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Generic Medicines Industry Association

Code Administration Committee Report

Operation of GMiA Code of Practice

December 2014

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1. Introduction

The GMiA Code Administration Committee (CAC) met on 4 November 2014 to complete its responsibilities under section 15 of the GMiA Code of Practice (Code). This report is the fourth 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 October 2013 – 30 September 2014.

3. Report on administration and implementation process of Code

The Code is administered by the GMiA secretariat. GMiA provides all members and non-members with support in the administration of the Code.

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 third edition of the Code was adopted by the GMiA on 29th January 2014. In 2013, GMiA undertook a detailed review of the Code of Practice and produced a third edition of the Code. The preparation of the third edition of the Code included:

- A thorough review of the recommendations from the *Working Group on Promotion of Therapeutic Goods*, of March 2011[1], to ensure all relevant recommendations are included in the Code;
- Amendments to the Code to ensure that its provisions do not raise any concerns under the *Competition and Consumer Act* 2010 (CCA) as GMiA does not intend to apply for ACCC re-authorisation of the Code; and
- Consultation with external stakeholders.

In June 2010 the Australian Government released a Position Paper with the objective of ensuring that decisions on management (including treatment options) for health needs are based on sound clinical evidence, not driven by incentives or other influences. The then Parliamentary Secretary for Health convened a working group to respond to the Position Paper. The then GMiA CEO was a member of this working group and the working group tabled a report with the Parliamentary Secretary of Health on 18 March 2011.

GMiA is pleased to have the opportunity to include, in the third edition of the Code, the recommendations from the Working Group on Promotion of Therapeutic Products as reported to the then Parliamentary Secretary, Catherine King, in March 2011. To this end several additions have been made to the GMiA Code:

. The *'High Level Principles'* as set out in the report prepared by the working group are included in section 6.3.1 of GMiA Code;

. The GMiA Code includes specific reference to the Operational Areas identified by the working group.

Under the third edition of the Code, the composition of the Code Complaint Committee has adjusted to increase the independence of the Committee. All industry representatives on the Committee have been removed.

Members will continue to report on educational events and non-price benefits. The timing of the preparation report will be streamlined. Reports will cover the period 1 July to 30 June.
Interim reports were prepared by Complying Members to bridge the transition between the second and third editions of the Code:

. An interim educational report was prepared by Complying Members for the period of 1 October 2013 – 30 June 2014;

. A non-price benefit report was prepared by Complying Members for the period 1 January – 30 December 2013 and an interim report was prepared for the period 1 January – 30 June 2014.

The revised Code introduced the concept of a "Complying Member". Complying Members must pro-actively opt to comply with the Code, and have provided a declaration of compliance with the Code. A list of Complying Members is listed on the GMiA website. This list includes but is not limited to:

- Alphapharm
- Apotex
- Aspen
- Actavis
- Hospira
- Sandoz

All GMiA Members have confirmed their intent to be "Complying Members".

Medicines Australia Code of Practice

The Australian Competition and Consumer Commission has granted interim authorisation to Medicines Australia for its Code of Conduct, a voluntary industry code of conduct for the prescription medicines industry in Australia. Interim authorisation is granted for the Code in terms of edition 17. Medicines Australia requested an extension of time to provide its response to the ACCC's draft determination and that the pre-decision conference be delayed until 28 November 2014. As a result, the ACCC will not be able to make a final determination in relation to the substantive application for authorisation of edition 18 of the code before the existing authorisation of edition 17 of the Code expires on 11 January 2015

During the annual meeting of the GMiA Code Administration Committee held on the 4th November 2014 the application from Medicines Australia for ACCC authorisation of their code and any potential impact on the GMiA Code was discussed.

The CAC noted the importance of separating the GMiA Code from the Medicines Australia Code, stating that the GMiA Code reflects the generic medicines market and the way generic medicine suppliers operate within that market.

Additionally, the CAC agreed that GMiA should continue to reject any call for increased transparency that would require reporting of commercially sensitive pricing information.

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, second and third editions of the Code 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.

Under the third edition of the Code of Practice, "Complying Members" prepared a prospective Annual Statement declaring their intent to comply with the Code and prepare a retrospective Annual Statement declaring their Compliance with the Code.

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. This is done through their extensive sales and marketing activities subject to the objectives and framework of the Code.

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.

In March 2014, GMiA presented at the annual meeting of the National Pharmacy Guild of Australia to advocate the benefits of timely access for all consumers to safe and cost effective generic medicines. GMiA participated in the State of the Industry Symposium at APP2014.

Further GMiA was a partner at the launch of the Medicines Shortages Information Initiative by the Assistant Minister for Health on 26th May 2014.

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 GMiA CEO currently sits on several industry committees including the Drug Utilisation Sub Committee (DUSC) and TGA Industry Working Group.

GMiA has a representative on the Medicines Australia convened Transparency Working Group.

These forums provide 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 are also heard by GMiA.

The GMiA CEO presents regularly at industry and stakeholder forums including but not limited to Eye for Pharma Conference on 8th October 2014 and the Future of the PBS Summit 5-6th May 2014.

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

The ongoing promotion of the ethical supply of generic medicines by GMiA to its Members is 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 be amended accordingly.

The marketing material of members is subject to annual spot checks. These spot checks are performed by the Independent Reviewer.

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.

The third edition of the Code of Practice requires that the GMiA hold a training workshop covering the contents of the Code and Members' obligations under the Code for Complying Members annually.

The GMiA annual Code of Practice workshop took place on 1st May 2014 and had representation by all member companies. Please see Appendix 1. For the Code workshop presentation.

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.*

On 29 January 2014, GMiA circulated a copy of the final third edition of the GMiA Code of Practice to a range of stakeholders notifying them of the date of adoption. At that time GMiA also highlighted the fact that the Association is a member of the Australian Government established Advisory Group tasked to oversee and guide implementation of recommendations relating to the self-regulation of the therapeutic goods sector.

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 in 2010. GMiA has appointed an independent Committee Chairman, an independent pharmacy representative, an independent medically qualified representative and a consumer representative to the GMiA Code Complaint Committee. A TGA representative has also been appointed as an observer to the Code Complaint Committee.

Under the third edition of the Code of Practice, the Code Complaint Committee will be adjusted to increase the independence of the Committee. All industry representatives on the Committee will be removed.

The CCC has been required on one occasion when it successfully adjudicated on one complaint on 31 January 2012.

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 the original brand of 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. Eight sets of reports are now posted on the GMiA website spanning the period 1 April 2010 – June 2014.

Reports summarising non-price benefits extended to pharmacists during the 2010, 2011, 2012, 2013 and 2014 calendar years are posted on the GMiA website.

Under the third edition of the Code of Practice, Members will continue to report on educational events and non-price benefits. The timing of the preparation report will be streamlined. Reports will cover the period 1 July to 30 June. All interim reports have been prepared by Complying Members to bridge the transition between the second and third editions of the Code.

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 30 June 2014. The independent reviewer has also conducted spot audits of Members' marketing and promotional material to determine compliance with the Code. Spot audits occur 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, 2011, 2012, 2013 and 2014 calendar years. The independent reviewer completed a short report, as required under section 13.9 of the Code, in October 2014.

Under this section of the Code, the independent review is required to make a general statement of the level of compliance by Members with the Educational Event reporting obligations under the Code. The independent reviewer reported,

"I did not identify any potential breaches of the Code from the information that I reviewed in each of the Educational Event Reports. Accordingly, there was a high level of compliance by Complying Members with their Educational Event reporting obligations under the Code."

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

Beyond the events discussed in this report, GMiA has not received any material correspondence from stakeholders pertaining to the Code over the period 30 September 2013 to 30 November 2014.

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 30 September 2013 – 30 November 2014 the Association received no complaints.

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

Recommendations:

1. **Review definition of 'Non price benefit report' given the reference used in the Code is no longer available.**

During the annual CAC meeting it was confirmed that the definition of non-price benefits and that the 'Annual Incentives Data Form' referred to is no longer publicly available.

> ***Non-Price Benefits*** *- means sales incentives as described in the Australian Government Department of Health and Ageing 'Annual Incentives Data Form' other than more favourable trading terms.*

The CAC agreed that reference to the form should be removed and proposed the following definition be put to the GMiA Board.

> ***Non-Price Benefits*** *- means sales incentives ~~as described in the Australian Government Department of Health and Ageing 'Annual Incentives Data Form'~~ other than more favourable trading terms.*

8. Appendix 1: Annual Code Workshop Presentation

Code Workshop 1Apr13.pdf