

Medicines Australia Code of Conduct Quarterly Report July - September 2016

The quarterly report of determinations of the Medicines Australia Code of Conduct and Appeals Committees

The Medicines Australia Code of Conduct was introduced in 1960 and is currently operating under Edition 18 (Effective 16 May 2015).

This report covers all complaints finalised between July and September 2016. Complaints finalised during this period were in relation to materials or activities conducted under Edition 18 of the Code.

Quarterly Reports preceding this Report are available from the Medicines Australia website <http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/>

How to contact Medicines Australia

Address:

Level 1, 16 Napier Close
DEAKIN ACT 2600

Phone: 02 6122 8500

Fax: 02 6122 8555

Email: secretarycodecommittee@medicinesaustralia.com.au

How do I obtain a copy of the Code?

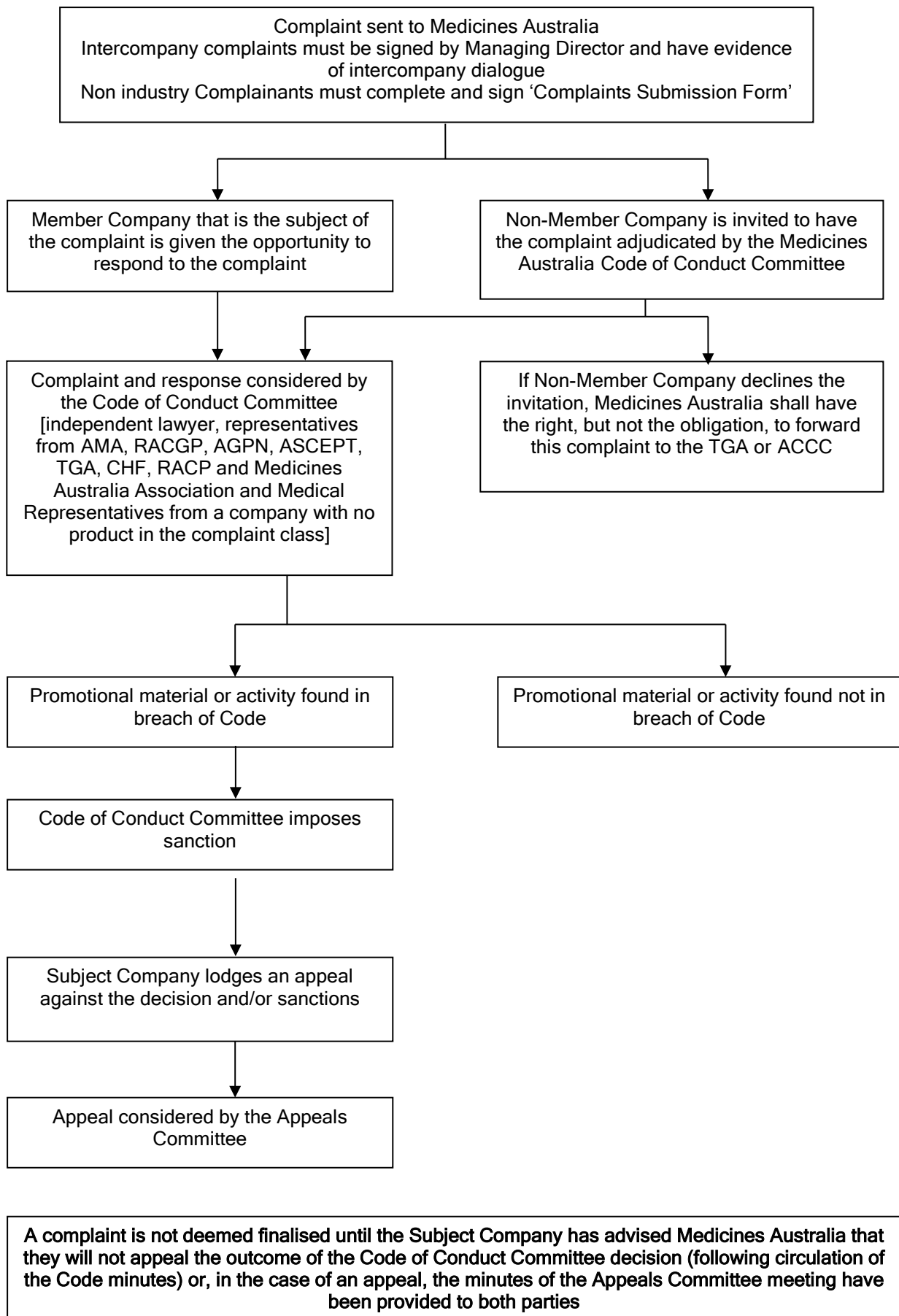
Copies of Edition 18 of the Code (effective from 16 May 2015) are available from Medicines Australia. An order form is available from <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>

The Code of Conduct and the Guidelines that accompany the Code are available from the website (<http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>)

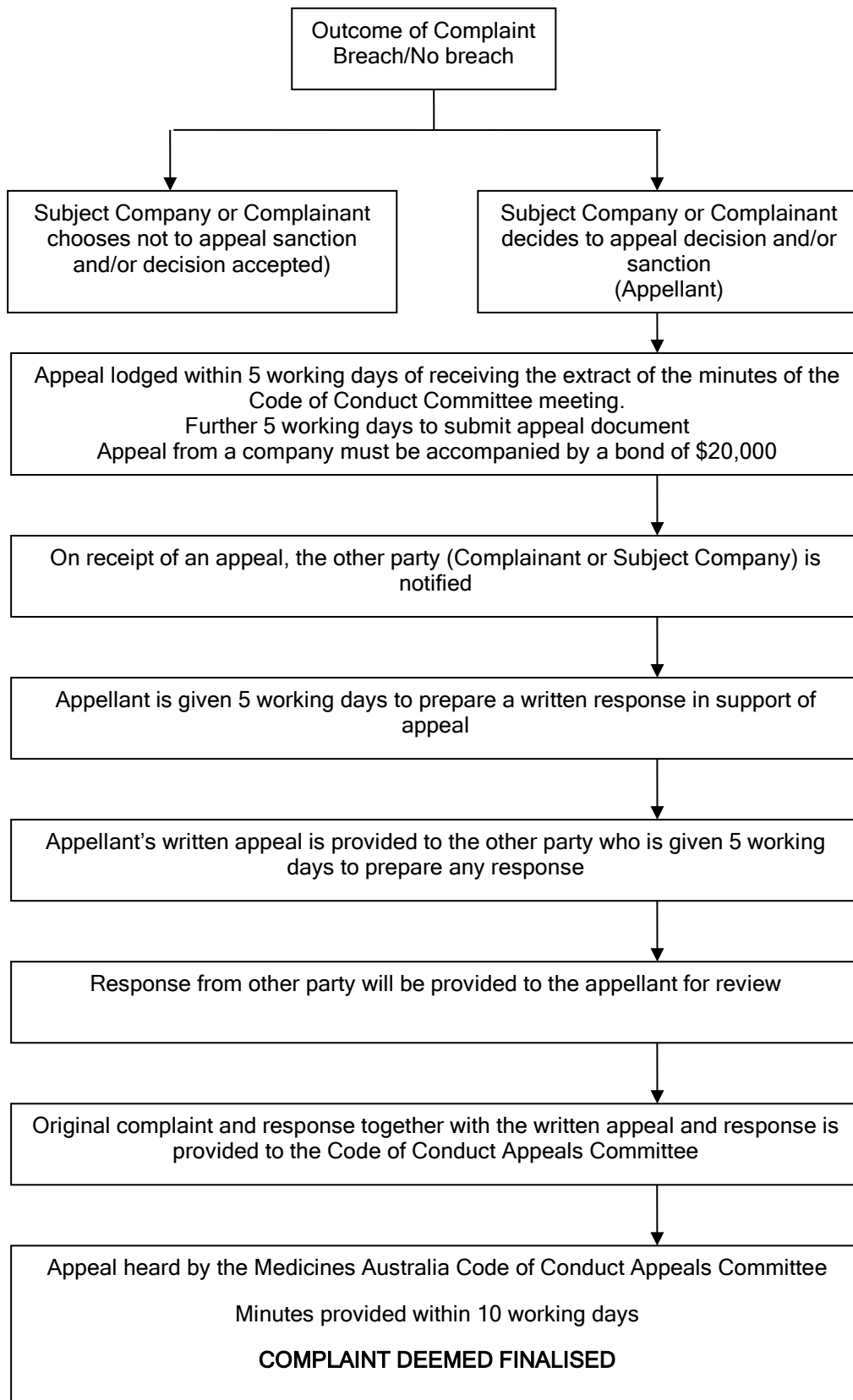
Contents

Medicines Australia Code of Conduct Complaints Handling Process.....	3
Medicines Australia Code of Conduct Appeals Committee Procedures	4
Committees and Secretariat	5
Sanctions that can be imposed by the Code of Conduct Committee	6
Table of finalised complaints July – September 2016.....	7
1137 – GSK Educational Event	8

Medicines Australia Code of Conduct Complaints Handling Process



Medicines Australia Code of Conduct Appeals Committee Procedures



Committees and Secretariat

The administration of the Code is supervised by the Code of Conduct Committee. The Code of Conduct Committee has the power to make a determination as to a breach of the Code, and impose sanctions. The right of appeal is available to both the Complainant and Subject Company. An appeal is heard by the Appeals Committee which has the power to confirm or overturn the decision and to amend or remove any sanctions.

Committee Member Biographies

Brief biographies for all Code, Appeals and Monitoring Committee members are available on the Medicines Australia website <https://medicinesaustralia.com.au/code-of-conduct/committee-membership/>

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of up to 5 trade practices lawyers

Representatives nominated by:

- Australian General Practice Network (AGPN)
- Australian Medical Association (AMA)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Consumers Health Forum of Australia (CHF)
- Royal Australasian College of Physicians (RACP)
- Royal Australian College of General Practitioners (RACGP)
- Medicines Australia Association Representatives (maximum 3)
- Medicines Australia Medical/Scientific Directors (maximum 2)

Observers (No voting rights)

- Therapeutic Goods Administration (TGA)
- Medicines Australia member companies' employees (maximum 2)
- Observer nominated by Medicines Australia (maximum 1)

Advisors (No voting rights)

- Secretary, Code of Conduct Committee
- Medicines Australia Chief Executive Officer or delegate
- Medicines Australia officer responsible for Scientific and Technical Affairs

Appeals Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of up to 5 trade practices lawyers

Representatives nominated by:

- The College and/or Society associated with the therapeutic class of the product subject to appeal
- The target audience to which the activity was directed eg: AMA, RACGP
- Consumers Health Forum of Australia (CHF)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Medicines Australia Association Representatives (maximum 2)
- Medicines Australia Medical/Scientific Director (maximum 1)

Advisors (No voting rights)

- Secretary, Code of Conduct Committee
- Medicines Australia Chief Executive Officer or delegate

Sanctions that can be imposed by the Code of Conduct Committee

Sanctions

If the Code of Conduct Committee finds a breach of the Code it may impose a sanction on the company found in breach. In order to determine an appropriate sanction the Committee will refer to the “Guidelines for determining Code sanctions” which are available on the Medicines Australia website. The following sanctions may be imposed:

Withdrawal of material or activity

Where promotional material or activity is found in breach of the Code the Committee will always require the company to cease use of the item or cease undertaking the activity.

Corrective letter

The Code of Conduct Committee will determine the audience for the letter based on the original distribution of the material found in breach of the Code.

Corrective advertisement

A corrective advertisement must be placed in the same publication as that found in breach of the Code.

Fines (applicable under Edition 17 of the Code)

<u>Breach</u>	<u>Fine</u>
Technical breach Minor breach	Maximum of \$100,000
Moderate	Maximum of \$150,000
Severe breach	Maximum of \$200,000
Severe breach where activities completed Repeat of previous breach	Maximum of \$250,000
Cumulative fine for multiple breaches	Maximum of \$300,000
Failure to complete corrective action in 30 calendar days Failure to pay a fine in 30 calendar days	Maximum of \$50,000
Abuse of the Code (in accordance with Section 25)	Maximum of \$200,000

Table of finalised complaints July – September 2016

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1137	GlaxoSmithKline Australia	Educational Event	N/A	Monitoring Committee	No Breach	n/a

1137 – GSK Educational Event

Subject Company: GlaxoSmithKline Australia Pty Ltd

Complainant: Monitoring Committee

Product: N/A

Complaint

Following its review of Education Event Reports, the Medicines Australia Monitoring Committee had referred an educational event organised by GSK and held in July 2015 for consideration by the Code Committee. The event was a Practical Asthma Management Meeting. The Monitoring Committee considered that the provision of a three course dinner including alcoholic beverages at a restaurant had exceeded the \$120 per head hospitality limit set out in the Code. The Monitoring Committee considered that the meals and beverages provided were excessive in relation to the educational content and duration of the meeting.

Sections of the Code

The promotional claims were alleged to be in breach of the following Sections of Edition 18 of the Code:

- 9.4.3 Meals and Beverages

Response

GSK responded that the number of attendees for the event had been incorrectly reported in the educational event report. The meeting was originally booked and catered for 28 attendees at a fixed cost per head of \$98 inclusive of GST. Through a number of late cancellations, the final number of attendees was 15. However the commitment to the restaurant had been confirmed and the costs incurred for the original number of attendees. GSK stated that the company strongly enforces the \$120 hospitality expenditure within the organisation, and this is reinforced through training and education provided to sales representatives.

Code of Conduct Committee decisions

The Code of Conduct Committee determined by unanimous decision that the activity was not in breach of Section 9.4.3 of the Code of Conduct.

Sanction

Having found no breach of the Code of Conduct, the Committee did not impose a sanction.

Consideration of the complaint

The Committee discussed the Educational Event that had been held at a Chinese restaurant in Brisbane on 22 July 2015. Edition 18 of the Code of Conduct became effective in May 2015, which saw the introduction of a maximum of \$120 per head excluding GST for food and beverage expenditure in relation to educational events. The Committee noted that this limit was well known to the company at the time of organising and holding this event.

The Committee reviewed the evidence provided by GSK, which detailed the planning for the event and receipt for the food and beverages, as well as the way in which the event had been reported to Medicines Australia.

The Committee noted that GSK's records showed that the event was originally booked for 28 attendees, with email correspondence between a GSK employee and the restaurant confirming the number of attendees on 20 July 2015, two days prior to the event. The number of attendees was confirmed by GSK through the receipt of RSVPs to the invitation it had circulated. The Committee reviewed a redacted sign in sheet for the event, which showed that 28 attendees had been expected and the number who had actually attended was 15. The Committee also noted the restaurant tax invoice for the event, which showed a set menu price of \$98 per head, inclusive of GST, charged for the confirmed 28 attendees.

The Committee also reviewed a report produced by GSK's internal event tracking system, which outlined the process by which the event had been organised and approved. The Committee noted that through this tracking system GSK retrieves the data required to report the educational event to Medicines Australia. The Committee noted that in the section that outlined the confirmed number of attendees, a GSK employee had entered the following details:

Confirmed Attendees		No Show
Number of HCP attendees	15	9
Number of Non-HCP attendees	0	0
Number of GSK employees	5	0
Total number of confirmed attendees	20	

The Committee noted that the Code of Conduct Guidelines (Edition 18, version 1 May 2015, page 99) states:

“The number of attendees reported in the table should be the number of healthcare professionals the company has paid for to attend that function. In most cases, this will be the confirmed number of attendees, however, in some instances where venues charge only for those who attend on the night the number of attendees will be lower. For example, if you invite 20 attendees, 15 confirm their attendance (and you are billed for 15) but on the day of the event 13 attend, the number reported would be 15.

The number of attendees does not include company staff”.

The Committee agreed that GSK should have excluded the 5 company staff who had attended the event from the confirmed attendees of 28 and reported 23 attendees. In addition, the hospitality costs should have been reported exclusive of GST at \$89 per person (with a total cost of \$2,047 for 23 healthcare professional attendees). If the event had been reported in this manner, the accurate cost per head would have been reflected in the report. However, the Committee did note that there remained a discrepancy in the number of attendees with the restaurant confirmed at 28 attendees and GSK’s reporting system showing 29 people (15 attendees, 9 ‘no-shows’ and 5 GSK staff).

Based on the information provided by GSK, the Committee agreed by unanimous decision that the event was not in breach of Section 9.4.3 of the Code as the hospitality was clearly under the \$120 (exclusive of GST) food and beverage limit. However, the Committee were disappointed by the careless manner in which this event appeared to have been reported within the company and the apparent lack of any checking process that resulted in this event being misreported in the published educational event report. The Committee noted that this event was reported in the 17th ‘round’ of Educational Event Reports (which first commenced in 2007). Therefore the process for reporting these types of activities should be very familiar to Medicines Australia member companies. The Committee were of the opinion that companies should have rigorous procedures in place that prevent both conduct that would breach the Code and misreporting of activities.

The Committee noted that the reporting of educational events is no longer required by Edition 18 of the Code of Conduct. The Secretariat advised that from 1 October 2015

transparency reporting will focus on transfers of value to individual healthcare professionals. The future reporting of payments and transfers of value for individual healthcare professionals will not include hospitality expenditure. The Committee were advised that expenditures relating to airfares, accommodation, conference registration, speaker and Advisory Board sitting fees and other consultancy fees will be reported. Some members of the Committee expressed concern that food and beverages will not be reported for individual educational events and that the new reporting regime will require strong internal processes to ensure that companies adhere to the Code requirements for expenditure on food and beverages.

Sanction

Having found no breach of the Code of Conduct, the Committee did not impose a sanction.
