Medicines Australia Code of Conduct Quarterly Report April – June 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 April and June 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/)

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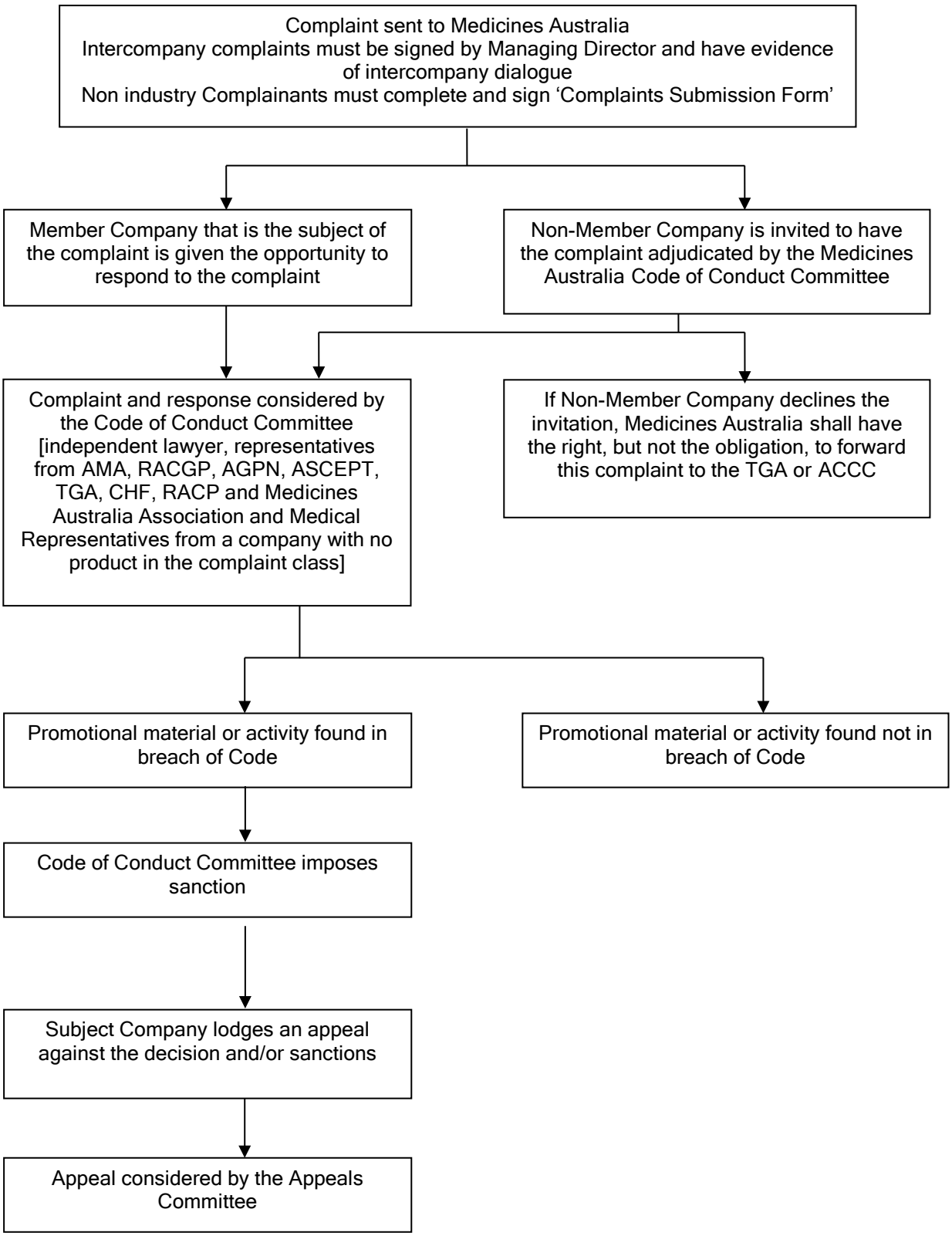
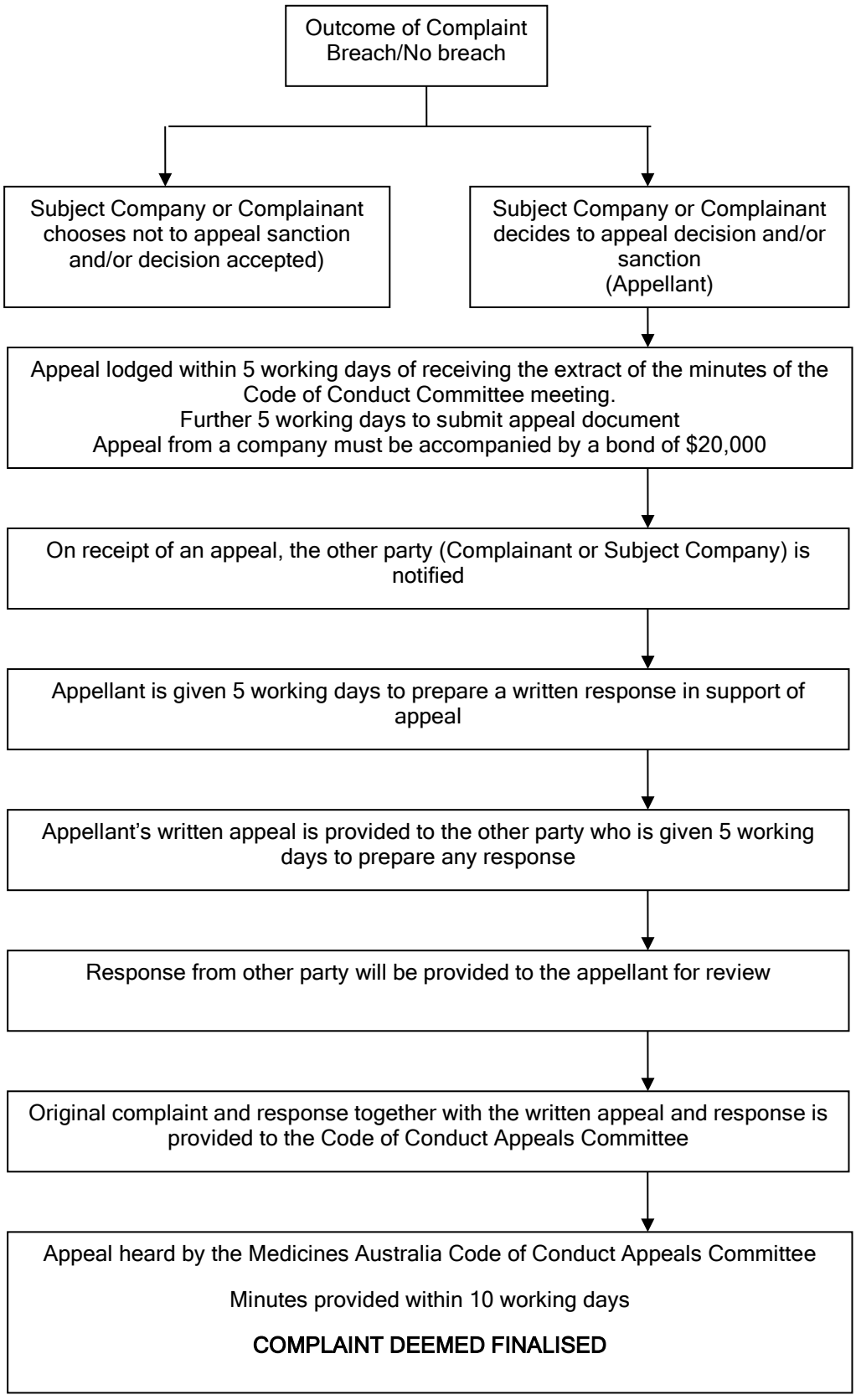
Medicines Australia Code of Conduct Complaints Handling Process



A complaint is not deemed finalised until the Subject Company has advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Code minutes) or, in the case of an appeal, the minutes of the Appeals Committee meeting have been provided to both parties

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)

Breach	Fine
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 April – June 2016

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1136	Bristol-Myers Squibb Australia Pty Ltd	Promotional Activities	Nivolumab	Merck Sharp & Dohme (Australia) Pty Ltd	Breach of Sections 1.1, 1.4 and 2.1.1.4	Pay a fine of $10,000

1136 – Nivolumab Promotional Activities

Subject Company: Bristol-Myers Squibb Australia Pty Ltd

Complainant: Merck Sharp & Dohme (Australia) Pty Ltd

Product: Nivolumab

Complaint
MSDA alleged that BMSA had conducted several activities promoting nivolumab prior to its registration. MSD alleged that BMSA had promoted nivolumab prior to registration at three company organised educational meetings, in an article published in *Research Review* and during sales calls with doctors

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

- 1.1 Responsibility
- 1.4 Unapproved Products and Indications
- 2.1.1.4 Company Commissioned Articles
- 5.1 Company Representative Roles and Ethical Conduct
- 9.5 Sponsored Educational Events
- 39 Company Compliance Procedures

Response
BMSA strongly denied that it had promoted nivolumab prior to its registration. BMSA stated that at the three educational events the speakers had been selected by independent organisers of the meetings or by a steering committee. All speakers were thoroughly briefed by BMSA on their obligations under the Code of Conduct.

With regard to the *Research Review* article, whilst the article had been sponsored by BMSA, the content had been determined independently by the publisher.

With regard to the alleged promotion during sales calls, BMSA denied that any of its sales representatives had promoted nivolumab prior to registration and stated that the data used by MSDA to support its allegation could not be relied upon to demonstrate such that promotion had occurred.

Code of Conduct Committee decisions
The Committee addressed each alleged breach of the Code separately as follows:

Educational Events
- MOGA event: The Committee found by majority decision a breach of Section 1.4 and by majority decision no breach of Section 9.5 of the Code
- WACOG event: The Committee found by majority decision a breach of Section 1.4 and by majority decision no breach of Section 9.5 of the Code
- COSA event: The Committee found by majority decision no breach of Sections 1.4 and 9.5 of the Code

Educational Item (*Research Review* article)
The Committee found no breach of sections 1.4 and 5.1 by unanimous decisions, but found by majority decision that the article was in breach of Section 2.1.1.4 of the Code.

Sales Activity
The Committee found by a unanimous decision no breach of Section 5.1 of the Code.

Widespread Promotion
The Committee found by majority decision that there had been a breach of Section 1.1 of the Code and by majority decision no breach of Section 39 of the Code.

Sanction
The Committee agreed by majority decision to impose a $10,000 fine.

Appeal
MSDA appealed the following Code of Conduct Committee decisions:
- The finding of no breach of Section 9.5 for any of the three events
- The finding of no breach of Section 1.4 in relation to the COSA event
- The finding of no breach of Section 1.4 in relation to the *Research Review* article
- The finding of no breach of Section 39 in relation to the alleged widespread promotion.

MSDA also appealed the level of sanction imposed. MSDA argued that the low level of fine signals that the Code Committee found the breach to be minor, whereas MSDA contends that promotion of an unregistered product should be considered a serious breach. MSDA argued that promotion of a product prior to its registration is contrary to a key tenet of the Code. MSDA also alleged that the activities were more widespread than initially identified.

It requested that the Appeals Committee extend the findings of breach to include those where the Code Committee found no breach of the Code, to reassess the seriousness of the breaches found, and to substantially increase the sanction imposed.

Appeal Response
BMSA rejected MSDA's assertions that the activities were more widespread or that they constituted a more serious breach of the Code than determined by the Code Committee. BMSA contended that MSDA has been unable to identify any error in the Code Committee's decisions and had vexatiously sought to re-agitate the issues it raised before the Code Committee. BMSA stated that it had accepted the decisions of the Code Committee and had already acted to bolster the documentation of its compliance processes. BMSA urged the Appeals Committee to dismiss the appeal.

Appeals Committee decision
The Appeals Committee was not persuaded that the decisions of the Code of Conduct Committee or the sanction imposed by it in relation to this complaint involved any error that required the decisions or sanction to be altered or set aside. The decisions and sanction imposed by the Code Committee were confirmed. The Appeals Committee agreed by unanimous decision to not uphold the appeal.

Sanction
The Appeals Committee agreed by unanimous decision that the fine of $10,000 imposed by the Code of Conduct Committee should not be varied.

Consideration of the complaint
The Code Committee found that the MSDA complaint was very difficult to follow which made the adjudication of the complaint challenging. The Committee noted that throughout the complaint, MSDA had referred to both "off label promotion" and "promotion of an unregistered product", when referring to the same activity. For the purpose of adjudicating on the complaint, the Committee understood that MSDA alleged that BMSA had undertaken promotional activities for nivolumab prior to its registration. The complaint was also very poorly collated with confusing labelling of appendices and indexes, which did not assist the Committee.

<u>Educational Events</u>

The Code Committee noted that MSDA had alleged that presentations at three educational meetings had included promotional messages for nivolumab, which at the time was not registered in Australia. MSDA had alleged that because BMSA had a role in the selection of the speakers, these activities were in breach of Sections 1.4 and 9.5 of the Code.

The Committee noted that in its complaint MSDA had referred to the three educational meetings as "BMS organised". However on review of the materials the Committee noted that two of these events (MOGA and WACOG educational events) were third party initiated events, and the third (COSA breakfast symposium) was a BMSA organised symposium held during the COSA meeting. The Committee determined that as different Code requirements potentially applied to these different meetings, it would review each meeting separately.

Medical Oncology Group of Australia Immuno-Oncology Dinner Symposium titled "Immuno-Oncology Forum: Insights and Advances" October 2015 (MOGA)
This dinner symposium was held as part of the MOGA I-O meeting in Melbourne in October 2015. As a platinum sponsor of the meeting, BMSA had been offered the opportunity to host a dinner symposium. BMSA had argued in its response to the complaint that although there had not been a specific independent steering committee convened for the dinner symposium, the independent steering committee for the overall MOGA I-O meeting had oversight of the dinner symposium and had selected the speakers.

The Committee reviewed the supporting documentation supplied by BMSA, which indicated that the selection of the speakers for the event had been made by the MOGA I-O steering committee. The Committee also noted, however, that input on the selection of speakers had been provided by a BMSA employee, who had attended the independent steering committee meetings.

The Committee discussed at length what constitutes independence of speaker selection in relation to these types of educational meetings. Some academic and healthcare professional members of the Code Committee noted that the role played by industry representatives in these steering committees is often that of secretariat and logistical assistance. For these types of events, in order to attract international speakers, honoraria and

travel support need to be provided. It was the Code Committee's opinion that the attendance of an industry representative at a steering committee meeting does not necessarily compromise its independence. The Committee agreed, however, that supporting evidence and documentation that outlines the steering committee's decision making processes needs to be comprehensive to provide evidence of its independence.

In relation to the MOGA I-O dinner symposium, the Code Committee agreed by majority decision that the final selection of the speakers had been made by the independent steering committee, with some recommendations from the BMSA employee.

The Committee noted that while one healthcare professional speaker was perhaps the most appropriate speaker for this event due to his involvement in the development of nivolumab, the fact that he is now a BMS (global) employee could give rise to a potential breach of the Code arising from his presentation content. The Committee reviewed the presentation slides provided. The Committee noted that whilst only 3 out of 50 of the BMS (global) employee's slides mentioned nivolumab, one did contain a promotional claim – *"Rapid and durable changes in target lesions"*.

On the basis of this single claim in one slide of the BMS (global) employee's presentation, the Committee found by majority decision that this presentation was in breach of Section 1.4 of the Code of Conduct as it had promoted an unregistered product.

The Committee agreed by majority decision that, while BMSA's involvement in the steering committee and its decisions could have been better documented to better demonstrate its independence, the activity was not in breach of Section 9.5 of the Code of Conduct.

Western Australia Clinical Oncology Group (WACOG) BMS sponsored dinner titled "New Immunotherapy Developments in the Treatment in Advanced Melanoma" – October 2015

The Committee noted that evidence provided by BMSA showed that WACOG had approached BMSA to sponsor a WACOG dinner. WACOG wished to provide the opportunity for WA specialist practitioners to hear the speakers presenting at the MOGA I-O meeting and requested that they also present at a specially convened WACOG event. The Committee noted that there had been no steering committee formed for this event and that it had been organised by WACOG. The Committee reiterated that BMSA's documentation for this event could have been clearer to demonstrate the independence of the event's organisation. The Committee agreed by majority decision that this activity was not in breach of Section 9.5 of the Code of Conduct.

The Committee noted that the BMS (global) employee had given the same presentation at the WACOG event as the MOGA I-O event, without modification. The Code Committee had previously noted that the BMS (global) employee's presentation contained a single slide with a promotional claim for an unregistered product. Therefore, the Committee agreed by majority decision that this activity was in breach of Section 1.4 of the Code of Conduct.

Clinical Oncology Society of Australia (COSA) Breakfast Symposium titled "The Immuno-oncology Revolution and Cancer Therapy" – November 2015

The Committee noted that this event had been held as part of the annual COSA meeting and was available to BMSA through their sponsorship of the overall event. The symposium had been included on the COSA meeting agenda and BMSA's sponsorship of the symposium had been disclosed. The Committee unanimously agreed that this was a BMSA organised event.

BMSA had convened an independent steering committee to determine the symposium content and speakers. The Committee noted that the BMS (global) employee had not been a speaker at this symposium. The two members of the steering committee had chaired and spoken at the symposium.

The Code Committee accepted that the COSA breakfast symposium content and speakers had been selected by the independent steering committee. The Committee noted that record keeping in order to provide evidence of the steering committee's independence could have been clearer and more robust. The Committee did not agree that promotion of nivolumab had occurred at this event.

The Committee agreed by majority decision that the activity was not in breach Sections 1.4 and 9.5 of the Code of Conduct.

Educational Item (Research Review)
The Committee noted that the item subject to complaint is an article titled *"Immune Checkpoint Blockade in the Treatment of Cancer"* that appeared in *Research Review's Educational series* in October 2015. It was further noted that when the article was published, acknowledgment of BMSA's sponsorship had been omitted. Once this error had been identified, it had been rectified in the online version of the article.

The Committee discussed *Research Review* and accepted that while there is industry sponsorship for particular articles, the sponsoring company has very little input into the articles' subject or content. The company's final review of the article is expected to pick up significant omissions or errors of fact, but the company is not able to influence the overall content of the article. The Committee discussed whether sponsorship interferes with the independence of an activity and agreed unanimously that sponsorship of an article does not make it a company commissioned article as MSDA had alleged. The overall editorial responsibility remains the publisher's.

The Committee agreed unanimously that the *Research Review* article was not in breach of Sections 1.4 and 5.1 of the Code of Conduct. The Committee also agreed unanimously that the omission of the sponsorship acknowledgement should have been picked up by BMSA in its review of the article. The Committee determined that this omission was a technical breach of Section 2.1.1.4 of the Code of Conduct.

Sales Activity
The Committee noted MSDA's allegation that BMSA's sales representatives had started to promote nivolumab prior to its registration. MSDA had cited IMS Health data as evidence to support this allegation. In its response to the complaint, BMSA stated that no promotional material had been developed for use by its sales representatives at the time the IMS Health data had been collected; materials had not been developed at that time. In addition BMSA had provided evidence that its sales representatives had been specifically instructed not to discuss nivolumab prior to its registration.

The Committee reviewed the IMS Health data provided by MSDA and noted that there was a small increase in healthcare professional reporting of interactions discussing nivolumab. The Committee noted that it had been a small increase in reporting and that IMS Health data reports subjective, self-reported recollections by healthcare professionals. These data cannot be differentiated into whether a BMSA sales representative had initiated a discussion, or had reactively responded to healthcare professionals' questions.

The Committee agreed unanimously that the IMS Health data did not provide sufficient evidence to substantiate that BMSA sales representatives had promoted nivolumab prior to its registration. The Committee agreed unanimously that there had been no breach of Section 5.1 of the Code of Conduct.

Widespread Promotion
The Committee discussed the overarching allegations made by MSDA that BMSA had engaged in widespread promotion of nivolumab prior to its registration, which was alleged to be in breach of Sections 1.1 and 39 of the Code.

The Committee agreed by majority decision that the breach of Section 1.4 of the Code in relation to the BMS (global) employee's presentation and the breach of Section 2.1.1.4 of the Code in relation to the omission of the sponsorship acknowledgement in the *Research Review* article, BMSA had not met its responsibilities as required by the Code of Conduct. The Code Committee determined by majority decision to find a breach of Section 1.1 of the Code.

It had also been alleged that BMSA did not have adequate compliance procedures and processes and was therefore in breach of Section 39 of the Code of Conduct. The Committee did not find any evidence from MSDA to support its allegations; rather BMSA had provided evidence to demonstrate its procedures to ensure compliance with the Code. The Committee agreed by majority decision that although these procedures could be reviewed and BMSA's documentation of its arrangements to ensure independence of steering committees associated with educational meetings could be improved, there had been no breach of Section 39 of the Code of Conduct.

Sanction
Having found breaches of the Code of Conduct, the Code Committee discussed the severity of these breaches. The Code Committee agreed by majority decision that the breaches of Sections 1.1 and 1.4 were minor as described by the Code of Conduct.

The Committee agreed that BMSA's involvement in the MOGA and WACOG events had been appropriate. However, documentation of the company's involvement with the independent steering committees when supporting this valuable exchange of information could be improved. The Committee did not want the Code to impede the robust scientific exchange of information when conducted in an appropriate, non-promotional manner. The Committee's decision that the MOGA I-O and WACOG educational events were in breach of the Code related only to one slide that contained a promotional claim.

The Committee agreed by majority decision that the breach of Section 2.1.1.4 was technical as described by the Code of Conduct. The Committee had determined that the omission of the acknowledgement of BMSA's sponsorship should have been picked up by BMSA in its review of the article. However this omission was promptly corrected by the publisher once identified.

The Committee agreed by majority decision that BMSA must pay a fine of $10,000.

Consideration of the Appeal

The Chairman explained the process for consideration of an appeal. The Appeals Committee must be persuaded that the findings of the Code of Conduct Committee (Code Committee) involved an error on the basis of which the decisions of the Code Committee should be set aside or varied.

The Chairman invited the MSDA representatives to give their appeal presentation. The following summarises that presentation and discussion with the Appeals Committee.

MSDA stated that it had appealed the Code Committee's decisions and sanction because it considers that the breaches were severe and widespread and that BMSA is also responsible for breaching Section 9.5 (in relation to the COSA event) and Section 39 (Company Compliance Procedures) of the Code. MSDA also appealed the sanction, as it considers that the penalty of $10,000 signals that the breaches were minor.

MSDA argued that there was insufficient evidence to show that the BMSA sponsored meetings were independent; that a significant proportion of slides presented at the meetings were promotional of an unregistered product and therefore the promotion was widespread; and that the *Research Review* article was not independent of BMSA and was unbalanced.

MSDA argued that BMSA had not provided evidence to demonstrate that the educational meetings were independent of BMSA. If independence cannot be demonstrated, BMSA was responsible for the meeting content. If an independent steering committee was formed, BMSA should provide evidence that it had briefed the steering committee on the company's obligations under the Code, including that any promotion can only be for a registered product.

MSDA considered that there should not have been a company representative on the steering committee for the COSA meeting if it is to be considered independent and free from company influence on speakers and content. In addition, MSDA considered it was not appropriate for BMSA medical or commercial employees to give a presentation at such meetings because this compromises the independence of the content. A speaker recommended by a sponsoring company may not promote unregistered products at a meeting just because the steering committee had endorsed the speaker.

MSDA discussed the MOGA Immuno-oncology (IO) meeting and the WACOG dinner meeting. BMSA had stated that it had recommended two of the three speakers. A member of the MOGA steering committee had been asked to approve the two speakers put forward by BMSA, but BMSA had not provided any evidence of any steering group discussion about their proposed speakers. One of the speakers is a BMS (global) employee. While he is a leading scientist, he cannot be considered independent. BMSA paid all speaker travel and honorariums associated with the meeting directly to the speakers. BMSA had stated that it had briefed the speakers and reviewed their slides prior to the meeting, however MSDA considers that the slides contained numerous promotional claims for an unregistered product.

MSDA argued that the evidence provided by BMS had not demonstrated beyond reasonable doubt that these meetings were organised independently of BMSA. MSDA contended that all three events breached Sections 1.1, 1.4 and 9.5 of the Code.

MSDA noted that the Code Committee had determined that only one slide from the BMS speaker's presentation was in breach of the

Code. MSDA highlighted the definition of promotion in the Code glossary. MSDA argued that 33 of the 157 slides presented by the three speakers at the MOGA-IO and WACOG meetings were promotional for nivolumab, which was not registered at the time.

MSDA referred to the BMSA COSA breakfast symposium held in November 2015, which the Code Committee had found was not in breach of the Code. MSDA argued that because a BMS medical employee was on the steering committee for this educational meeting, it was difficult to assert that BMS had not exerted undue influence on speaker selection and topics. Therefore, the speaker selection and content was not independent of BMSA. Although BMSA stated that it had briefed the steering committee and speakers to not discuss off label indications and had requested the speakers' slides for review, nevertheless 30 of the 120 slides presented contained promotional information about the positive attributes or the rate of adverse effects of an unregistered product, and were therefore promotional.

MSDA contended that the evidence provided by BMSA did not support that the three educational meetings were independent. At least one fifth of the slides presented across the three meetings were promotional of an unregistered product. The BMS employee had presented 6 promotional slides for nivolumab, not just one slide as determined by the Code Committee. MSDA argued that in addition to breaching sections 1.1 and 1.4 of the Code, all three of the meetings also breached Code Section 9.5.

In relation to the *Research Review* article "Immune Checkpoint Blockade in the Treatment of Cancer", BMSA had stated in its correspondence to MSDA that the company had suggested the title for the article, had funded it and had the right of final review. MSDA considered that the article was not balanced because in the "Clinical efficacy of PD-1/PD-L1 inhibitor" section only efficacy for nivolumab was included and not other immuno-oncology agents as would be expected from the article's title. Nivolumab was unregistered at the time the article was published. Due to the involvement by BMSA in suggesting the title, funding and final review of the article, MSDA considered that the article was not independent and was a Company Commissioned Article under Section 2.1.1.4 of the Code and should have been identified as an advertorial. MSDA appealed the Code Committee finding and argued that the *Research Review* article should be found in breach of both Sections 2.1.1.4 and 1.4 of the Code.

A member of the Appeals Committee noted that the publisher of *Research Review* had provided a statement that the article had been produced independently of BMSA. The Committee member asked whether MSDA had also sponsored articles in this publication. MSDA responded that it had rejected some offers to sponsor articles, but had sponsored a couple of articles in *Research Review*.

MSDA concluded its appeal presentation by asking the Appeals Committee to consider the evidence that BMSA had engaged in widespread promotion of an unregistered product at three educational meetings and in an unbalanced educational item. MSDA argued that there were at least 63 slides presented at the educational meetings which promoted an unregistered product. The content of these meetings and the *Research* article was not independent of BMSA and therefore it is responsible for this conduct.

MSDA asked the Appeals Committee to review the Code Committee findings that there had been minor breaches of sections 1.1, 1.4 and 2.1.1.4 of the Code. MSDA argued that promoting an unregistered product fundamentally undermines the Code and should be considered serious breaches and attract a higher fine than $10,000. MSDA argued that the promotion of an unregistered product was widespread and that BMSA should also be found in breach of Sections 9.5 and 39 of the Code.

At the conclusion of MSDA's presentation, the Appeals Committee sought some clarifications.

A member of the Committee asked about MSDA's position on BMSA's proposal, made during the inter-company dialogue, to send a clarification letter to healthcare professionals who had attended the three educational meetings. BMSA had stated in its response to the complaint that MSDA had rejected this proposal. MSDA responded that it had not been able to reach agreement with BMSA on the content of the corrective letter as BMSA had been unwilling to admit that it had breached the Code. MSDA asked that the Appeals Committee reconsider the fine imposed, which is too low for having promoted an unregistered product.

A member of the Committee asked MSDA if it accepted that, if it was determined that all of the educational meetings were independent of BMSA, all of the material presented by the speakers was independent of the company and could not be found to have been promoting an unregistered product. MSDA responded that it would expect more balance in the presentations, but accepted that if the meetings were truly independent then the selection of speakers and content presented is the responsibility of the organising committee.

The Chairman then invited BMSA to give its presentation in response to the appeal.

BMSA opened its presentation noting that BMS has a strong global position on compliance and ethical conduct and has a robust compliance program in Australia and globally. BMSA's compliance rules are stronger than the Code and the company has a good record of Code compliance. Whatever the level of breach that is found against BMSA, it has implications for the local and global company. BMS takes any breach seriously in Australia and globally to make sure that it is not repeated. BMSA has accepted the Code Committee's decision and has put in place actions to avoid similar breaches.

BMSA noted that in its presentation MSDA had omitted from the definition of promotion in the Code that it includes "… for the purpose of encouraging usage of that product".

BMSA highlighted that the context for the three educational meetings was recent advances in treating cancers that previously had few therapeutic options. Immuno-oncology is a significant advance in cancer treatment for which there is a great demand for more information. BMSA takes seriously the need to educate physicians whilst maintaining compliance with the Code of Conduct.

BMSA referred to Section 29.1 of the Code, which states: "The Appeals Committee shall not uphold an appeal unless it is persuaded that the findings of the Code Committee or the sanction imposed by it, involved an error on the basis of which they should be set aside or varied." BMSA asserted that MSDA had not presented any evidence that the Code Committee had made an error. MSDA had only re-asserted its original complaint in its appeal. BMSA considered that MSDA's appeal sought to discredit the Code Committee.

BMSA asserted that the three educational meetings were independent of the company. MSDA had not provided any evidence of the lack of independence of these events. A steering committee had determined the speakers and content of the BMSA-sponsored MOGA-IO event, which was repeated for WACOG at their request. The COSA breakfast symposium was sponsored by BMSA, with an independent steering committee. All three events were run in accordance with the Code. Code Section 9.5 allows a company to suggest possible speakers, but the final selection remains the responsibility of the steering committee. All speakers had been briefed by BMSA in relation to avoiding promotion of an unregistered product or unlicensed use of a product and evidence of these briefings had been provided to the Code Committee. BMSA noted that it had provided testimonials from the speakers at the MOGA, WACOG and COSA meetings stating that they had received these briefings. BMSA accepted that it could improve the documentation of the steering committee's decisions about speakers and meeting content.

BMSA argued that the presentations at the three events were intended to facilitate the exchange of important knowledge for the benefit of medical science and patients. Attending clinicians expect to receive information about clinical trial results. The percentage of slides in each presentation that mentioned nivolumab was very small – 15 percent of 381 slides. The presentations also included data on non-BMS products – 7 percent of the slides referred to MSDA's product pembrolizumab. 70 percent of the slides did not mention any product. There had been no brand names or scheming that identified specific products. Any meetings with the speakers involved BMSA medical staff and not staff with commercial functions.

BMSA asserted that the evidence it had provided of having appropriately briefing the speakers, of the independent control of the meetings' content and the testimonials from speakers declaring their independence supported the independence of the three educational events from BMSA. BMSA argued that the payment of speakers' honoraria and organisation of their travel does not affect the speakers' independence and ensures compliance with the Code.

BMSA argued that as it is a global leader in cancer medicines it is often asked for advice about potential speakers. The email in which the chairman of the steering committee for the MOGA event was asked to approve the proposed speakers was the culmination of a dialogue about speakers where the final decisions were made by the independent committee. A BMSA medical department staff member had attended the steering committee meetings for the COSA event to assist with the logistics for the event, which is consistent with BMSA company policy.

In relation to the *Research Review* article, BMSA stated that this is an independent publication. Companies have no say in the content of articles they sponsor, but have the opportunity to identify errors or omissions prior to publication. The original publication should have disclosed BMSA's sponsorship, which the publisher has acknowledged was its error. As soon as this omission was identified, it was corrected by the publisher. BMSA has accepted the Code Committee's decision to find BMSA in breach of the Code in relation to this omission.

BMSA expressed its disappointment that MSDA had criticised the Code Committee, which had reviewed all the slides identified by MSD and determined that only one slide presented by the BMS global employee was promotional. BMSA referred to the Code Guidelines for determining sanctions and argued that the Code Committee had taken all relevant criteria into account and imposed a sanction that was appropriate to the breaches found. BMSA noted that MSDA had argued that the Code Committee had found that the COSA meeting was not in breach of the Code solely because the BMS global speaker had not also presented at that meeting. However, the Code Committee had also accepted the independence of the steering committee for the COSA event.

BMSA gave a closing summary of its response to the appeal. It argued that MSDA had not presented any new information or reasoning to suggest that the Code Committee had erred. BMSA acted properly and in accordance with the Code by maintaining the independence of the speakers and the organisation of the three educational events. Payment of honoraria directly to speakers and arranging their travel ensures Code compliance and is standard industry practice.

An Appeals Committee member asked BMSA to explain why it considers that direct payment of speakers' honoraria and arrangement of their travel is consistent with Section 9.5.1, which requires that sponsorship of an independent educational event must not be paid to an individual healthcare professional. The Committee member noted that there is no definition of 'sponsorship' in the Code. BMSA responded that it had sponsored the MOGA and COSA events; this sponsorship was paid to the event organisers, not to an individual healthcare professional. Speaker honoraria are paid directly to the speakers by the company, which also arranges their travel. As previously stated, this ensures Code compliance.

BMSA concluded its presentation, starting that it accepts that it should improve its documentation to demonstrate the independence of steering committees it establishes. BMSA also accepts responsibility for not picking up the error of omission in *Research Review*.

The Chairman then invited MSDA to make its closing remarks.

MSDA rejected BMSA's comments that MSDA sought to discredit the Code Committee. These comments were inflammatory and unfounded.

MSDA has internal company standards to ensure the presentation of balanced and fair information at independent scientific meetings that it sponsors. MSDA argued that BMSA appears to apply a different standard. BMSA had admitted that there was no steering committee for the MOGA-IO dinner meeting or WACOG meeting. Therefore BMSA is ultimately responsible for the content presented at the meetings which it sponsored. MSDA considers that the presentations at the three events were not fair and balanced and the company-sponsored events could not be described as true scientific exchange.

The Chairman thanked the representatives from MSDA and BMSA for their presentations and excused them from the meeting to allow the Appeals Committee to deliberate on the appeal.

The Appeals Committee acknowledged the high level of interest amongst Australian clinicians in receiving information about clinical research for which outcomes have been presented at overseas meetings. The

educational events subject to this complaint had provided the opportunity for Australian clinicians to hear from international experts. However, the Committee also noted that context and timing of meetings is an important consideration. At the time these events were held, nivolumab was about to be approved in Australia. There would have been considerable interest within the oncology clinician community about this and other immuno-oncology products.

The Appeals Committee considered the independence of the speaker selection and content for the three meetings.

The Appeals Committee discussed whether having a medical person from a company attend steering committee meetings compromised the independence of the committee. It was accepted that it can be important for a company representative to be present, from the medical function, to ensure that the content of the meeting that a company has agreed to sponsor remains within the agreed therapeutic scope. There had been no evidence provided to the Committee that suggested that the BMSA staff member had any influence on the final speaker selection or content of presentations.

The Appeals Committee discussed the selection of the BMS global employee as a speaker at the MOGA-IO and WACOG meetings. Company representatives on the Committee advised that they would be very cautious about approving a company staff member giving a presentation at an educational meeting that is intended to be independent. This is particularly critical if the educational meeting is held immediately prior to the registration of a new product that might be discussed at the meeting. The inclusion of a company speaker could create the impression that the company was taking the opportunity to encourage interest in the product pre-launch. However, in this instance the particular speaker is a recognised world expert in the field of immuno-oncology who works in the development of new molecules in BMS's biologics discovery centre. The Committee accepted that the MOGA steering committee had approved the speaker's inclusion in the program due to his credentials and background. The speaker's affiliation with BMS was clear in his presentation slides. The Appeals Committee agreed that the inclusion of a company speaker in the program for an independent scientific meeting would be an exception rather than a general rule and should only occur if endorsed by the independent steering committee for the meeting.

The Appeals Committee concluded that it had not been persuaded by MSDA's appeal. The Appeals Committee considered that the three educational events were sufficiently independent of BMSA, through the involvement of independent steering committees. The Code Committee appeared to have given appropriate consideration to all the material presented to it and made a reasonable judgement about the independence of the arrangements for the three educational events. MSDA had not provided any evidence that the Code Committee had made an error in reaching its decisions.

The Appeals Committee discussed the content of the presentations at the three events. It was noted that speakers had presented information about adverse effects from the medicines, not just information about effectiveness. The Committee noted that BMSA had acknowledged that it had the opportunity to review the speakers' slides. However, there was no evidence that BMSA had influenced the speakers to present information about nivolumab. Indeed, the speakers had provided testimonials asserting that they had developed their presentations independently. The content of the presentations given at each of the three educational events appeared to have been developed independently by the speakers.

The Appeals Committee concurred with the Code Committee that one slide presented by the BMS employee included a promotional claim for nivolumab, which was not registered at the time, but did not agree with MSDA's assertion that other slides presented by this or other speakers were also promotional in the context in which they were presented. The Appeals Committee was not persuaded that the Code Committee had made an error in finding the MOGA-IO and WACOG meetings in breach of Section 1.4 of the Code and not in breach of Section 9.5. The Appeals Committee was also not persuaded that the Code Committee had made an error in finding the COSA breakfast meeting was not in breach of the Code.

The Appeals Committee discussed MSDA's appeal that the *Research Review* article was not independent of influence from BMSA. The Committee noted that the publisher had provided a definitive statement that it appoints

an independent clinical expert in each therapeutic area to select clinical papers and provide a commentary on their relevance to Australian clinicians. Whilst the publication is supported by pharmaceutical company sponsorship, companies have no influence on content. The Committee concluded that MSDA had not provided any evidence to refute the independence of the *Research Review* article.

The Appeals Committee noted that the Code recognises that there is a degree of tension between purely promotional events and those that are educational. Section 9.5 of the Code deals with when educational events may be sponsored by companies and what requirements should be imposed on sponsoring companies. Section 1.4 must be read in light of the requirements in Section 9.5, as well as the definition of 'promotion' in the Code. The Appeals Committee noted that when dealing with statements about the positive attributes of a product, there needs to be a purposive element of encouraging the usage of the product.

The Appeals Committee noted that MSDA had put forward a number of propositions in its appeal letter with regard to its interpretation of the Code and its internal company standards. The Appeals Committee thought that MSDA appeared to be suggesting imposing standards that went beyond the requirements of Section 1.4 and 9.5 which do not seem to be justified, although companies may choose to observe higher standards.

The Appeals Committee was not persuaded that the decisions of the Code of Conduct Committee or the sanction imposed by it in relation to this complaint involved any error that required the decisions or sanction to be altered or set aside. The decisions and sanction imposed by the Code Committee were confirmed. The Appeals Committee agreed by unanimous decision to not uphold the appeal.

The Appeals Committee noted that the educational events and review article subject to this complaint were considered on their merits and the specific arrangements and context for the conduct. The Code of Conduct Committee's decisions and the Appeals Committee's decision to not uphold MSDA's appeal should not be taken as establishing a general precedent from which companies may model their conduct.

Sanction

As the appeal was not upheld, the Appeals Committee considered whether there was any reason that the sanction should be varied. The Committee agreed by unanimous decision that it had not been persuaded there was any reason to vary the sanction and confirmed that the fine of $10,000 imposed on BMSA by the Code Committee should remain.

Further, as the appeal had not been upheld, the Appeals Committee agreed unanimously that the appeal bond of $20,000 should be retained by Medicines Australia.