee identifies a concern. GMiA sought to follow the same process as Medicines Australia.

GMiA wrote to the sponsor of the pop-up statement, Alphapharm, on 12 May 2011 forwarding the letter from Medicines Australia and inviting Alphapharm to make a response to GMiA.

Alphapharm responded to GMiA on 19 May 2011 advising that the pop-up menu was due for removal and had been taken off. Alphapharm also noted that:

- In their view the statement, "*Expanded PBS listing*" is a statement of fact and not promotional;

- The PBS statement on the EpiClub site was considered important information for patients already prescribed EpiPen to be aware of at the time.

Effectiveness of the external complaint handling process

The receipt by GMiA of its first complaint has ensured that GMiA is mobilised to consider any potential future complaints raised by stakeholders. The independent members of the Code Complaint Committee have all signed a contract with GMiA and GMiA is mobilised to convene the Code Complaint Committee as required.

GMiA expects to handle any potential future complaints in a more timely manner now that it has processed the first complaint.

The second complaint was received from an industry association, Medicines Australia, and GMiA sought to follow a process closely aligned with the process that would have been followed by Medicines Australia if the issue had pertained to the activities of one of its members.

7. Recommendations for future amendments to the Code and/or its implementation

The CAC noted that adherence to the Code by Members appears to be substantial. To formally acknowledge the high standard of behaviour by Members, the CAC recommended that:

- The GMiA Board requires that Members provide an annual statement to the GMiA for the purposes of the CAC annual review confirming:
    - their compliance with the Code;
    - their establishment of an internal complaints handling system as required under section 11 of the GMiA Code;
    - steps they have taken to ensure that their employees, contractors and agents are fully aware of the GMiA Code as required under section 8 of the GMiA Code;
    - provision of corporate or policy statements on their ethical business conduct; and
    - other relevant aspects of their standard of behaviour.

8. Appendix 1: Stakeholder consultation

From: Kate Lynch
Sent: Wednesday, 7 September 2011 12:54 PM
To: 'admin@gmia.com.au'
Subject: Annual Review of the administration of the GMiA Code of Practice

Dear All,

To maintain the high standards of business practice and behaviour the GMiA is currently in the process of completing its annual review of the administration of the GMiA Code of Practice.

The reporting process on the operation of the Code will incorporate the annual report of the Code Administration Committee in addition to summarising all monitoring activities reported by the Association's independent monitor.

Ongoing review of the operation of the Code is carried out at regular intervals of time and the GMiA encourages continual dialogue and consultation with its members, stakeholders and interested parties.

In compliance with the Code and to maintain open discussion and feedback GMiA has prepared an *Interim report on the Operation of the GMiA Code of Practice* which is posted on the GMiA website. Educational events extended by members during 1 April 2010 – 31 March 2011 and members' reporting of non-price benefits to pharmacy over 2010 are also available on the GMiA website. The GMiA website can be accessed at http://www.gmia.com.au/code-of-practice.html

The current review will be conducted in October 2011 and we would like to take this opportunity to extend an invitation to stakeholders to provide feedback and comments during the month of September 2011. This information can be sent to the GMiA via return email, our website or posted to the office at PO Box 222, Pymble BC NSW 2073.

Kind Regards,

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Circulated to representatives from the following organisations:

ARCS Australia

Ausbiotech

Australian Self Medication Industry

Australian Medical Association

Choice

Complementary Healthcare Council of Australia

Consumer Health Forum

Department of Health & Ageing

Department of Innovation, Industry, Science and Resources

GMiA Board

GMiA Members and Associate Members

Independent members of GMiA Code Complaints Committee

Medical Technology Association of Australia

Medicines Australia

National Pharmacy Services Association

National Medicines Policy Committee

NPS

NSW Clinical Excellence Commission

Panel convened by Parliamentary Secretary for Health to review TGA Transparency

Pharmaceutical Society of Australia

Pharmacy Guild of Australia

Therapeutic Goods Administration