MEDICINES AUSTRALIA

CODE OF CONDUCT

ANNUAL REPORT

2007/2008
## Complaint Determinations

**Table 2: Code of Conduct Complaints July 2007 – June 2008**

This table provides a summary of each complaint finalised in 2007/2008. To view the detailed report on each complaint please click on the complaint number.


<table>
<thead>
<tr>
<th>Complaint Number</th>
<th>Subject Company</th>
<th>Material Activity</th>
<th>Product</th>
<th>Complainant</th>
<th>Outcome (Sections of the Code where one or more breaches found)</th>
<th>Sanction</th>
</tr>
</thead>
<tbody>
<tr>
<td>870</td>
<td>AstraZeneca</td>
<td>Information to the general public</td>
<td>Choice</td>
<td>No Breach 9.4</td>
<td>N/A</td>
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<td>871</td>
<td>GSKA</td>
<td>Media release</td>
<td>Tykerb</td>
<td>Roche</td>
<td>No Breach 12.1.1</td>
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<td>872</td>
<td>Roche</td>
<td>Media releases</td>
<td>GSKA</td>
<td>Following appeal: Breach 1.1, 1.3.1, 9.2.1, 9.2.4, 9.3, 9.4</td>
<td>Following appeal: Remove media releases from website, Fine $110,000</td>
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<td>No Breach 1.5, 9.6, 9.6.1, 9.6.4, 9.10</td>
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<td>GSKA no breach 12.3</td>
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<td>873</td>
<td>GSKA</td>
<td>Promotional material</td>
<td>Seretide</td>
<td>AstraZeneca</td>
<td>Breach 1.1, 1.2.2, 1.3, 1.7</td>
<td>• Withdraw item • Corrective letter • Fine $50,000</td>
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<td>874</td>
<td>Mundipharma</td>
<td>Information and promotional material provided at an education event</td>
<td>Norspan</td>
<td>Healthcare professional (GP)</td>
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<td>Complaint Number</td>
<td>Subject Company</td>
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<td>Promotional material</td>
<td>Seretide</td>
<td>Pfizer &amp; Boehringer Ingelheim</td>
<td>Following appeal: Breach 1.3 Preamble to 3, 3.1.1.3 No Breach 1.2.2</td>
<td>Following appeal: • Withdraw item • Fine $50,000</td>
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<td>Promotional brochure</td>
<td>Famvir</td>
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<td>Eligard</td>
<td>AstraZeneca</td>
<td>Following appeal: Breach 1.1, 1.2, 1.3, 1.7</td>
<td>Following appeal: • Withdraw item • Corrective letter • Fine $50,000</td>
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<td>882</td>
<td>Allergan</td>
<td>Allergan Event</td>
<td>Botox/Juvederm</td>
<td>Monitoring Committee</td>
<td>Breach 6.2.2, 10.2, 10.8 No Breach 6.2.1, 6.6</td>
<td>• Fine $175,000</td>
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<td>AstraZeneca</td>
<td>Promotional material</td>
<td>Crestor</td>
<td>Pfizer</td>
<td>Repeat Breach 1.3, 1.7</td>
<td>• Fine $80,000 • Company had undertaken to send a corrective letter</td>
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<td>884</td>
<td>Orphan Australia</td>
<td>Promotional Material</td>
<td>Tetrabenzine</td>
<td>Healthcare professional (hospital doctor)</td>
<td>Considered by Code of Conduct Committee and referred back to the complainant for further information</td>
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<td>885</td>
<td>Eli Lilly</td>
<td>Dear healthcare provider letter</td>
<td>Actos</td>
<td>GSKA</td>
<td>Breach 1.10, 3.3 No Breach 1.1, 1.2, 1.3</td>
<td>• Company had already sent corrective letter • No further corrective action required</td>
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<td>Lipitor</td>
<td>AstraZeneca</td>
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<td>AstraZeneca</td>
<td>Breach 1.3.1 No Breach 10.5</td>
<td>• Withdraw item • Fine $25,000</td>
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<td>Lumigan</td>
<td>Pfizer</td>
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<td>Abbott</td>
<td>Promotional material</td>
<td>Reductil</td>
<td>iNova</td>
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<td>Amgen Educational Event AM-217</td>
<td>Monitoring Committee</td>
<td>Breach 6.2.1, 6.2.2, 10.2 No Breach 10.8</td>
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<td>Complaint Number</td>
<td>Subject Company</td>
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<td>Following appeal: Fine $50,000</td>
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<td>CSL</td>
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<td>Breach 10.2, 10.2, 10.8</td>
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<td>Servier Educational Event SV-154</td>
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<td><strong>Fine $20,000</strong></td>
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<td>Octagam</td>
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<td>Withdraw materials • Corrective letter • Fine $50,000</td>
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<td>909</td>
<td>Pfizer</td>
<td>Representatives’ Conduct</td>
<td>Pfizer Conduct</td>
<td>AstraZeneca</td>
<td>Breach 1.1, 1.2, 1.3, 1.7, 4.3, 4.4, 10.5, 10.8</td>
<td>Corrective letter • Provide new procedures &amp; evidence implementation of compliance procedures • Fine $200,000</td>
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<td>Servier Educational Event SV-428</td>
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<td>Breach 6.2.1, 10.2, No Breach 6.2.2, 10.8</td>
<td>▲ Fine $50,000</td>
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<td>Servier Educational Event SV-493</td>
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<td>Solvay Educational Event SOL-9</td>
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<td>Breach 10.2, No Breach 6.2.1, 6.2.2, 10.8</td>
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<td>944</td>
<td>AstraZeneca</td>
<td>Promotional Material</td>
<td>Heartburn &amp; reflux products</td>
<td>TGA</td>
<td>No Breach 9.4, 9.5, 9.6</td>
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<td>945</td>
<td>Schering Plough</td>
<td>Promotional Material</td>
<td>Olmetec</td>
<td>AstraZeneca</td>
<td>Breach 12.1</td>
<td>▲ Publish corrective advertisement ▲ Fine $50,000</td>
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<td>946</td>
<td>CSL</td>
<td>Promotional Material</td>
<td>Influenza Vaccine</td>
<td>HCP (academic)</td>
<td>No Breach 1.1, 1.3, 9.4, 9.5</td>
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Seretide (873)

Subject Company: GlaxoSmithKline Australia (GSKA)

Complainant: AstraZeneca

Product: Seretide

Complaint
The complainant alleged that the Seretide detail aid contained several claims that are not consistent with the body of evidence and the key findings of the referenced study stand in direct contrast to the claims.

Issue 1: Excel Study – alleged manipulation of data by GSK

Claim 1
“However, there was a significant difference in the rate of moderate to severe exacerbations over time, in favour of Seretide, in the last two months (p=0.006)”

Claim 2
“New evidence: the benefits of Seretide’s long lasting control” and graph entitled “Number of Moderate to Severe Exacerbations”

Claim 3
“57% lower rate of moderate to severe exacerbations with Seretide”

Claim 4
“Seretide is “….significantly superior to [Symbicort] in reducing the rate of moderate/severe exacerbations with regular, stable dose treatment” “together with the “EXCEL Claims”

Sections of the Code
Material alleged to be in breach of the following Sections of the Code:
• 1.1 Nature and Availability of Claims
• 1.2.2 Level of Substantiating Data
• 1.3 False or Misleading Claims
• 1.7 Comparative Statements

Response
GSKA stated that the sales aid subject to complaint was not in breach of the Code as it has relied on the appropriate body of evidence and correctly presented the data contained in the relevant peer reviewed publications.

Code Committee determination
The Code Committee unanimously found breaches of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code in relation to all claims under both Issues 1 and 2 of the complaint.

Sanctions
• Take immediate action for the prompt withdrawal of the Detail Aid and permit that no further appearance of the item in its current form or in a manner that conveys the same or similar meaning.
• Corrective letter to all general practitioners and respiratory physicians who had been detailed with the item found in breach.
• Fine of $50,000

Consideration of the complaint
Issue 1: Excel Study – alleged manipulation of data by GSK

Claim 1
“However, there was a significant difference in the rate of moderate to severe exacerbations over time, in favour of Seretide, in the last two months (p=0.006)”

Claim 2
“New evidence: the benefits of Seretide’s long lasting control” and graph entitled “Number of Moderate to Severe Exacerbations”
Claim 3
“57% lower rate of moderate to severe exacerbations with Seretide”

Claim 4
“Seretide is “…significantly superior to [Symbicort] in reducing the rate of moderate/severe exacerbations with regular, stable dose treatment” “together with the “EXCEL Claims”

Members of the Committee were of the view that the graph adapted from the R. Dahl et al Study (the Excel study) depicting the number of moderate to severe exacerbations placed undue emphasis on this subgroup of the study without adequately explaining the primary endpoints which found that “the mean rate of all exacerbations over 24 weeks was similar in both treatment groups [salmeterol /fluticasone propionate combination (SFC) and formoterol/budesonide combination (FBC)]”. It was not sufficiently clear to a reader that the number of moderate to severe exacerbations related to 10% of subjects treated with Seretide and 11% of subjects treated with Symbicort who had moderate to severe exacerbations throughout the study period. The lower rate of moderate to severe exacerbations with Seretide was obtained from a post hoc subgroup analysis and was not a pre-determined study endpoint. The Committee noted that the summary of the study in the published reference described the further post hoc analyses that were conducted. The Committee noted that the primary endpoint was not stated in the tabulation describing the Excel study on the page opposite the graph; only in the text under the table.

The Committee considered the clinical relevance of the numerical imbalance between the treatment groups with respect to the number of moderate or severe exacerbations in the Excel study. Whilst the difference was just statistically significant in the final eight weeks of the study, the Committee questioned the clinical relevance. The Committee considered that the numerical difference observed in the study should have been regarded as hypothesis generating rather than a sound basis for making a major claim of superiority of Seretide over Symbicort. The Committee considered that the referenced data was inadequate as the basis for the claims.

The Committee also expressed concern at the conflation in the promotional material of the statistical data represented in Table 2 and Figure 3 in the Dahl et al paper, which gave the adjusted mean rate of exacerbations per year, with the representation of Figure 2 of the Dahl paper which was the cumulative number of exacerbations. The figure of 57% reduction in the rate of exacerbations was not derived from the cumulative number of moderate/severe exacerbations but rather from the adjusted mean rate per year for moderate/severe exacerbations.

Members also commented that as this material was being detailed to general practitioners the definitions of moderate and severe as used in the study should have been stated in the promotional material as the study definitions were not necessarily the same interpretations as Australian practitioners would use.

Members were of the view that by substituting the word ‘is’ into the claim in place of the study outcome statement which used ‘was’ makes a generalisation of the study data which is not appropriate. (Use of “Seretide is “…significantly superior…” instead of the stated conclusion “SFC was found…”)

The Committee concluded unanimously that the claims and associated graphical representation of data from the Excel study on pages 7 and 8 of the detail aid were unbalanced, misleading and made an unfair comparison with Symbicort. The data were inadequate, being a post-hoc secondary analysis of a sub-group of questionable clinical significance, on which to basis a major comparative claim. Lack of qualifiers makes this table and claim misleading and was in breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code.

Issue 2 Asthma control relating to inspiratory flow rate

Claim 1
“Accuhaler - for long lasting control in an award winning device”

Claim 2
Graph titled “Inspiratory flow rate” with the claim “Accuhaler is the only asthma dry powder inhaler to deliver consistent dosing even at low inspiratory flow rates” with transparent overlay information on Symbicort Turbuhaler.
Members of the Committee expressed concern that one reference was a 1998 abstract (in-house company information) that had never been published providing the Seretide Accuhaler data and this was used to make comparisons with data generated in 2004 for Symbicort. Whilst noting the qualifying statement that the graphs were adapted from two separate in vitro studies, members were of the view that the comparison on a single graph was inappropriate as the evidence for Seretide was of inadequate quality, being an abstract of an unpublished in-house study, on which to base a comparative claim. Also, the clinical relevance of the in vitro data has not been established. The claim for ‘long-lasting control’ was not relevant to the data presented in the graph, which only related to dose delivered at different inspiratory flow rates. Members concluded that the graph was misleading, unbalanced, and the substantiating data was selective and inadequate. It made an unfair comparison with Symbicort Turbuhaler.

Members also commented that because the Accuhaler device is ‘award winning’ as a technological achievement, this does not constitute an endorsement of the clinical outcome of its use with a medicine.

The Committee found a breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code in relation to Claims 1 and 2 under Issue 2.

Members were of the view that this was a moderate breach and whilst there was no potential for patient harm there was the potential for having an effect on how the medical profession will prescribe the product.

The Committee also commented that GSKA should take more care when preparing detail aids or leave behind materials for healthcare professionals. Poor quality information does not enhance the image of the industry and whilst there was no allegation of a breach of Section 10.8 members were concerned that the level of information and education in this item could reduce confidence in the industry.

**Sanctions**

Having found several breaches of the Code, the Committee considered an appropriate sanction.

The Committee determined that GSKA should:

- Take immediate action for the prompt withdrawal of the Detail Aid found in breach of the Code and advise medical representatives that no further appearance of any item in its current form or in a manner that conveys the same of similar meaning is permitted.
- Send a corrective letter to all general practitioners and respiratory physicians who had been detailed with the item found in breach. The letter should communicate to recipients that the promotional material for Seretide had been found in breach of the Code.
- On the basis of the primary endpoints in the Excel study no significant difference had been found between Symbicort Turbuhaler and Seretide Accuhaler.
- Claims for superiority of Seretide over Symbicort had been found in breach of the Code because they could not be adequately substantiated.
- The promotional material had included claims regarding dose delivery at different inspiratory flow rates that were based on selective data that could not be substantiated.
- Pay a fine of $50,000. In imposing this fine the Committee stated that it had taken into account the requirement for a corrective letter as well.
**Seretide (879)**

**Subject Company:** GlaxoSmithKline Australia (GSKA)

**Complainants:** Boehringer Ingelheim & Pfizer Australia (Pfizer)

**Product:** Seretide

**Complaint**
The complainants alleged that GSKA had not provided adequate references to substantiate the claim “Add Seretide COPD to slow disease progression” (COPD is chronic obstructive pulmonary disease) and that the claims in relation to the PBS listing for Seretide for COPD were misleading.

**Sections of the Code**
Materials alleged to be in breach of the following Section of the Code:
- 1.2.2 Level of Substantiating Data
- 1.3 False and Misleading Claims
- Preamble to Section 3, Promotional Material
- 3.1.1.3 Primary Advertisement

**Response**
GSKA stated that it had relied on an appropriate body of evidence and correctly represented the data from the relevant peer-reviewed publications. In relation to the PBS listing claim, GSKA stated that a reader would be sufficiently alerted to the restricted benefit listing for Seretide.

**Code of Conduct and Appeals Committee determinations**
*Add Seretide COPD to slow disease progression*
By a unanimous decision the Committee found no breach of Sections 1.2.2 or 1.3 of the Code (Decision confirmed by the Appeals Committee)

“We are now PBS listed for COPD” and “Seretide is now listed for COPD”
By a majority decision the Committee found a breach of Section 1.3 of the Code.

By a unanimous decision the Committee found no breach of the preamble to Section 3 of the Code. (No appeal)

**No PBS information on the advertisement flap**
By a unanimous decision the Committee found a breach of the preamble to Section 3 and Section 3.1.1.3 of the Code. (No appeal)

**Sanction**
- Withdraw material found in breach
- Pay a fine of $50,000

**Code of Conduct Committee**

**Consideration of the complaint**
The Committee considered the chronology of events and key issues in relation to this complaint:

*Jones & Agusti 2006*
- Questions the reliability of 1977 study on change in FEV1 (forced expiratory volume in one second) as the sole measure of COPD progression.
- Offers a list of several indices and recommends use of several measures of disease progression rather than one.

- Three year study in COPD of all cause mortality
- Included a number of measures including:
  - Quality of Life (QoL): St George's Respiratory Questionnaire (SGRQ)
  - Number of exacerbations
  - FEV1

*Letters to the Editor of the NEJM after the publication of TORCH, 24 May 2007*
- P J Barnes: rate of decline in FEV1 not significant
- P Calverley, the primary author of the TORCH study, responded: rate of decline in lung function could not be inferred from the spirometric data in the TORCH study.

*Data on rate of decline*
- Poster of the analysis of the TORCH data presented at European Respiratory Society (ERS).
- Further analysis of the TORCH data has been completed and presented at ERS, which showed that the rate of decline in FEV1 does change with the salmeterol/fluticasone propionate combination - this now supersedes the
previous statements on the rate of decline.

27 July 2007 advertisement subject to complaint published

3 August 2007 complaint from Boehringer Ingelheim & Pfizer sent to GSK

17 August 2007 GSK wrote to Boehringer Ingelheim/Pfizer with a proposal about including a combination of indices in the Seretide COPD advertisements
- improvements in QoL
- improvement in exacerbations
- improvements in “lung function over time”
- reduction in inflammation

27 August 2007 teleconference between Boehringer Ingelheim, Pfizer and GSK
- Agreement achieved on indices of disease progression
- Disagreed that there is sufficient evidence (rate of declines in FEV1)

17 September 2007 complaint submitted to MA

Indices of positive impact on COPD progression available for Seretide from TORCH study
- Exacerbations: statistically significant
- QoL: statistically significant
- FEV1: statistically significant at end of study (rate not included in first publication - subsequently shown to be statistically significant)
- Indices of inflammation (Barnes 2006)

Complaint 1: “Add Seretide COPD to slow disease progression”
Members were of the view that having reviewed the studies provided by the parties to the complaint, there is evidence to support the concept that more than one marker should be taken into account when considering the “rate of disease progression” in COPD. Members stated that collectively the references supported the claim.

While agreeing that the broad scope and measures of outcomes were valid in disease progression and QoL some members were of the view that there could be more qualification and explanation within the body of the advertisement and more comprehensive referencing. The Committee noted that the references to support the claim listed in the advertisement were the Seretide Product Information, the TORCH study (Calverley et al NEJM) and Barnes (2006). The further analysis of the TORCH data presented at the ERS was not included as a reference. However, the TORCH study did demonstrate statistical improvements in FEV1, exacerbation rates and QoL measures. In a unanimous decision the Committee found no breach of Sections 1.2.2 and 1.3 of the Code

“We are now PBS listed for COPD” and “Seretide is now listed for COPD”
Members were of the view that while the mandatory PBS box appeared on the second page of the advertisement, the statements “We are now PBS listed for COPD” and “Seretide is now listed for COPD” in large font on the front page gave the impression that Seretide was PBS listed for all COPD patients, without qualification. Members commented that while it may be reasonable to expect a reader to turn the page, is was misleading to not have qualified or referenced the very large and bold statements to ensure a reader would be directed to a statement on the same page which advised that the restricted PBS benefit was for a discrete subgroup of COPD patients.

In a majority decision the Committee found a breach of Section 1.3 of the Code and in a unanimous decision the Committee found no breach of the preamble to Section 3 of the Code.

No PBS information of the advertisement flap
Having reviewed the advertisement subject to complaint in the form it appeared (Australian Doctor 27 July - first page inserted after page 8 with flap after page 56) members determined that the item should be treated as two advertisements, the first comprising the two full-sized pages appearing after page 8 and the second comprising the ‘flap’ page appearing after page 56. The Committee noted that GSKA had not been able to provide any evidence that it had requested Australian Doctor to publish the advertisement as a centrefold. The Committee commented that a company should be able to provide evidence of instructions for publications, for example the date of publication and positioning in the publication.
The Committee considered that the information on the flap advertisement should have complied with all requirements for an advertisement, including the PBS information, as it was separate from the other advertisement which contained the mandatory PBS information.

In a unanimous decision the Committee found a breach of the preamble to Section 3 and Section 1.3 of the Code.

Sanction
Having found several breaches of the Code, the Committee considered an appropriate sanction. The Committee considered that this constituted a moderate breach of the Code. Whilst there was no suggestion of major patient safety issues, the use of a broad statement pertaining to PBS reimbursement for COPD without adequate qualification may influence prescribers in their choice of product for those patients whose COPD is less likely to benefit.

The Committee determined that GSKA should:
- Take immediate action to cease using the advertisements found in breach of the Code and not use them again in the same or similar form unless they fully comply with the Code.
- Pay a fine of $50,000

The Committee considered and determined that there was no requirement for corrective action.

Appeals Committee

Boehringer Ingelheim/Pfizer appeal
An appeal was lodged by the complainants Boehringer Ingelheim and Pfizer against the decision of the Code Committee to find no breach in relation to the claim “Add Seretide COPD to slow disease progression”. Boehringer Ingelheim and Pfizer stated that their complaint had sufficiently emphasized the importance and significance to the market of this claim and had inadequately described the appropriate context in which to assess the claim and this may have contributed to the Committee arriving at, what the companies believe is, an incorrect decision. Boehringer Ingelheim and Pfizer believe that to substantiate the claim ‘slows disease progression’ GSKA must provide evidence that Seretide slows deterioration in the lung function measure FEV1 (Forced Expiratory Volume in one second)

GSKA response to the appeal
GSKA stated that Boehringer Ingelheim/Pfizer had had ample opportunity to present the context and emphasis in their argument to GSKA in intercompany dialogue and the Code of Conduct Committee. GSKA also maintained that Boehringer Ingelheim/Pfizer had not provided any new information or demonstrated an error in the Code of Conduct Committee’s process to warrant this appeal. GSKA stated that the promotional material and claims were consistent with current local and international evidence-based COPD treatment guidelines.

Consideration of the appeal
The following summarises the Boehringer Ingelheim appeal as presented:
- Boehringer Ingelheim and Pfizer consider that the Code Committee erred in not adequately considering the magnitude of the claim “Add Seretide COPD to slow disease progression”, which is a significant and new claim with respect to COPD and is not supported by evidence or the Product Information (PI).
- COPD indication for Seretide is “For the symptomatic treatment of patients with severe COPD (FEV1<50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular beta 2 agonist bronchodilator therapy.”
- The claim is in breach of Section 1.2.2 because there is no unequivocal or highest level of evidence to support the claim and therefore the claim is also false and misleading and in breach of Section 1.3.
- The PI includes no indication for “slowing of disease progression”, the COPD indication is only for symptomatic treatment.
- The TORCH study is a very big and important long term COPD study
  - Primary outcome was difference in all cause mortality for the comparison between the combination regimen and placebo (which did not achieve conventional levels of statistical significance).
  - Secondary outcomes
    - frequency of COPD exacerbations
Health status according to St George’s Respiratory questionnaire

Other outcomes
- COPD related mortality
- ‘On treatment’ mortality
- Severe COPD exacerbations
- Clinic post-bronchodilator FEV1 (which is not equivalent to rate of decline in FEV1)
- TORCH does not address “disease progression” - focus was on mortality.
- Statistical analysis of TORCH does not support the claim that the treatment reduces mortality.

In relation to the other reference for the claim, Barnes et al (American Journal of Respiratory and Critical Care Medicine, 2006):
- It was “a proof-of-principle study to ascertain whether inhaled therapy can modify inflammation in COPD”.
- Methodology included bronchial biopsies and induced sputum from 140 subjects.
- Conclusion: The combination of salmeterol and fluticasone propionate has a broad spectrum of anti-inflammatory effects in both current and former smokers with COPD.
- It does not address COPD disease progression and does not support the claim.

In making the claim that Seretide slows disease progression, GSKA is in breach of:
- Code Section 1.2.2 Level of substantiating data as none of the references (the Seretide PI, Calverley 2007, Barnes 2006) address disease progression
- Code Section 1.3 False or misleading claims
  - Current Australian and global evidence-based COPD treatment guidelines - only smoking cessation has been shown to slow disease progression.
  - Under current regulatory guidelines, trials specifically designed to investigate rate of decline in FEV1 are needed to claim slowing of disease progression.

The following is a summary of the expert evidence presented:
- A graph was referenced from an article by Fletcher and Peto in the British Medical Journal, June 1977 describing the natural decline in lung function measured by FEV1.
- The ‘Holy Grail’ of COPD Research is to modify the rate of decline of lung function as measured by FEV1. Whilst there have been multiple randomised clinical trials attempting to prove an intervention changes the rate of decline, these have only been able to shift the curve to the right (indicating delayed onset of decline) but the rate of decline remains unaffected.
- The results of various trials were discussed:
  - Effects of Budesonide on mild COPD - rate of decline the same
  - ISOLDE Trial in more severe COPD - no difference in rate of decline
  - Pooled Analysis of seven studies on FEV1 rate of decline - no difference
- TORCH Study
  - There is no analysis in the published study of the rate of decline in FEV1.
  - The further data analysis of post-bronchodilator FEV1 showed the rate of decline was significantly different with Seretide but is only in abstract, has not received peer review or been published.
  - This result is at variance with other studies.
  - The methodology behind the further analysis was not described in the TORCH publication.
  - Quality control of spirometry such as calibration of instruments, performance of test, has not been described or published; this is particularly important because the study was of 6112 patients in 444 centres in 42 countries.
- Is the FEV1 the appropriate measure of disease progression?
  - Conventionally and universally accepted as the measure of progression.
  - Jones and Augusti (2006) suggest rate of decline of FEV1 or health status but the rate of decline in health status is known to be less with fluticasone since ISOLDE study (2000), yet there has been no change to the guidelines that
state that only smoking cessation is effective in changing the rate of decline in lung function.

- Patient centred outcomes (TDI, exercise capacity, health status) are accepted as measures of treatment effect but not of disease progression.

- The published TORCH study does not support a claim for the study medications to slow progression of COPD.

- There are a number of abstracts with data to demonstrate an effect of drugs on disease progression but these need to be peer reviewed before they can lead to the claim that the Holy Grail has been found.

The following summarises the GSKA response to the appeal:

- GSKA do not agree that an error in the Code Committee’s process or outcome has occurred.

- Boehringer Ingelheim/Pfizer has had ample opportunity to present their case in the original complaint.

- GSKA does not believe that the complainant placing “insufficient emphasis” on the claim and “inadequately describing the appropriate context” equates to altering medical validity of data presented.

- No new information has been provided by Boehringer Ingelheim /Pfizer.

- The Code Committee Members unanimously found the claim not in breach.

- There is evidence to support the concept that more than one marker should be taken into account when considering the “rate of disease progression” in COPD.

- Members of the Code of Conduct Committee stated that collectively the references supported the claim.

- Boehringer Ingelheim/Pfizer maintain that rate of decline in FEV1 is the only relevant measure of COPD disease progression.

- GSKA’s claim is consistent with local and international, evidence-based treatment guidelines
  - GOLD
  - COPD-X (Australasian)

- International guidelines recognise the need for multiple disease indices including:
  - Inflammation
  - Exacerbations
  - Quality of life

- Lung Function

- International GOLD guidelines support the use of multiple disease markers as indicators of disease progression:
  - “Patients with COPD are heterogeneous in terms of their clinical presentation, co-morbidities, underlying lung pathology, disease severity, and rate of disease progression. Thus it is highly unlikely that a single measure can accurately assess the severity of COPD, predict patient prognosis, and evaluate the effectiveness of therapy, thereby measuring all dimensions of the disease.”

  - “Since inflammation is a feature of COPD, it follows that anti-inflammatory therapies may have clinical benefit in controlling symptoms, preventing exacerbations, and slowing the progression of the disease” (GOLD Guidelines 2005).

- Jones and Agusti recognised the need for multiple markers of disease progression: “The concept of a single global marker has the attraction of simplicity and convenience but may not be appropriate to a complex, multi-component disorder such as COPD” (Jones & Agusti 2005).

- The 2007 GOLD Guidelines recognise several markers of disease progression ”...neither bronchodilator nor oral glucocorticosteroid reversibility testing predicts disease progression, whether judged by decline in FEV1, deterioration of health status, or frequency of exacerbations......”(GOLD Guidelines 2007).

- Boehringer Ingelheim/Pfizer had questioned the validity of the TORCH study as supporting evidence for changing the rate of decline in lung function and questioned the methodology for assessing FEV1 in TORCH.

- TORCH is the largest and most comprehensive study of COPD. It compared combination therapy and monotherapy with long acting beta agonist and inhaled corticosteroids versus placebo. TORCH showed statistically significant advantages for Seretide in health status, frequency of exacerbations, use of oral steroids, and - probably most importantly clinically - protection against a decline in lung function. Change in rate of decline in
FEV1 can be obtained from the TORCH data; the quality control on spirometry was adequate.

- The further analysis of TORCH for FEV1 rate of decline is being peer reviewed for publication.
- There is a body of evidence that supports having more than one marker of COPD disease progression.
- GSKA maintained their original position regarding this claim - that it is supported by the body of evidence including local and international guidelines.

Following questions in relation to the spirometry measurements in the TORCH study, it was stated that there were 26,000 spirometric observations available for the analysis. Spirometers were calibrated according to the manufacturers’ recommendations and a calibration log was kept. Lung function data were reviewed centrally during the study and queried if values differed significantly in consecutive visits. The standard deviation of the FEV1 measurements was comparable to that of previous studies where spirometry was performed using more vigorous quality control. With 26,000 observations any error would be balanced out.

A Member of the Appeals Committee questioned the Boehringer Ingelheim representatives concerning their interpretation of the primary outcome in the TORCH study (all-cause mortality), which very nearly reached statistical significance at a p-value of 0.052. The response was that TORCH probably did show a real change in mortality rate despite not achieving conventional levels of statistical significance, but that in his opinion this is not the same as disease progression.

An opinion was put forward that it is appropriate to measure treatment effects from a patient-centred perspective, recognising that these effects do not always correlate well with changes in FEV1. However, in his opinion the measure of disease progression in COPD is universally regarded to be measured by change in FEV1.

The Boehringer Ingelheim and GSKA representatives left the meeting following these presentations.

The Committee considered the primary audience for this item, which was published in Australian Doctor, how a general practitioner would view the claim “slows disease progression”, and how the interpretation of such a claim might impact prescribing of the product. Members considered that the academic or clinical researcher’s view of “slows disease progression” may differ from that of a general practitioner, and also from that of a specialist respiratory physician. Healthcare professional members of the Committee took the view that “slows disease progression” could mean, to the target audience, delaying the onset of worsening of a disease or death, rather than necessarily a slowing of the rate of decline of an organ’s function. Some members also commented that if an individual patient’s FEV1 measurement remained at the same level but the patient reported fewer exacerbations, an increase in normal activity levels and better ability to perform day to day tasks, improved sleep, or less breathlessness they would consider these effects to indicate ‘delayed’ or ‘slowed’ disease progression. Members considered that a GP would be unlikely to rely solely on FEV1 measurements as the indicator of COPD disease progression.

Members discussed the additional analysis of change in FEV1 from the TORCH data, which has not been published in a peer reviewed journal. It was noted that an abstract may not be used as the sole supporting evidence for a claim but can be used as a secondary reference to support other evidence. The abstract of the additional analysis of decline in FEV1 had not been referenced in the advertisement. Members expressed caution about reliance on the unpublished additional analysis to support the claim if FEV1 was the only measure of disease progression.

Members were of the view that, on balance, there is sufficient evidence taken in its entirety to support the notion that more than one marker could be taken into account when considering the “rate of disease progression” in COPD, not just change in FEV1. In considering the published TORCH study as an example, some members of the Appeals Committee expressed their concern in principle about companies making promotional claims based on analyses of secondary endpoints from a study for which the primary endpoint did not reach conventional levels.
of statistical significance. In this particular case, however, Members agreed with the Code of Conduct Committee that the claim in question was also supported by the broad balance of evidence, including the Barnes et al study, for which the primary endpoint was reduction in inflammation, the TORCH study secondary endpoints and the Seretide Product Information.

Members considered that the claim was not inconsistent with the Product Information, although Seretide is not specifically indicated for slowing COPD disease progression.

The Appeals Committee agreed with the decision and reasoning by the Code of Conduct Committee that collectively the cited references supported the claim:

"While agreeing that the broad scope and measures of outcomes were valid in disease progression and QoL some members were of the view that there could be more qualification and explanation within the body of the advertisement and more comprehensive referencing. The Committee noted that the references to support the claim listed in the advertisement were the Seretide Product Information, the TORCH study (Calverley et al NEJM) and Barnes (2006). The further analysis of the TORCH data presented at the ERS was not included as a reference. However, the TORCH study did demonstrate statistical improvements in FEV1, exacerbation rates and QoL measures. In a unanimous decision the Committee found no breach of Sections 1.2.2 and 1.3 of the Code."

The Committee also considered that many COPD Guidelines take a broader view of disease progression than only considering FEV1. Further, the claim would be read in the context of the statement above the claim - "reducing inflammation decreases exacerbations and helps to slow disease progression".

The Appeals Committee did not uphold the appeal and as such the claim "slows disease progression" was determined to be not in breach of Sections 1.2.2 and 1.3 of the Code.

The Appeals Committee strongly recommended that GSKA should immediately implement inclusion of the qualifying statement with the disease progression claim that was offered during intercompany dialogue and review the referencing used to support the claim, as recommended by the Code Committee.
Subject Company: GlaxoSmithKline Australia (GSKA)

Complainant: Medicines Australia Monitoring Committee

Event: Educational Event GSK-308

Code of Conduct Committee Meeting
21 April 2008

Complaint from the Monitoring Committee
The Monitoring Committee asked that GSKA provide justification for the overall extent of the hospitality provided at the educational event with respect to the duration of the educational component and the number of delegates for whom accommodation was provided.

Sections of the Code:
Conduct alleged to be in breach of the following Sections of the Code:
- 6.2.1 Hospitality
- 6.2.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

Response
GSKA denied any breach of the Code.

GSKA stated that the information originally provided to Medicines Australia was incorrect due to a communication error between GSKA and the event organising company. The figures provided to the Code Committee have been reconciled and reflect actual costs excluding GST.

The educational component was over six hours and included the opportunity to meet the international expert.

Code Committee determination
In a majority decision the Committee found no breach of Sections 6.2.1, 6.2.2, or 10.8 of the Code.

Consideration of the complaint
The Committee noted that while the program extended over two days some of the sessions were optional (including the Sunday morning one hour session). While finding no breach of the Code in relation to the accommodation and hospitality provided, members expressed concern that the actual educational component was bordering on being insufficient to justify provision of two nights accommodation for the majority of delegates.

Members were also concerned about the supplementary fee payable by partners who wished to attend the dinners did not fully cover the cost of the dinner on the first night. In reviewing the invitation and comparing this to GSKA’s statement of costs for the dinner, the Committee was of the view that the partner payment for the Friday night was less than that required to cover all costs. Section 10.2 of the Code states a company must not pay for or subsidise the costs attributable to partners or family members.

The Committee asked that GSKA respond to a possible breach of Section 10.2 of the Code in relation to the partner payment for the dinner on the first night of the educational event.

Code of Conduct Committee Meeting
16 June 2008

Further response from GSKA
GSKA responded that a potential breach of Section 10.2 may have occurred. If such a breach did occur, it was inadvertent and
GSKA apologised to the Committee. All meals were charged at $80 per head for partners; however as the beverages were on an ‘as-consumed’ basis this cost was not factored into the cost for partners. Only one registrant took their partner to the dinner concerned and there are no records to show whether this person consumed any beverages. GSKA are examining options to ensure such a discrepancy does not occur in the future.

Sections of the Code
- 10.2 Hospitality (partner payment)

Code Committee determination
In a unanimous decision the Committee found a breach of Section 10.2 of the Code.

Sanction
- Pay a fine of $20,000

Consideration of the complaint
The Committee noted the response from GSKA and that there did not appear to be a deliberate attempt to subsidise partner costs. Members also noted that GSK was reviewing its internal policies in relation to the way in which partner costs are charged.

While acknowledging that there was only one partner in attendance, members were of the view that as $80 per head had been the advertised cost in the program, the event could potentially have been attended by a much larger number of partners.

The Committee was of the view that the Code was quite clear that a company could not pay for, or subsidise the costs of a partner with respect to food and beverages, accommodation or travel. Members also referred to a previous educational event complaint heard at the 21 April Code meeting in which a company had been fined for subsidising partner costs.

In a unanimous decision the Committee found a breach of Section 10.2 of the Code.

Sanction
Having found a breach of the Code the Committee considered what sanction/s should be imposed.
Subject Company: GlaxoSmithKline Australia (GSKA)

Complainant: Medicines Australia Monitoring Committee

Event: Educational Event GSK-690

Complaint
The Monitoring Committee had asked that GSKA provide justification for the overall extent of the hospitality provided at the educational event with respect to the duration of the education provided and provide detail on the accommodation provided.

Sections of the Code
Conduct alleged to be in breach of the following Sections of the Code:
- 6.2.1 Hospitality
- 6.2.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

Response
GSKA denied any breach of the Code.

GSKA advised that the original costs reported to Medicines Australia were incorrect due to communication issues with the event organising company. The costs provided to the Code of Conduct Committee are reconciled actual costs excluding GST and staff costs.

The event was held nationally, rather than regionally to accommodate the engagement of high quality speakers. The program included lectures, expert panel Q & A and workshops facilitated by international and local experts in diabetes. Delegates who could not travel to the location by a morning flight were provided with two nights accommodation.

Code of Conduct Committee determination
In a majority decision the Committee found a breach of Section 6.2.1 of the Code. In a unanimous decision the Committee found no breach of Sections 6.2.2, 10.2 of the Code. In a majority decision no breach of Section 10.8 of the Code was found.

Sanction
- Pay a fine of $100,000

Consideration of the complaint
The Committee noted that while the event was held over two days, less than five hours of actual education was provided. The education started after lunch on Saturday and included only two hours of education on Sunday morning. Members were of the view that in order to justify providing extended hospitality over a weekend the educational component should be greater than five hours.

The Committee stated that the complaint was not in relation to the venue but the hours of education with respect to the hospitality (nights of accommodation and meals and beverages), that is the balance between education and hospitality. Members noted that one attendee from Queensland was provided with three nights accommodation.

The Committee agreed that where it is not possible for a delegate to fly to the venue on the day in time for the start of the meeting it was appropriate to provide accommodation the night prior to the event commencing. However, in this case the presentations did not start until after lunch on Saturday, therefore the Committee did not accept the necessity to provide...
accommodation for delegates on Friday night. The Committee considered that there was insufficient education to justify the hospitality provided and found a breach of Section 6.2.1 of the Code. The Committee also noted that the dinner was held at an entertainment venue.

In a majority decision the Committee found a breach of Section 6.2.1 of the Code. In a unanimous decision the Committee found no breach of Sections 6.2.2 and 10.2 of the Code. In a majority decision no breach of Section 10.8 of the Code was found.

**Sanctions**
Having found a breach of the Code the Committee considered what sanction/s should be imposed.

The Committee determined that GSKA should:
- Pay a fine of $100,000
GSK Educational Event (906)

<table>
<thead>
<tr>
<th>Description of function</th>
<th>Venue</th>
<th>Professional status of attendees</th>
<th>Hospitality provided</th>
<th>Total cost of hospitality</th>
<th>Number of attendees</th>
<th>Total cost of function</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD SPECIALIST Meeting 2 Day Diabetes Forum with Presentation by International Speaker. Educational Content 5.5 Hours</td>
<td>Four Points By Sheraton, Darling Harbour, NSW</td>
<td>Endocrinologists, Cardiologists, Epidemiologists</td>
<td>Accommodation, Flights, Transfers, Food and Beverages, Off Site Dinner, Dinner Transfers, Parking</td>
<td>79,949.00</td>
<td>91</td>
<td>$93,244 (Includes Venue Hire, Audio-Visual Hire And Materials Developed Specifically For This Meeting)</td>
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</tbody>
</table>

**Subject Company:** GlaxoSmithKline Australia (GSKA)

**Complainant:** Medicines Australia Monitoring Committee

**Event:** Educational Event GSK-691

**Complaint**
The Monitoring Committee had asked that GSKA provide justification for the overall extent of the hospitality provided at the educational event with respect to the duration of the education provided and the detail on the accommodation requirements.

**Sections of the Code**
Conduct alleged to be in breach of the following Sections of the Code:
- 6.2.1 Hospitality
- 6.2.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

**Response**
GSKA denied any breach of the Code.

GSKA advised that the original costs reported to Medicines Australia were incorrect due to communication issues with the event organising company. The costs provided to the Code of Conduct Committee are reconciled actual costs excluding GST and staff costs.

The event was held nationally, rather than regionally to accommodate the engagement of high quality speakers. The program included lectures, expert panel Q & A and workshops facilitated by international and local experts in diabetes. Delegates who could not travel to the location by a morning flight were provided with two nights accommodation.

**Code Committee determination**
In a majority decision the Committee found a breach of Section 6.2.1 of the Code. In a unanimous decision the Committee found no breach of Sections 6.2.2 and 10.2 of the Code. In a majority decision no breach of Section 10.8 of the Code was found.

**Sanction**
- Pay a fine of $90,000

**Consideration of the complaint**
The Committee noted that at this two day event 6.5 hours of actual education was provided. Members were of the view that while this event had a more substantial educational component than the ‘GP GOLD event’ (GSK-690 904) it was still borderline as a weekend event. For this event only one hour of education was provided on Sunday morning, which members considered was small justification for providing two nights accommodation.

The Committee accepted that where it is not possible for a delegate to fly into the venue on the day of the meeting it was appropriate to provide accommodation the night prior to the event commencing. However, in this instance the educational sessions did not commence until 11.00 am, which would allow most delegates to fly in that morning, other than those from Western Australia.

The Committee stated that the complaint was not in relation to the venue but the quality and duration of education provided with respect to the accommodation provided. The Committee considered that the program could have been structured in
a manner that would have necessitated providing only one nights accommodation and food and beverages.

The Committee considered that there was insufficient education at the meeting to justify the hospitality provided; that is there was an inappropriate imbalance between hospitality and the education and therefore found a breach of Section 6.2.1 of the Code.

In a majority decision the Committee found a breach of Section 6.2.1 of the Code. In a unanimous decision the Committee found no breach of Sections 6.2.2 and 10.2 of the Code. In a majority decision no breach of Section 10.8 of the Code was found.

**Sanctions**
Having found a breach of the Code the Committee considered what sanction/s should be imposed.

The Committee determined that GSKA should:
- Pay a fine of $90,000