

# Medicines Australia Code of Conduct Quarterly Report October - December 2015

## 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 October and December 2015. Complaints finalised during this period were in relation to materials or activities conducted under Edition 17 and 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/>

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### 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/>

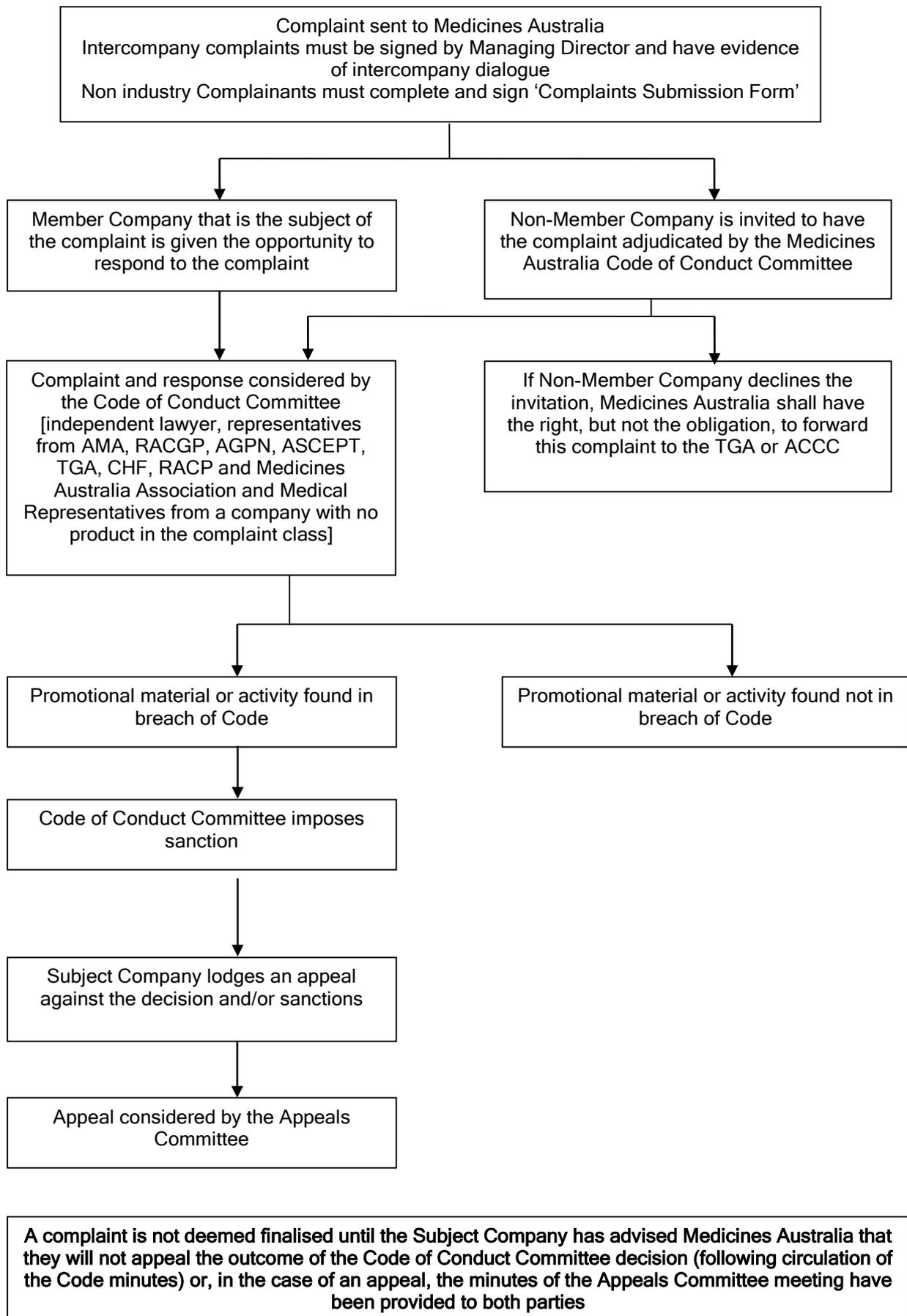
The Code of Conduct and the Guidelines that accompany the Code are available from the website (<http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>)

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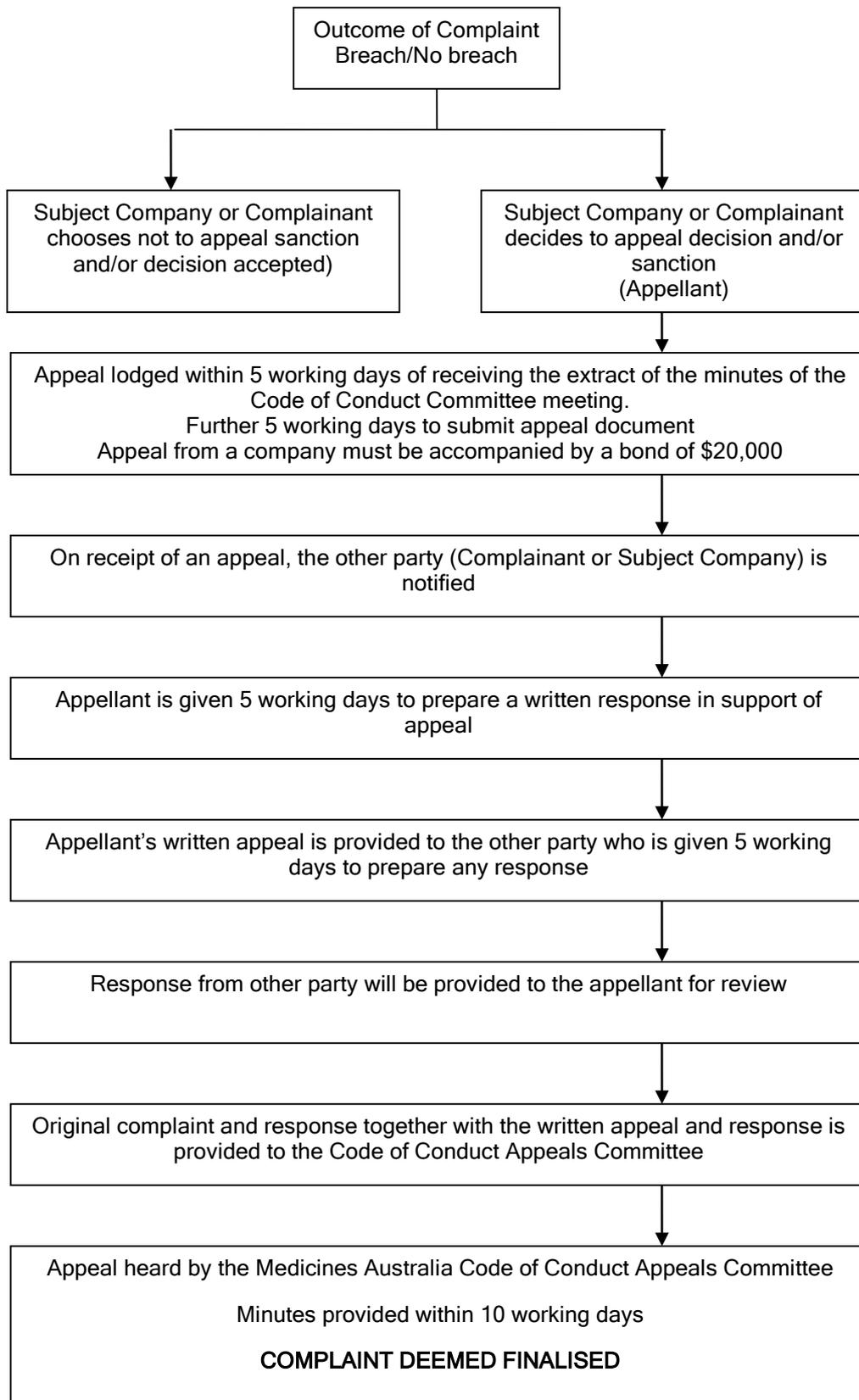
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## Medicines Australia Code of Conduct Complaints Handling Process



## 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 October – December 2015

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
<a href="#">1129</a>	Servier Laboratories	Advertisement	Valdoxan	Healthcare Professional	Breach of Sections 1.2.2 and 1.3	Pay a fine of \$100,000
<a href="#">1130</a>	Eli Lilly	Education Event	n/a	Monitoring Committee	No breach	n/a
<a href="#">1131</a>	Merck Serono	Education Event	n/a	Monitoring Committee	Breach of Section 9.4.3	Pay a fine of \$10,000
<a href="#">1132</a>	Pfizer	Education Event	n/a	Monitoring Committee	No breach	n/a
<a href="#">1133</a>	Takeda	Education Event	n/a	Monitoring Committee	No breach	n/a

## 1129 – Valdoxan Advertisement

**Subject Company:** Servier Laboratories (Aust) Pty Ltd

**Complainant:** Healthcare Professional

**Product:** Valdoxan

### Complaint

Dr Thomas alleged that an advertisement for Valdoxan, published in the July 2015 edition of *Australian Doctor*, is in breach of the Code. Specifically, Dr Thomas contended that the references used to substantiate the claim “*An effective antidepressant recommended first line in 2013 clinical guidelines*” are insufficient and inappropriate. Dr Thomas argued that neither the first reference, the Product Information, or the second reference, an article by Malhi et al (2013) were clinical guidelines. The claim therefore could not be adequately substantiated and was false and misleading.

Dr Thomas further alleged that Servier had selectively chosen positive studies in the promotion of this product and had ignored several unpublished studies that reported negative findings for agomelatine. Dr Thomas asserted that in doing so, Servier is in breach of Section 9.13 – Discredit to and reduction of confidence in the Industry.

### Sections of the Code

The promotional material is alleged to be in breach of the following Sections of Edition 18 of the Code:

- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims
- 9.13 Discredit to and Reduction of Confidence in the Industry

### Response

Servier disagreed with Dr Thomas’ assertions. Servier argued that the claim is appropriately substantiated, is current, accurate, balanced and is not misleading. Servier is confident that the claim for Valdoxan is able to be substantiated by the literature; the data used to support the claim is consistent with other guidelines and analyses.

Servier strongly rejected the assertion that the company had withheld data, and were affronted by Dr Thomas’ allegation that it had committed scientific fraud. The studies referred to by the complainant had been provided to Taylor D. et al for their analysis; two of these studies had since been published

and one study with relevant safety data had been submitted to the TGA and the data had been included in the Product Information. Servier denied it was in breach of Section 9.13 of the Code.

### Code of Conduct Committee decisions

The Committee reviewed the advertisement for Valdoxan that was published in the July 2015 edition of *Australian Doctor*. The Committee noted that the complaint centered on the claim “*An effective anti-depressant recommended first line in 2013 clinical guidelines*”, which was referenced to the Valdoxan Approved Product Information and the article *Pharmacological management of unipolar depression* by Malhi et al (2013).

The Committee considered that the reference to the Approved Product information for this claim was appropriate as it related to the phrase “an effective antidepressant”, which was consistent with the Code of Conduct requirements.

The Committee reviewed the Malhi et al paper, noting that it was a literature review of evidence available through PubMed and MEDLINE, which built upon the authors’ previously published clinical practice recommendations for bipolar disorder. The study aims were stated to be “to provide clinically relevant, evidence-based recommendations for an individualized formulation for pharmacotherapeutic management”.

The Committee noted that the study authors or the journal editors had used the terms “clinical practice guidelines” and “recommendations” in the Key Words section describing the paper. However, a number of Committee members noted that a literature review is not generally understood as being clinical guidelines. Clinical Guidelines are usually developed through consultation and discussion between relevant clinicians and published by a relevant medical college or society. The Committee noted that a draft “Clinical Practice Guideline: Mood Disorders”, prepared by a working group of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) that included the co-authors of the Malhi et al (2013) paper, was currently under public consultation. However, these Clinical Practice Guidelines were not final and Servier had not referenced these guidelines to substantiate the claim subject to complaint.

The Committee discussed the meaning conveyed by the claim “*recommended first line*” and whether this could be substantiated by the Malhi et al paper. This paper refers to a number of different antidepressants as being first line options, including agomelatine (the active ingredient in Valdoxan), but the Malhi et al paper is a single literature review. The Committee reviewed the meta-analysis by Taylor et al published in the *British Medical Journal* in March 2014. The complainant had observed that this meta-analysis had included a number of unpublished studies whereas the Malhi et al paper had only considered published studies. Taylor et al had found that published studies were more likely than unpublished studies to suggest advantages for agomelatine. Taylor et al had concluded that agomelatine was unsuitable as a first line treatment due, in part, to the requirement for monitoring of liver function. This, therefore, did not support the claim subject to complaint.

The majority of the Committee considered that the claim subject to complaint was misleading because it implied that the Malhi et al (2013) literature review was a clinical guideline that had been generally accepted and endorsed by clinical experts or a medical college, whereas the study was a published literature review. The majority of the Committee also considered that the claim could not be adequately substantiated because the Malhi et al 2013 paper did not necessarily reflect the full body of evidence.

A minority of the Committee did not agree that prescribers would be misled by the claim’s reference to 2013 clinical guidelines. These Committee members considered that the use of lower case text for “clinical guidelines”, which indicated that the claim did not refer to particular guidelines, and the clear reference to the Malhi et al publication would not mislead prescribers as to the status of the guidance supporting the claim. A minority of the Committee considered that the claim had been adequately substantiated by the Malhi et al paper, which had been published in a well-recognised peer-reviewed journal. Further, these Committee members noted that the claim “recommended first line” was consistent with the draft RANZCP Clinical Practice Guideline, albeit this Guideline was not yet final.

The Committee agreed that by a majority decision that the claim was in breach of Sections 1.2.2 and 1.3 of the Code as it was

misleading and could not be adequately substantiated.

The Committee then considered the alleged breach of Section 9.13 of the Code. The Committee noted that Servier had provided reports of all completed trials sponsored by the company to Taylor et al for their meta-analysis. Further, two of these studies had since been published and one had been submitted to the TGA and relevant safety information had been included in the Valdoxan Product Information. The Committee determined by unanimous decision that although it had found that the claim was misleading and unable to be substantiated, the conduct did not bring the industry into disrepute.

### **Sanction**

Having found the claim to be in breach of Sections 1.2.2 and 1.3 of the Code, the Committee discussed the severity of the breach. The Code Committee agreed by majority that the breach was moderate as defined by the Code.

The Code Committee agreed by majority decision that:

- The claim must be withdrawn from use and must not be used again in the same or similar form in future materials
- Servier must pay a fine of \$100,000

The Committee considered whether corrective action was required and unanimously agreed that a corrective letter or advertisement may confuse healthcare professionals rather than correct any misleading interpretation in this instance.

### **Appeal**

Servier appealed the size of the fine imposed by the Code of Conduct Committee but not the decision of the Code of Conduct Committee to find that the claim was in breach of the Code. Servier asserted that the Code of Conduct Committee had erred in its reasoning in finding that conclusions of Malhi et al. were inconsistent with those of Taylor et al., which then led the Committee to impose a higher fine. Servier accepted that the Malhi et al. paper is not equivalent to a College Guideline, but rejected the Code of Conduct Committee’s conclusion that it is not representative of the body of evidence.

Further, Servier argued that the fine imposed by the Code of Conduct Committee was inconsistent with, and considerably higher than, fines imposed in relation to other recent

complaints where breaches of the same or similar sections of the Code had been found.

### **Appeal Response**

Dr Thomas responded to Servier's appeal, stating that the findings of the Code Committee were well-considered and appropriate. Further, Dr Thomas asserted that Servier had not provided sufficient grounds for varying the decision or the sanction imposed.

### **Appeals Committee decision**

The Appeals Committee was not persuaded that the Code of Conduct Committee had erred in its reasoning for finding that the claim was in breach or its rationale for the fine imposed. The Appeals Committee agreed unanimously not to uphold the appeal.

### **Sanction**

The Appeals Committee agreed unanimously that the sanction of \$100,000 imposed by the Code of Conduct Committee was appropriate and did not accept Servier's arguments for it to be reduced.

In not upholding the appeal, the Appeals Committee agreed unanimously that the \$20,000 appeal bond should be retained by Medicines Australia.

### **Consideration of the Appeal**

The Chairman introduced the Appeals Committee members to the Servier representatives. The Secretariat advised that Dr Thomas would not be attending the Appeals Committee meeting in person or by teleconference.

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

The Servier representative stated that Servier was appealing size of the fine only, not the findings of breaches determined by the Code Committee. Servier noted that it accepted the Code Committee's conclusion that the Malhi et al. paper is not equivalent to a College Guideline. However, Servier contended that

the Code Committee had made two errors in reaching its decision that it believes influenced the Code Committee to impose a higher fine. Additionally, Servier argued that the size of the fine was out of step with recent breaches of the same and/or similar Code sections.

Servier noted that in his response to the appeal, Dr Thomas had included other argument that was not relevant to the basis for the appeal; specifically issues relating to publication bias. Servier advised the Appeals Committee that while it respects the right of individuals to hold alternative views, the accusation of publication bias is not relevant to the references cited in the advertisement; nor is it within the scope of the Code of Conduct to address.

Servier advised the Appeals Committee that in its response to the original complaint, it had provided the Code Committee with five additional studies that supported the conclusions of the Malhi et al. paper that Valdoxan (agomelatine) can be used as a first line treatment. These additional studies all represented Level 1 evidence according to the NHMRC's hierarchy of evidence. It is the combined outcomes of all these studies that form the body of evidence, and Servier argue that outcome of the Malhi et al. study is not inconsistent with the other five studies.

Servier noted that the Code Committee Reasons for Decision state that "*Taylor et al. had concluded the agomelatine was unsuitable as a first line treatment due, in part, to the requirement for monitoring of liver function. This, therefore, did not support the claim subject to complaint.*" Servier advised the Appeals Committee that the conclusion of the Taylor et al. study, under the heading 'Conclusion', actually state: "*...agomelatine is no less effective than comparator antidepressants... As such it serves as an appropriate alternative to these longer established antidepressants, although its relative cost, the small risk of hepatic toxicity, and need for liver function monitoring should be noted.*" The Code Committee's Reasons for Decision further stated that "*... the claim could not be adequately substantiated because the Malhi et al. 2013 paper did not necessarily reflect the full body of evidence*". Servier asserted that the Code Committee's misreading of the Taylor et al. conclusion led the Code Committee to think that the Taylor et al. study conflicted with the conclusions of the Malhi et al. paper. This error had unduly

influenced the Committee in its determination of the size of the fine imposed.

Further, Servier contended that the Code Committee had been unduly influenced by the inclusion of unpublished studies in Taylor et al. paper. Servier reminded the Appeals Committee that Taylor et al. was a meta-analysis which, despite including unpublished studies that had not been considered by Malhi et al., still concluded that “*agomelatine is no less effective*” than other antidepressants. This result formed the basis for the conclusion of Taylor et al. that agomelatine was an appropriate alternative to other first line antidepressants.

Servier accepted the Code Committee’s decision that the use of the word “guideline” in the claim for Valdoxan may be misleading. Servier explained that it had chosen not to reference the RANZCP’s clinical practice Guidelines for the treatment of depression and bipolar disorder current at the time, as these were several years out of date. The updated Guidelines were published in December 2015. Servier noted that the authors of the RANZCP’s 2015 Clinical Practice Guidelines – Mood Disorders is largely the same as that of the Malhi et al. study and the conclusions are identical – that is, that agomelatine can be used as first-line treatment for depression.

One Appeals Committee member questioned why the 2013 Therapeutic Guidelines for use of psychotropic medicines were not considered as part of the body of evidence. These Guidelines state that agomelatine should be used second-line. Servier acknowledged that the 2013 Therapeutic Guidelines recommended using agomelatine second-line. However, this recommendation was due to the lack of any meta-analyses of clinical evidence, which is no longer the case. Servier chose to reference the claim to the Malhi et al. paper rather than the Therapeutic Guidelines because the former reflected the current body of evidence.

Servier then discussed the amount of the fine imposed relative to fines imposed for other similar breaches in recent Code of Conduct complaints. Servier had provided an analysis of previous breaches of the same sections of the Code that were deemed to be “moderate” by the Code Committee. Servier presented a table showing other moderate level breaches determined during 2014 and 2015 relating to the same sections of the Code found in breach in the Valdoxan 1129 complaint. In the other

complaints the subject companies were fined \$30,000 (complaint 1124), \$40,000 (complaint 1118), and \$45,000 (complaint 1126). Servier accepted that no two complaints are the same and extrapolating from the Reasons for Decision is difficult, however the fine imposed on Servier by the Code Committee was 2 to 3 times that imposed for other recent similar breaches.

Servier asked the Appeals Committee to take into account Servier’s history of not being found in breach of the Code and the scope of publication of the Valdoxan advertisement when considering the appropriateness of the fine. Specifically, Servier referenced the *Principles for determining sanctions* in the Code of Conduct Guidelines (Edition 18, version 1, pages 136-137). Servier noted that two breaches had been found relating to one claim in a single advertisement. Although the advertisement had been in use for approximately 12 months, it was published in a pulse or intermittent fashion in cycles of 1-2 months at a time, not continuously. Servier also noted that the claim was not outside the approved indications and it was not deemed to be comparative in nature. Nor was the claim found to have any safety implications for patients or promotion to the general public, which would attract a higher fine. Servier further highlighted its complaint history, noting that this was its first breach in this therapeutic area and that Valdoxan was registered in 2010. No complaints had been made by competitor companies about the advertisement. Servier noted that the last time it had been found in breach of the Code was seven years ago in 2009.

The Appeals Committee queried Servier’s reliance on the Malhi et al. paper, which was published as a journal supplement; these are paid publications and do not necessarily go through the same peer review process for original research published in the primary journal. Servier responded that the basis for the appeal was that both the Malhi et al. paper and the Taylor et al. meta-analysis clearly showed that agomelatine is as effective as other antidepressants and can be prescribed first-line. In addition, the Therapeutic Goods Administration had approved Valdoxan for use first-line in depression. Servier considers that the Code Committee had erred in its interpretation of this evidence, which led the Committee to impose a higher fine.

The Chairman thanked the Servier representatives for their presentation and

excused them from the meeting to allow the Committee to deliberate on the appeal.

The Chairman reiterated to the Appeals Committee that Servier was not appealing the finding of having breached the Code, but that the amount of the fine is out of step with other complaints of a similar nature. The Appeals Committee's task is to consider whether the Code Committee had erred in relation to its rationale for imposing the fine of \$100,000.

The Appeals Committee considered the audience to which this advertisement was distributed, noting that it had been published in the *Australian Doctor Weekly*, which is aimed primarily at general practitioners rather than specialist psychiatrists. The Appeals Committee were of the opinion that this opened up the possibility of patient safety concerns, given the hepatic monitoring requirements for Valdoxan which may not be well-known by general practitioners. The Appeals Committee also agreed with the Code Committee that the advertisement may have an influence on prescribing.

The Appeals Committee discussed the Code Committee's interpretation of the Taylor et al. paper as described in its Reasons for Decision and fully concurred with the Code Committee's interpretation. Specifically, the Appeals Committee noted that the conclusion of the study stated *"That agomelatine is no less effective than comparator antidepressants is also noteworthy given its relatively small risk of sexual adverse effects, insomnia, and discontinuation reactions... As such it serves as an appropriate alternative to these longer established antidepressants, although its relative cost, the small risk of hepatic toxicity, and the need for liver function monitoring should be noted"*. The Appeals Committee considered that the use of the words "appropriate alternative" would be more likely to be understood as use as second-line treatment following the longer established agents. This interpretation was supported by the statement earlier in the Taylor et al. paper, under 'Agomelatine – place in treatment', where it was stated that agomelatine is *"unsuitable as a first-line treatment"*. The Appeals Committee agreed with the Code Committee that this was a moderate breach of the Code for which the maximum fine that may be imposed for a single breach of the Code is \$150,000.

The Appeals Committee reviewed the previous complaints cited by Servier as a further rationale for reducing the fine. It was noted that in each cited complaint the Code Committee had found breaches on the potential to mislead prescribers and lack of substantiating evidence. The Committee also reviewed other complaints finalised during the last two years where a fine had been imposed and the amount of these fines. There had been another moderate breach (complaint 1121) where a fine of \$90,000 had been imposed, resulting from breaches of the Code other than sections 1.2.2 or 1.3. The Appeals Committee was not persuaded that the amount of the fine was inconsistent with other fines imposed by the Code Committee.

The Appeals Committee concurred with the Code Committee's interpretation of the evidence provided by Servier in its response to the original complaint, in particular the conclusions of the Taylor et al. paper. The Appeals Committee found that the Code Committee had not erred in its reasoning for finding breaches of the Code or the sanction it had imposed. The Appeals Committee noted that the Code Committee did not require Servier to undertake any form of corrective action, which would also been a consideration in relation to the amount of the fine. The Appeals Committee considered that the advertisement had the potential to influence a large number of prescribers, given the length of time the advertisement had been in use. The Appeals Committee was not persuaded by Servier's arguments that the Code Committee's decisions or sanctions were the result of any error of understanding or interpretation.

The Appeals Committee agreed unanimously to confirm the Code Committee's original decision and to not uphold the appeal.

### **Sanction**

As the appeal was not upheld, the Appeals Committee agreed unanimously that the sanction of \$100,000 imposed by the Code Committee should not be varied. 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.

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## 1130 – Eli Lilly Education Event

**Subject Company:** Roche Products Pty Ltd

**Complainant:** Monitoring Committee

**Product:** n/a

### Complaint

Following its review of Education Event Reports and subsequent request for clarification, the Medicines Australia Monitoring Committee referred an educational event organised by Eli Lilly held in June 2014 for consideration by the Code Committee. The Monitoring Committee had considered that the expenditure on alcohol at this meeting was excessive in relation to the educational content and duration of the meeting. The alcoholic beverages included two bottles of wine at a cost of \$96 each, as well as three individual glasses of wine. The meeting, which was held in a restaurant, provided two hours of educational content in relation to Men's Health.

### Sections of the Code

The educational event was alleged to be in breach of the following Sections of Edition 17 of the Code:

- 9.4.3 Meals and Beverages

### Consideration of the complaint

Details of event as originally reported by Eli Lilly:

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Promotional Meeting - Out of Institution Lilly run educational meeting with product content Men's Health Duration of education = 2 hrs 00 min	Villa D'Este, 49 Outram St, West Perth WA 6005	General Practice	2/3 course meal with alcoholic/ nonalcoholic beverages	Food & Beverage = \$953	8	Food & Beverage = \$953 AV Equipment = \$1992 Honorarium = \$750

The Committee reviewed the correspondence from the Monitoring Committee and the response from Eli Lilly, which related to an educational event as part of the *Men's Health Meeting* series held in association with the *Men's Health Workshop* in Perth in 2014. The Committee noted that the event subject to complaint was held at a well-known restaurant in the Perth area, in a private room. On reviewing the agenda, the Code Committee noted that the event included 2 hours of educational content provided in two one hour

### Response

Eli Lilly had denied that the educational meeting was in breach of the Code. Eli Lilly responded that the hospitality provided was reasonable and appropriate, compliant with Lilly Australia policies and procedures and was not in breach of the Code.

Lilly Australia was concerned that the cost of the alcohol provided was the key consideration for the Monitoring Committee's complaint. Lilly stated it has strong internal policies and procedures setting strict limits for expenditure on meals and beverages provided at educational events. The educational meeting concerned was consistent with these limits. The total cost of hospitality provided at the meeting was \$94.40 per person (exclusive of GST).

### Code of Conduct Committee decision

The Committee agreed in a majority decision that the dinner held in June 2014 in association with the Men's Health Workshop in Perth was not in breach of Section 9.4.3 'Meals and Beverages' of the Code of Conduct.

presentations. The event was attended by 8 general practitioners and two Eli Lilly staff members.

The Code Committee noted that the Monitoring Committee's concern relating to this event centred on the provision of alcohol; specifically the cost of the bottles of wine purchased. The Code Committee noted that the total hospitality expenditure for the event was \$943.38 (excl GST), with alcohol making up \$224.40 of that expense. The alcohol provided at the meeting

consisted of two \$96 bottles of wine, along with additional three single glasses of wine. The Committee noted that the cost of alcoholic beverages represented approximately 20% of the total hospitality expense. The Code Committee also noted that the food and beverages cost per person was \$94.40.

The Code Committee noted that Eli Lilly had engaged a third party to manage the event on its behalf. The event was held at a location that was considered to be acceptable according to Eli Lilly's internal guidelines and industry expectations. Eli Lilly advised that the selection of food and beverages was made by the third party, often several weeks prior to the event. No Eli Lilly staff were involved in the selection of the wines on the night of the event.

In its response, Eli Lilly had provided a price comparison between the restaurant and a leading liquor retailer for the particular wine selected for the event, which showed that the restaurant mark-up on the wine was approximately 50%. The Code Committee noted this; however it agreed that many restaurants include a significant mark up on the price of wine and this was not relevant to the consideration of the complaint. Further, the Code Committee considered that the mark up on alcohol benefits the restaurant and does not change the public perception of industry purchasing expensive wine at evening educational events.

The Code Committee reviewed the menu and wine lists for the restaurant and noted that there were other wine options available that were cheaper and would have been more appropriate choices. Further, the Code Committee noted that a different venue with lower prices also could have been selected. The Code Committee noted that there were many restaurant venue options available in the area which would have provided lower priced alcoholic beverages and a lower overall per head cost.

The Code Committee agreed by majority decision that the expenditure on alcohol for this event was not in breach of the Code. The Code Committee noted, however, that the expenditure on the two bottles of wine was at the upper limit of what was considered to be consistent with the Code. More appropriate options would have been available to the organisers that would have been more in line with community expectations.

## Sanction

As no breach was found, no sanction was imposed by the Code Committee.

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## 1131 – Merck Serono Education Event

**Subject Company:** Merck Seono Pty Ltd

**Complainant:** Monitoring Committee

**Product:** n/a

### Complaint

Following its review of Education Event Reports and subsequent request for clarification, the Medicines Australia Monitoring Committee referred an educational event supported by Merck Serono held in August 2014 for consideration by the Code Committee. The event was a hospital Department's Clinical Meeting. The Monitoring Committee considered that the provision of a two course lunch including alcoholic beverages at an off-site restaurant was not appropriate or in proportion to the educational purpose of the event. 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 educational event is alleged to be in breach of the following Sections of Edition 17 of the Code:

- 9.4.3 Meals and Beverages

### Response

Merck Serono denied that this event was in breach of the Code of Conduct. The Clinical meeting and demonstration of an injection device had occurred at the hospital with two neurologists and several nursing staff. As there were limited facilities at the hospital for lunch, Merck Serono and two medical staff had lunch at a nearby restaurant. The company acknowledged that lunch at an off-site restaurant location may not be acceptable in a city area, where there are a variety of options for lunch. However, finding a suitable place for lunch in Albury is not as easy; the limited availability of alternative venues should be taken into consideration.

Merck Serono argued that the length of the meeting (2.5 hours) and that it was a mixed educational meeting and sales call, due to the infrequency of visits to the regional centre,

should be taken into account. Merck Serono considered that the hospitality provided was not excessive and was in proportion to the educational duration and purpose of the meeting.

#### Code of Conduct Committee decisions

The Committee agreed in a unanimous decision that the lunch provided in Albury in August 2014 to two healthcare professionals

#### Consideration of the complaint

Details of the event as original reported by Merck Serono

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Merck Serono contributed to The Albury Hospital Neurology Department Clinical Meeting. This event was organised by The Albury Hospital Neurology Department and Merck Serono was not responsible for inviting the attendees or organising the educational content of the meeting. 1 hour education.	Broad Gauge, Albury, Victoria	Neurologists	Lunch and beverages	\$153.86	2	\$153.86

The Code Committee noted that this event comprised a mixture of sales discussions, in-service training activities with neurologists and nurses and some educational content. The Code Committee noted that Merck Serono confirmed that the sales and in-service sections of the activity were conducted within the hospital during a two and a half hour session prior to lunch. The decision to continue discussions with two neurologists off-site over lunch was made on the day by Merck Serono staff.

The Code Committee understood Merck Serono's justification for having the lunch in a restaurant and not at the hospital to be that the company staff had travelled a significant distance for this meeting (approximately 3 hours by car). Further, the Code Committee noted Merck Serono's rationale that there is only a basic coffee shop/café onsite at Albury Hospital and there are limited café type options in Albury as compared with a metropolitan centre. Merck Serono staff chose to travel offsite to a nearby restaurant to continue the discussions. Merck Serono had argued that the meal provided was not out of proportion to the overall educational purpose of the meeting.

The Code Committee noted that the Monitoring Committee was concerned about a number of

was in breach of Section 9.4.3 'Meals and Beverages' of the Code of Conduct.

#### Sanction

The Committee determined that the breach was minor as defined in the Code. The conduct found in breach must not be repeated in the same or similar form. In a majority decision, the Committee imposed a fine of \$10,000.

factors relating to this event. The Monitoring Committee considered that the event should not have been held offsite, and that the hospitality provided was excessive in relation to the education provided. Further, the Monitoring Committee was concerned at the amount of alcohol provided during the lunch, after which the healthcare professionals may have returned to duty, and that the company staff were continuing their travel by car.

The Code Committee agreed with the Monitoring Committee that the hospitality appeared to be the primary purpose for the part of the meeting that had been held in the restaurant, and that the educational component was secondary. Regardless of the sales or in-service purpose of this event, the hospitality at the restaurant was only provided to two healthcare professionals. Merck Serono had acknowledged that the discussions during the lunch were more informal and comprised limited educational content. Therefore, on balance, the Code Committee considered that the hospitality provided at the lunch was excessive and out of proportion to the quality and content of education provided at the event.

The Code Committee considered that there would have been a number of more suitable

options available for the provision of hospitality for this activity, such as having it catered either by the hospital or a local supplier or a more suitable venue could have been chosen. The Code Committee shared the Monitoring Committee's concern as to the provision of alcohol at the lunch, which included several glasses of wine and bottles of alcoholic cider. The Code Committee accepted that the Code of Conduct does not explicitly state that alcohol should not be provided during a lunch. However, the provision of alcohol increases the cost of the hospitality and, in this case, contributed to the overall lack of proportionality between the educational purpose and hospitality provided.

The Committee determined in a unanimous decision that the educational event was in breach of Section 9.4.3 of the Code of Conduct, Edition 17.

#### **Sanction**

The Committee determined that the breach was minor as defined in the Code. The conduct found in breach must not be repeated in the same or similar form.

In a majority decision, the Committee imposed a fine of \$10,000.

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## **1132 – Pfizer Education Event**

**Subject Company:** Pfizer Australia Pty Ltd

**Complainant:** Monitoring Committee

**Product:** n/a

#### **Complaint**

Following its review of Education Event Reports and subsequent request for clarification, the Medicines Australia Monitoring Committee referred an educational event hosted by Pfizer held in August 2014 for consideration by the Code Committee.

The Monitoring Committee considered that the cost of the hospitality provided at both the pre-forum dinner and the forum dinner was excessive in relation to the educational content and duration of the meeting. In its consideration of the event and Pfizer's initial response to the Monitoring Committee, the

Monitoring Committee did not agree that Code of Conduct Committee decisions concerning the cost of hospitality at educational events reviewed in 2008/09 should determine whether hospitality at the same or similar cost is acceptable in 2014. The Committee considered that community opinion in Australia and internationally has changed considerably since that time.

#### **Sections of the Code**

The educational event was alleged to be in breach of the following Sections of Edition 17 of the Code:

- 9.4.3 Meals and Beverages

#### **Response**

Pfizer strongly rejected the allegation that hospitality provided at the Clinical Infectious Diseases Forum was excessive or inappropriate for the educational content and duration of the meeting. Pfizer considered that the hospitality provided at the educational meeting was fully compliant with Section 9.4.3 of Edition 17 of the Code.

In relation to the Pre-Forum Speakers' dinner, Pfizer argued that as a consultant dinner, consideration of educational content or duration was not relevant. Rather, the requirement is to consider whether the hospitality provided was reasonable in the circumstances. Pfizer contended that the cost of the dinner at the Pre-Forum was consistent with the requirements of Section 9.8.4, which relates to consulting arrangements with healthcare professionals, and Code precedent.

Pfizer considered that hospitality provided at both dinners was not excessive and was consistent with the Code of Conduct Edition 17.

#### **Code of Conduct Committee decisions**

The Committee agreed in a majority decision that the dinner held on Friday 1 August 2014 prior to the Clinical Infectious Diseases Forum was not in breach of Section 9.4.3 'Meals and Beverages' of the Code of Conduct.

The Committee agreed in a unanimous decision that the dinner held on Saturday 2 August 2014, following the first day of the Forum, was not in breach of Section 9.4.3 'Meals and Beverages' of the Code of Conduct.

## Consideration of the complaint

Details of event as originally reported by Pfizer:

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Pfizer Hosted Meeting - Infectious Disease Forum. Educational Content - 14 hr(s).	Sheraton on the Park Hotel, Sydney, NSW.	Infectious Disease Specialists	Flights \$40,414, 83 Flights, Accommodation \$36,618, 152 Room Nights, Transfers \$3,970, Parking \$1,732, Meal / Drinks (Conf Package 1, \$10,240, 128 Attendees, Conf Package 2, \$9,658, 128 Attendees, Dinner, \$16,478, 125 Attendees) Other Costs: Speaker Fees (13 Speakers, \$24,169, 4 Speaker, No Fee), Speaker Expenses \$48,524, Audio Visual \$25,510, Room Hire \$17,964, Printed Materials \$3,878, Programme Dev/Logistics \$17,000, Co-Ord Expenses \$7,569, Co-Ord Fee \$31,817, Other \$3,413	\$119,110.00	128	\$298,954.20

The Code Committee noted that this complaint related to two evening meals provided in association with the Infectious Disease Forum:

- 1) A speakers' dinner prior to the Forum, held at Prime Steak Restaurant and Grill Room on 1 August 2014; and
- 2) The Forum dinner, held at the Australian Museum on 2 August 2014.

The Code Committee noted the Monitoring Committee's concerns that the per head cost for each of these dinners was high. The Code Committee reviewed each dinner separately in the context of the educational event.

### Speakers' Dinner

In its response, Pfizer advised the Code Committee that the purpose of the Speakers' dinner on 1 August 2014 was to bring together the international and local speakers, as well as other key leaders and organisers for this event, in order to introduce them to each other, discuss the program and logistics for the event on the following day. Pfizer noted that the restaurant venue was chosen for its proximity to the hotel; at the time of the event, the Sheraton on the Park did not have an in-house restaurant.

The Code Committee agreed that such preparatory meetings are important to the successful running of an event, to give an opportunity for international speakers and local speakers and organisers to meet and discuss

the conduct of the event in advance. However, some members of the Code Committee felt that to hold this meeting over dinner at a well-known and relatively expensive restaurant was excessive. These Committee members thought that there would have been more suitable options in-house at the hotel, regardless of whether there is an onsite restaurant, or at another more reasonably priced restaurant in the nearby vicinity.

A majority of the Code Committee members considered that whilst the cost of the hospitality provided at the Speakers' dinner was high at \$121.12 per person, there was a legitimate purpose for bringing the speakers and organisers together prior to the Forum and that the hospitality was not particularly excessive. The Committee agreed by a majority decision that the Speakers' dinner was not in breach the Code of Conduct. The Committee agreed unanimously, however, that the cost of hospitality provided at this dinner was at the upper limit of what would be acceptable for this type of activity. It was noted that this event was adjudicated under Edition 17 of the Code, and that the \$120 per head limit imposed under Edition 18 should only be reached in exceptional circumstances where there is substantial education provided. Under Code Edition 18 it is expected that in most circumstances the cost of a meal and beverages will be well below \$120 (excluding GST and gratuities).

### Forum Dinner

The Code Committee noted that this dinner was held following the first day of the Infectious Disease Forum. The Forum was a 2 day event, with 7.5 hours of education on the first day, with 2 hours of educational presentations at the dinner. The dinner was held at the Australian Museum at a cost of \$131.82 per person, which included the service charge for alternate plating.

Pfizer outlined in its response that as, with the Speakers' dinner, the venue was chosen for its proximity to the hotel at which the Forum was held. Further, the hotel venue did not have a room of a sufficient size to accommodate the 145 invited guests.

The Code Committee accepted that it would be difficult to accommodate 145 delegates in a hotel venue for dinner. The Code Committee did note, however, that possibly there were other suitable venues available in the vicinity that would have offered a lower cost evening meal. The Code Committee considered that this event, like the Speaker Dinner, was at the upper limit of acceptable expenditure on hospitality under Code Edition 17. However, the dinner for the delegates had followed a full day of education and there had been educational presentations given during the dinner. The Code Committee agreed in a unanimous decision that the Forum Dinner was not in breach of the Code of Conduct.

### **Sanction**

As no breach was found, no sanction was imposed by the Code Committee

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## **1133 – Takeda Education Event**

**Subject Company:** Takeda Pharmaceuticals Australia Pty Ltd

**Complainant:** Monitoring Committee

**Product:** n/a

### **Complaint**

Following its review of Education Event Reports and subsequent request for clarification, the Medicines Australia Monitoring Committee referred hospitality provided to healthcare professionals who had attended the American Diabetes Association 74<sup>th</sup> Scientific Meeting for consideration by the Code Committee. This was a 5 day event held in San Francisco in June 2014. The Monitoring Committee's concerns relate to evening meals provided to healthcare professionals during the

meeting and in particular expenditure on alcoholic beverages at these dinners. The Monitoring Committee considered that the expenditure on alcoholic beverages at three dinners was high, out of proportion to the expenditure on food and was excessive.

### **Sections of the Code**

The educational event is alleged to be in breach of the following Sections of Edition 17 of the Code:

- 9.7.7 Sponsorship of Healthcare Professionals to Attend Educational Events: Meals and Beverages

### **Response**

Takeda stated that it is mindful of the obligations of member companies and takes compliance with the Code very seriously in all dealings with healthcare professionals. Takeda believed that its expenditure on meals and beverages complied with the quantitative guidance provided in the Code of Conduct Guidelines and was not in breach of the Code of Conduct.

Takeda had expressed concern that at no stage throughout its correspondence with the Monitoring Committee was it provided with any objective basis for the Committee's opinion that the hospitality provided was excessive. Takeda noted that the average per head cost of the food and beverages at the three dinners was between \$118.22 and \$81.40, which was not excessive in light of the extensive education provided at the meeting.

Takeda detailed the specific expenditure on alcoholic beverages at the three dinners identified by the Monitoring Committee. Takeda argued that the cost of the wine was below the average cost of wine available for selection at each restaurant and that the per head cost of alcoholic beverages at each dinner was reasonable and was not excessive. Takeda further argued that the Monitoring Committee had adopted a narrow, arbitrary and subjective view of what was excessive related to the proportion of the total cost of hospitality spent on alcoholic beverages. Takeda denied that any of the dinner events was in breach of the Code.

### **Code of Conduct Committee decision**

The Committee agreed in a majority decision that the three dinners provided in San Francisco in June 2014 for healthcare professionals attending the American Diabetes Association Scientific Meeting were not in breach of Section 9.7.7 of the Code of Conduct Edition 17.

## Consideration of the complaint

Details of event as originally reported by Takeda:

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Educational Duration: 5 days/30 hours Sponsorship for healthcare professionals to attend the American Diabetes Association 74th Scientific Meeting. The event was organised by an external party and Takeda was not responsible for inviting the attendees or organising the educational content.	Moscone Centre, San Francisco, California, USA	Endocrinologists	Meals, International travel, accommodation & travel expenses	53,723.35	5	57,473.34 Includes: Hospitality - 53,723.35 Congress Registrations - 3,750.00

The Code Committee noted that the Monitoring Committee's concerns centered on the provision of alcohol at three dinners in San Francisco as part of a sponsorship of 5 healthcare professionals to attend the American Diabetes Association Scientific Meeting. Specifically, the Monitoring Committee had expressed concern regarding the following aspects of the hospitality:

- Ozumo Restaurant: the provision of two bottles of wine at \$81 and \$95, along with a number of single glasses of wine and bottles of beer. The alcohol expenditure at this event was USD\$222 for 10 guests.
- Wayfare Tavern: the provision of two bottles of wine at \$82 each, and two bottles of wine at \$78 each, at a total cost of USD\$320 for 12 guests, which represented nearly 30% of the total hospitality expenditure (excluding taxes and other fees).
- Slanted Door: the provision of spirit drinks and wine totalling USD\$166 for 8 guests, representing more than 30% of the hospitality expenditure (excluding taxes and other fees).

The Code Committee noted that alcohol, especially wine, is considerably more expensive in restaurants in the United States than it is in Australia. A minority of members of the Code Committee, however, felt that regardless of higher costs at international restaurants, there had been less expensive alcoholic beverage options available at each of these restaurants, and there would have been more appropriately priced restaurant options available in San Francisco. However, a majority of the Committee members considered that the overall per head cost at each of the three dinners was acceptable and took into account the higher cost of alcoholic beverages including wine in US restaurants.

The Code Committee agreed by majority decision that the hospitality provided at the three dinners associated with these sponsorships was not in breach of the Code.

### Sanction

As no breach was found, no sanction was imposed by the Code Committee