
# Second Independent Review Report

# for

# Generic Medicines Industry Association Code of Conduct

## 27 August 2012

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## Background

1. The Generic Medicines Industry Association (GMiA) accepts as Members Australian entities that predominantly manufacture and/or sell Generic Medicines (Products) in the Australian Market and/or manufacture Generic Medicines for export (Members).

2. It is a condition of Membership to the GMiA that Members adopt the code and comply with the Code.

3. The Code is principle based, 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.

4. One of the requirements of the Code is that the GMiA Board will appoint an independent reviewer for a period of two years to review the Educational Event Reports submitted by Members and conduct spot audits of Member's marketing and promotional material in relation to particular products on two separate occasions each year to determine compliance with the Code.

5. In February 2011, the GMiA appointed Mr David Johnson (Managing Director of Watchdog Compliance) as the Independent Reviewer for the purposes of clause 13 of the Code.

6. On 28 September 2011, I provided my report on the first year to the GMiA for the purposes of clause 13.9 of the Code.

7. This is my report on the second year for the purposes of clause 13.9 of the Code. The relevant periods for this report are:

   7.1. 1 April 2011 to 30 September 2011; and

   7.2. 1 October 2011 to 31 March 2012.

## Independent Reviewer

8. Clause 13.7 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 GMiA or any Member prior to being initially appointed to the role of Independent Reviewer.

9. As at the date of this report, I confirm that I do not have, and have never had, any professional or personal affiliation with either GMiA or any Member other than conducting the first Independent Review for the purposes of clause 13 of the Code.

10. 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 13 years experience in trade practices law as a lawyer, auditor and compliance professional.

11. 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.

12. 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 Australian Competition and Consumer Commission ('ACCC').

## Scope of the Review

13. The scope of the Review was determined by reference to the responsibilities of the independent reviewer specified at clause 13 of the Code.

14. Accordingly, the scope of the Review was to:

    14.1. review the Educational Event Reports submitted by Members to determine whether any events disclosed in Educational Event Reports may potentially breach the Code;

    14.2. conduct spot audits of member's marketing and promotional material in relation to particular products on two separate occasions each year to determine compliance with the Code;

    14.3. refer any matters to the Code Complaint Committee (CCC) if the Independent Reviewer forms the opinion that an Educational Event or marketing / promotional material may breach the Code; and

    14.4. prepare a short note outlining the basis for his concerns and providing that note to the CCC and the relevant member;

    14.5. prepare a short note each year containing the following information:

    - a general statement of the level of compliance by Members with the Educational Event reporting obligations under the Code;
    - a description of the matters he has referred to the CCC;
    - any suggested changes to the Educational Event reporting system which may, in the Independent Reviewer's opinion, enhance the effectiveness or transparency of the system.

## Educational Event Reports

15. The Code requires each Member to provide a report to GMiA on all Educational Events for Healthcare Professionals who prescribe or dispense prescription medicines which are held or sponsored by that Member by:

    15.1. completing the table as set out at Appendix 2 to the Code; and

    15.2. providing a copy of the completed table for the period 1 April to 30 September and 1 October to 31 March in each year within two months of the end of each six-month period.

16. The role of the 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.

17. An Educational Event is defined by the Code as:

> *any education focussed event providing current and relevant medical information to prescribing or dispensing Healthcare Professionals that is supported, either financially or administratively, by a Member(s).*

18. Relevantly, clause 10.1.2 of the Code provides that Members must observe the following principles in relation to any Educational Events which they provide to Healthcare Professionals:

    i. *the purpose of all Educational Events must be to provide current and relevant medical information to Healthcare Professionals;*

    ii. *before offering any Educational Event to Healthcare Professionals the Member must be satisfied that there is a genuine medical need for the particular Educational Event;*

    iii. *the name of the Member which is funding the Educational Event must be clearly disclosed to all potential participants in any marketing material prior to the Educational Event being held;*

    iv. *Members must ensure that the costs of Educational Events are not disproportionate to the value to be gained by participants from the educational content of the Educational Event;*

    v. *Members must ensure all Educational Events devote at least seventy five (75) percent of the scheduled conference time to the provision of educational content;*

    vi. *Members must not pay for meals, accommodation or travel for any relative or associate of a participant at an Educational Event;*

    vii. *Members must take all reasonable steps to minimise the cost of Educational Events, for example by charging participants a*

*registration fee, by selecting less expensive conference facilities, or by conducting educational events in major cities rather than in remote areas; and*

viii. *delegates at Educational Events must not be paid for their attendance unless they have an additional role at the event such as presenting a paper or acting as MC.*

19. In reviewing the Educational Event Reports consideration was therefore given to whether any information disclosed in those reports could indicate that a Member has not observed the principles specified at clause 10.1.2 of the Code.

20. The information required to be disclosed in the Educational Event Reports is specified in the table at Appendix 2 to the Code. Namely:

    20.1. Description of event;

    20.2. Venue;

    20.3. Description of attendees;

    20.4. Hospitality provided;

    20.5. Total cost of hospitality;

    20.6. Number of attendees;

    20.7. Total cost of event.

21. A Member will have satisfied their obligation in relation to providing an Educational Event Report to the GMiA if they provide the report in the format of the table at Appendix 2 to the Code containing this information.

22. For the Reporting Periods 1 April 2011 to 30 September 2011 and 1 October 2011 to 31 March 2012, GMiA members included:

    22.1. Alphapharm Pty Limited;

    22.2. Apotex Pty Ltd;

    22.3. Ascent Pharmaceuticals Limited;

    22.4. Aspen Pharmaceuticals Limited;

22.5. Hospira Pty Limited; and

22.6. Watson Pharma Pty Ltd.

**Reporting Period: 1 April 2011 to 30 September 2011**

23. For the period 1 April 2011 to 30 September 2011, Educational Event Reports were provided to the GMiA by the following Members:

23.1. Alphapharm Pty Limited;

23.2. Ascent Pharmaceuticals Limited;

23.3. Aspen Pharmaceuticals Limited; and

23.4. Hospira Pty Limited.

24. Watson Pharma Pty Ltd and Apotex Pty Ltd confirmed that they did not carry out any Educational Events for the period 1 April 2011 to 30 September 2011.

**Reporting Period: 1 October 2011 to 31 March 2012**

25. For the period 1 October 2011 to 31 March 2012, Educational Event Reports were provided to the GMiA by the following Members:

25.1. Alphapharm Pty Limited;

25.2. Ascent Pharmaceuticals Limited; and

25.3. Hospira Pty Limited.

26. Aspen Pharmaceuticals Limited, Apotex Pty Ltd and Watson Pharma Pty Ltd confirmed that they did not carry out any Educational Events for the period 1 October 2011 to 31 March 2012.

27. We reviewed each of the Educational Event Reports submitted by these Members to determine whether any events disclosed in Educational Event Reports may potentially breach the Code.

28. We did not identify any potential breaches of the Code from the information that we reviewed in each of the Educational Event Reports.

## Spot audits of member's marketing and promotional material

29. The Review requires spot audits of member's marketing and promotional material in relation to particular products on two separate occasions each year to determine compliance with the Code.

30. Clause 6.9 of the Code sets out requirements for Members in relation to 'promotional and marketing activities'.

31. For the period 1 April 2011 to 31 March 2012, we were provided with marketing and promotional material in relation to particular products on two separate occasions from the following Members:

    31.1. Alphapharm Pty Limited;

    31.2. Apotex Pty Ltd;

    31.3. Ascent Pharmaceuticals Limited;

    31.4. Aspen Pharmaceuticals Limited; and

    31.5. Hospira Pty Limited.

32. Watson Pharma Pty Ltd advised that it did not produce any marketing or promotional material during this period.

33. We reviewed the marketing and promotional material provided to us and did not identify any potential breaches of the Code.

## Referral of matters to the Code Complaint Committee (CCC)

34. The Independent Reviewer is to refer matters to the Code Complaint Committee (CCC) if the Independent Reviewer forms the opinion that an Educational Event or marketing / promotional material may breach the Code; and prepare a short note outlining the basis for the concerns and providing that note to the CCC and the relevant member.

35. We did not refer any matters to the CCC.

## A general statement of the level of compliance by Members

36. The Independent Reviewer is to make a general statement of the level of compliance by Members with the Educational Event reporting obligations under the Code.

37. There was nothing to indicate any level of non-compliance by Members from the information that was provided in the Educational Event Reports.

## Any suggested changes to the Educational Event reporting system

38. Clause 13.9 of the Code requires this report to include any suggested changes to the Educational Event reporting system which may, in the Independent Reviewer's opinion, enhance the effectiveness or transparency of the system.

39. The purpose of the Educational Event Reporting system is to require 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.

40. 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 Members to the GMiA twice a year and are posted in the GMiA website.

41. In our opinion, the Educational Event Reporting system has been adopted and implemented by Members and the GMiA. However we note that some reports were required to be resubmitted to include information required at Annexure 2 to the Code.

42. We acknowledge that the said reports noted in clause 41 have now been resubmitted in compliance with Annexure 2 to the Code and have been re-posted on the GMiA website.

43. Accordingly, we would suggest that the GMiA take steps to reinforce to Members that their Educational Event Reports must be provided in the format

of the table at Appendix 2 to the Code and contain all the information specified in the table at Appendix 2 to the Code.

44. Report authorised on 27 August 2012 by:

David Johnson
Managing Director