GBMA
Generic and Biosimilar Medicines Association

Code Administration Committee Report

Operation of the GMiA/GBMA Code of Practice

December 2015

INTRODUCTION

The Code Administration Committee (CAC) met on 30 November 2015 to complete its responsibilities under section 14 of the GMiA Code of Practice (Code). This report is the fifth annual report prepared by the CAC for the GMiA Board regarding the effectiveness of the Code.

In July 2015, the Generic Medicines Industry Association (GMiA) changed its name to the Generic and Biosimilar Medicines Association (GBMA).

SCOPE OF REPORT

This report considers the operation of the GMiA Code of Practice (Code) over the period 1 October 2014 – 30 November 2015.

CODE ADMINISTRATION AND IMPLEMENTATION PROCESS

The Code is administered by the GMiA (now GBMA) secretariat.
The first edition of the Code was adopted by GMiA Members and introduced on 1 March 2010. GMiA submitted the second edition of the Code to the ACCC for authorisation on 30 March 2010. ACCC authorisation was granted on 3 November 2010.

In 2013, GMiA undertook a detailed review of the Code and produced a third edition. In preparing the third edition, GMiA conducted a thorough review of the recommendations from the Working Group on Promotion of Therapeutic Goods, of March 20111, to ensure all relevant recommendations are included in the Code. GMiA made amendments to the Code to ensure that its provisions do not raise any concerns under the Competition and Consumer Act 2010 (CCA) as GMiA did not intend to apply for ACCC re-authorisation of the Code for the third edition. In addition, GMiA consulted with external stakeholders.

The third edition of the Code was adopted by GMiA on 29 January 2014.

The third edition of the Code introduced the concept of 'Complying Members'. Complying Members must pro-actively opt to comply with the Code, and have provided a declaration of compliance with the Code.
Complying Members include:

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

[1] 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.

The third edition requires Complying Members to report on educational events and non-price benefits.

During its meeting of the 30 November, the CAC discussed and agreed to a number of recommendations made by the GBMA Board for amendments to the Code.

EFFECTIVENESS OF THE 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, The Purpose 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.*

Complying Members promote awareness of generic medicines through their extensive sales and marketing activities subject to the objectives and principles of the Code.

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

Complying Members promote timely access to safe and cost-effective generic medicines through their continued efforts to market those medicines subject to the objectives and principles of the Code.
In March 2015, GMiA presented at the annual meeting of the Pharmacy Guild of Australia to advocate the benefits of timely access for all consumers to safe and cost effective generic medicines.
Complying Members regularly promote timely access to safe and cost effective generic medicines with activities to challenge patents through the Australian legal system.

Complying Members also advocate for changes to Australia's intellectual property system for pharmaceuticals and on international trade agreement negotiations that will promote timely access to generic medicines in Australia.

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.

Representatives from Complying Members participate in the Generic Medicines Working Group (GMWG), which was established under the Strategic Agreement signed by the Minister for Heath, Hon Sussan Ley and GMiA in May 2015. The Strategic Agreement recognises the important role of generic and biosimilar medicines in delivering affordable healthcare.

GMiA participates on the government's Health Industry Forum, is a member of the Medicines Partnership of Australia, and the GMiA CEO currently sits on several industry committees including the Drug Utilisation Sub Committee (DUSC) and TGA Industry 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.

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 12 June 2015 and had representation by all Complying Members. The Code workshop presentation is included in appendix 1.

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.

The GMiA Code of Practice is highlighted during slide presentations made by the GMiA CEO and a copy of the Code is publicly available on the GMiA website. There are now 5-years' worth of educational event and non-price benefit reports publicly accessible on the website that demonstrate conduct consistent with community and professional expectations.

GMiA notes there have been two media enquiries on the reports. One was a request for a definition of a non-price benefit, and the other was seeking to understand why one member reported significantly higher overall expenditure on educational events.

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 11 of the Code. Stakeholders can make complaints about the activities of Members to the GMiA via post, email or the GMiA website.

Additionally, members are made aware of the importance of ensuring robust internal complaints handling processes and the need to provide ongoing employee education regarding obligations under the Code.

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 was adjusted to increase the independence of the Committee and all industry representatives on the Committee were removed.

The CCC has been required on only one occasion to date 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.

There are now 5-years' worth of publicly accessible reports on educational events run by Complying Members for healthcare professionals. Available on the new GBMA

website, these reports demonstrate transparency and conduct consistent with community and professional expectations.

INDEPENDENT REVIEWER

As set out in section 12 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 July 2014 and 30 June 2015. 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. The independent reviewer completed a short report, as required under section 12.9 of the Code, in November 2015.

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."

The independent reviewer has now reported this statement in every report from 2011 to 2015.

DOCUMENTATION OF ANY MATERIAL CORRESPONDENCE RECEIVED FROM STAKEHOLDERS PERTAINING TO THE CODE

GMiA has not received any material correspondence from stakeholders pertaining to the Code over the period 1 October 2014 – 30 November 2015.

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 October 2014 – 30 November 2015, GMiA received no complaints. No complaints have been referred to the Code Complaint Committee (CCC) since 2012, and this could demonstrate the appropriateness of complying members' internal component handling processes.

RECOMMENDATIONS FOR FUTURE AMENDMENTS TO THE CODE AND/OR ITS IMPLEMENTATION

The GMiA Board proposed a number of amendments to the Code for consideration by the CAC in its meeting of 30 November 2015. The amendments seek to:

1. Remove the requirement for educational event and non-price benefit reporting.

The rationale for removing reporting requirements includes the significant compliance burden placed on members in an era of decreasing margins for generic medicines. GBMA members have consistently demonstrated transparency and appropriate conduct over the past five years as evidenced in publicly available reports on the GBMA website.

Medicines Australia has removed this requirement of its members in the 18th edition of its Code. It should be noted that GMiA members operate under a different business model to Medicines Australia members, where the latter seek to change prescribing behaviour. Lavish events have never been a feature of the generic medicine business model as evidenced by very low reported expenditure per-head. This minimal educational event expenditure, coupled with a different model, is the basis upon which the GBMA Board has requested removing the requirement to report.

The CAC agreed to make this amendment to the Code.

2. Remove the requirement for a spot-audit of marketing material.

The CAC agreed that spot auditing of marketing material is less relevant for generic medicines than brand medicines as most material is aimed at advising pharmacists of the availability of new generic medicines.

The CAC agreed to make this amendment to the Code.

3. Combine the two Annual Statements into one Statement declaring a members' compliance with the Code both retrospectively and prospectively.

The CAC agreed that combining the two annual statements is a sensible amendment.

The CAC agreed to make this amendment to the Code.

The CAC recommended changes be made to the GMiA Code of Practice, including changing the association name and reference to biosimilars, producing a fourth edition GBMA Code of Practice.

The CAC noted that with the removal of the requirement for reporting of events and non-price benefits, and spot-auditing of marketing materials, the role of the independent reviewer is redundant. The fourth edition Code must therefore be amended accordingly.

APPENDIX 1 – ANNUAL CODE WORKSHOP PRESENTATION

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Generic and Biosimilar Medicines Association

Making medicines affordable

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