



Independent Review Report

for

Generic Medicines Industry Association Code of Conduct

27 January 2016

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Background

1. The Generic and Biosimilar Medicines Association (GBMA), formerly called the Generic Medicines Industry Association (GMiA), accepts as Members Australian entities that are dedicated to the supply and/or manufacture of affordable therapeutic goods in the Australian market. Members are bound by a commonality of supply and/or manufacture of Generic Medicines (Products) in the Australian market.
2. The Generic Medicines Industry Association Code of Conduct (the Code) is a principle based code of conduct, providing guidance in a single document, on the different legislation, regulation and guidelines with which Sponsors of Generic Medicines listed on the Australian Register of Therapeutic Goods (ARTG) comply. The current edition of the Code at the time of this report is the 3rd Edition dated November 2013.
3. Members of GBMA may voluntarily choose to be bound by the terms of the Code (Complying Members).
4. One of the requirements of the Code is that the GBMA Board will appoint an independent reviewer for a period of three years to review any Educational Event Reports submitted by Complying Members and conduct spot audits of Complying Member's marketing and promotional material in relation to particular products on one occasion per year to determine compliance with the Code (Independent Reviewer).
5. In February 2011, the GBMA appointed me as the Independent Reviewer for the first three years of the Code. In June 2014, GBMA reappointed me as the Independent Reviewer.
6. This report covers the period 1 July 2014 to 30 June 2015.

Independent Reviewer

7. Clause 12.7 of the Code requires that the Independent Reviewer be legally trained and have experience in trade practices law. The Independent Reviewer must not have or have had any professional or personal affiliation with either GBMA or any Complying Member, Member or non-Member prior to being initially appointed to the role of Independent Reviewer.
8. As at the date of this report, I confirm that I do not have, and have not had, any professional or personal affiliation with either GBMA or any Complying Member, Member or non-Member prior to being initially appointed to the role of Independent Reviewer. For the purposes of this report a 'non-Member' means a supplier of generic medicines that is not a member of the GBMA.
9. I also confirm that I am legally trained and have experience in trade practices law. I have degrees in economics and law from the Australian National University and am admitted as a solicitor and barrister in the ACT. I have over 16 years' experience in trade practices law as a lawyer, auditor and compliance professional.
10. Since December 2003, I have been the Managing Director of Watchdog Compliance. In this role I have assisted many companies and individuals to comply with their legal obligations arising under the *Competition and Consumer Act 2010* (formerly the *Trade Practices Act 1974*) and other trade practices laws.
11. Prior to founding Watchdog Compliance, I was an in-house lawyer for the Australian Competition and Consumer Commission (ACCC) and a senior lawyer with Australian Government Solicitor where I provided a broad range of legal services to the ACCC.

Scope of the Review

12. The scope of the review was determined by reference to the responsibilities of the Independent Reviewer specified at clause 12 of the Code.
13. Accordingly, the scope of the review was to:
 - 13.1. review the Educational Event Reports submitted by Complying Members to determine whether any events disclosed in Educational Event Reports may potentially breach the Code;
 - 13.2. conduct spot audits of Complying Members' marketing and promotional material in relation to particular products on one occasion per year to determine compliance with the Code;
 - 13.3. refer any matters to the Code Complaint Committee (CCC) if I form the opinion that an Educational Event or marketing / promotional material may breach the Code, and prepare a short note outlining the basis for my concerns and providing that note to the CCC and the relevant Complying Member;
 - 13.4. prepare a short note containing the following information:
 - a general statement of the level of compliance by Complying Members with the Educational Event reporting obligations under the Code;
 - a description of the matters I have referred to the CCC;
 - any suggested changes to the Educational Event reporting system which may, in my opinion, enhance the effectiveness or transparency of the system.

Complying Members

14. For the Reporting Period 1 July 2014 to 30 June 2015, the Complying Members were:
 - 14.1. Alphapharm Pty Ltd;
 - 14.2. Apotex Pty Ltd;
 - 14.3. Arrow Pharmaceuticals Pty Ltd;
 - 14.4. Hospira Pty Ltd;
 - 14.5. Sandoz Pty Ltd.

Findings

15. Clause 12.9 provides that this report is to contain the following information:
 - 15.1. a general statement on the level of compliance by Complying Members with the Educational Event reporting obligations under the Code;
 - 15.2. a description of the matters I have referred to the CCC; and
 - 15.3. any suggested changes to the Educational Event reporting system which may, in my opinion, enhance the effectiveness or transparency of the system.

General Statement of the level of Compliance by Complying Members with Educational Event Reporting Obligations under the Code

16. Clause 9.1 of the Code requires each Complying Member to provide a report to GBMA on all Educational Events for Healthcare Professionals who prescribe or dispense prescription medicines which are held or sponsored by that Complying Member by:
 - 16.1. completing the table as set out at Appendix 2 to the Code; and
 - 16.2. providing a copy of the completed table for the period 1 July to 30 June in each year within two months of the end of each period.

17. The Reporting Period for this review is 1 July 2014 to 30 June 2015.
18. The role of the Independent Reviewer in relation to the Educational Event Reports is to review these reports to determine whether any events disclosed in Educational Event Reports may potentially breach the Code.
19. An Educational Event is defined by the Code as:

any education focused event providing current and relevant medical information to prescribing or dispensing Healthcare Professionals that is supported, either financially or administratively, by a Complying Member(s).
20. Relevantly, clause 6.9.7 of the Code lists the principles that Complying Members will observe in relation to any Educational Events which they provide to Healthcare Professionals.
21. In reviewing the Educational Event Reports consideration was therefore given, in so far as it could be ascertained from the information provided in the reports, to whether any information disclosed in those reports could indicate that a Complying Member has not observed the principles specified at clause 6.9.7 of the Code.
22. The information required to be disclosed in the Educational Event Reports is specified in the template at Appendix 2 to the Code. Namely:
 - 22.1. Description of event;
 - 22.2. Venue;
 - 22.3. Description of attendees;
 - 22.4. Hospitality provided;
 - 22.5. Total cost of hospitality;
 - 22.6. Number of attendees;
 - 22.7. Total cost of event.

23. A Member will have satisfied their obligation in relation to providing an Educational Event Report to the GBMA if they provide the report in the format of the table at Appendix 2 to the Code containing this information.
24. For the period 1 July 2014 to 30 June 2015, Educational Event Reports were provided to the GBMA by the following Complying Members:
 - 24.1. Alphapharm Pty Ltd;
 - 24.2. Hospira Pty Ltd;
 - 24.3. Sandoz Pty Ltd.
25. The GBMA advised me that the other Complying Members did not carry out any Educational Events for the period 1 July 2014 to 30 June 2015.
26. I reviewed each of the Educational Event Reports submitted by these Complying Members to determine whether any events disclosed in Educational Event Reports may potentially breach the Code.
27. The only anomalies I identified were two events listed in the Educational Event Report from Sandoz Pty Ltd, being that there was no entry for the total cost of hospitality. Upon querying these anomalies, I was informed by Sandoz Pty Ltd that one of those events did not take place and should have not appeared in the table and there was no hospitality costs incurred for the other event.
28. Accordingly, I did not identify any potential breaches of the Code from the information that I reviewed in each of the Educational Event Reports.
29. The Code requires Complying Members to submit their Educational Event Report within two months of the reporting period required by the Code (i.e. by no later than 31 August 2015). Hospira Pty Ltd and Sandoz Pty Ltd submitted their Educational Event Reports within the required period. Alphapharm Pty Ltd submitted its Educational Event Report after the required period. I was informed that the delay by Alphapharm Pty Ltd in submitting its Educational Event Report was due to changes to its software.

30. Accordingly, the only non-compliance by Complying Members with their Educational Event reporting obligations under the Code was the delay by Alphapharm in submitting its Educational Event Report.

A description of the matters referred to the CCC

31. Clause 12.4 of the Code provides that if I form the opinion that an Educational Event or marketing / promotional material may breach the Code, I can refer the matter to the CCC for further consideration.
32. Clause 12.5 of the Code provides that in the event that I form the view that an Educational Event or marketing / promotional material may breach the Code, I am to prepare a short note outlining the basis for my concerns. This document is to be provided to the CCC and the relevant Complying Member.
33. As noted above, I did not identify any potential breaches of the Code from the information that I reviewed in each of the Educational Event Reports.
34. In terms of marketing / promotional material, clause 12.3 of the Code provides that I am to conduct spot audits of member's marketing and promotional material in relation to particular products on one occasion each year to determine compliance with the Code.
35. Clause 6.10 of the Code sets out requirements for Complying Members in relation to 'promotional and marketing activities'.
36. For the period 1 July 2014 to 30 June 2015, I was provided with marketing and promotional material in relation to particular products on one occasion from all the Complying Members.
37. I reviewed the marketing and promotional material provided to me to determine compliance with the Code by the Complying Member.
38. I did not identify any potential non-compliance with the Code by any Complying Member from the marketing and promotional material provided to me.

39. As I did not form the opinion that any Educational Event or marketing / promotional material may breach the Code, I did not refer any such matters to the CCC.

Any suggested changes to the Educational Event reporting system

40. Clause 12.9 of the Code requires this report to include any suggested changes to the Educational Event reporting system which may, in my opinion, enhance the effectiveness or transparency of the system.
41. The purpose of the Educational Event reporting system is to reduce actual and potential conflicts of interest between Complying Members and Healthcare Professionals responsible for prescribing and dispensing prescription medicines. The Code lists principles in clause 6.9.7 directed at achieving this outcome.
42. The information required to be provided in Educational Event Reports is set out in the table at Annexure 2 to the Code. The completed tables are provided by Complying Members to the GBMA each and are to be posted on the GBMA website within four months of the applicable period.
43. In my opinion, the Educational Event Reporting system has been adopted and implemented by Complying Members and the GBMA.
44. I do not have any suggested changes to the Educational Event reporting system which may, in my opinion, enhance the effectiveness or transparency of the system.
45. Report authorised on 27 January 2016 by:



David Johnson
Managing Director