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Allens Arthur Robinson <sup>+</sup>

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## Annexure 4



# MEDICINES *Australia*

BETTER HEALTH THROUGH RESEARCH AND INNOVATION



Code of Conduct | 2002  
Annual Report

Welcome to Medicines Australia's Code of Conduct Annual Report for the year ending 30 June 2002. This report provides information regarding the activities of the Code of Conduct and Monitoring Committees for the period 1 July 2001 to 30 June 2002. The material covered in this report provides a valuable insight into the operations of the Code of Conduct and the Committees that administer it.

Medicines Australia was formerly known as the Australian Pharmaceutical Manufacturers Association (APMA) until July, 2002.

## Commitment

Medicines Australia and its members are committed to promoting the concept of good health via the quality use of prescription medicines. As stated in the Code of Conduct, the industry recognises that medicines play a vital role in the prevention, amelioration and treatment of disease states and the industry undertakes:

- To provide medicines that conform to the highest standards of safety, efficacy and quality;
- To ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience; and
- To use professionalism in dealing with healthcare professionals, public health officials and the general public.

The industry is committed to the quality use of medicines and rational prescribing, and urges that its medicines are used only in accord with the directions and advice of healthcare professionals.

The industry is committed to maintaining the standards set out in the Code of Conduct when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation.

## Content

The Code of Conduct requires Medicines Australia to report on all complaints adjudicated by the Code of Conduct Committee and not subject to any outstanding appeals. This report therefore contains all final decisions of the Code of Conduct and Appeals Committees for the period 1 July 2001 to 30 June 2002.

At the end of this report, the text of the Sections of the Code of Conduct referred to in this report can be found.

This report has been prepared from the minutes of the meetings of the Code of Conduct Committee and the Code of Conduct Appeals Committee and reflects the process of those meetings. It should not be assumed that external audiences would enjoy the industry's familiarisation or understanding of these processes or the provisions of the Code of Conduct. It is therefore required that this Annual Report be kept confidential within the health care industry and not provided to any external audiences.

Any questions on the Code of Conduct or this report should be referred to the Secretary of the Code of Conduct Committee at Medicines Australia. Copies of the Code of Conduct can also be obtained by contacting Medicines Australia or by visiting the Medicines Australia's website ([www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au))

# Summary of Results

1 July 2001 - 30 June 2002

## Results

APMA received a total of 49 complaints for evaluation by the Code of Conduct Committee during the 12 months from 1 July 2001 to 30 June 2002. Two of these complaints were not finalised as at 30 June, 2002 due to appeals and have not been included in this report. Two complaints that were held over from the previous year and finalised in the 2001-2002 year are included in this report.

The following tables are a summary of the complaints received by the APMA during this period.

## Source of Complaints

<b>Complaints received from</b>	<b>Number</b>
APMA Member Company	33
Non-Member Company	1
Therapeutic Goods Administration	1
Health Care Professionals	11
External Organisations	3
<b>Total of new complaints in 2001/2002</b>	<b>49</b>

## Results from the Consideration of Complaints


	<b>Number</b>
Complaints held over from 2000/2001	2
Partial Breach	1
Resolved following dialogue between two companies	1
Complaints received in 2001/2002	49
Breach	14
Partial Breach	14
No Breach	9
Complaints Withdrawn	9
Complaint not considered given to similarity to a previous complaint	1
Complaints held over until next reporting period	2

## Length of Time to Resolve Complaints

	<b>Days</b>
Shortest	21
Longest	172
Average	61
Average for complaints without an appeal	39
Average for complaints involving an appeal	112

## Performance Indicators

The Code of Conduct requires the disclosure of performance indicators regarding the time to consider complaints and the activities undertaken to increase health care professional's awareness of the Code of Conduct.



For complaints that did not go to appeal, the average number of days taken to finalise these complaints was 39 days. Due to the large number of complaints (increased from 27 complaints in 2000/2001 to 37 in 2001/2002) and appeals (increased from 4 appeals in 2000/2001 to 11 appeals in 2001/2002) considered by the Code of Conduct Committee and the sourcing of external experts for the Code of Conduct Appeals Committee meetings and the seeking of clarification from an external complainant to ensure their complaint could be considered by the Code of Conduct Committee the days taken to finalise complaints has increased from the previous year.

## Activities undertaken to increase awareness of the Code of Conduct

Throughout the year, APMA provided presentations, along with Code of Conduct information kits, to member and non-member companies and external stakeholders including a number of marketing and communications companies totalling over 150 participants.

## APMA Code of Conduct Committee

The Code of Conduct Committee met 11 times during this reporting period. The following table indicates the attendance of the external members of the Committee. As of September 2001, Edition 13 of the Code of Conduct requires the participation of an Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) member at each Committee meeting and the possibility of up to two APMA member company representatives to act as observers to enhance transparency and understanding of the Code process.

### External Organisation

#### Number of Meetings Attended

Therapeutic Goods Administration	10
Consumers' Health Forum	9
Patient Support Group	11
ASCEPT	11
Royal Australian College of General Practitioners	9
Australian Medical Association	6

## Acknowledgments

The success of both the Code of Conduct and Code of Conduct Appeals Committees can be attributed to the participation and diligence of their Chairmen and members. APMA would like to thank these individuals for their continued commitment and diligence to the APMA Code of Conduct. In particular the contribution of Mr Gaire Blunt, Mr Ian Tonking and Mr Oscar Shub in their roles as chairman of the Code of Conduct and Code of Conduct Appeals Committees is acknowledged.

APMA would also like to acknowledge the invaluable support and expertise provided by Ms Fiona Woodard.

# Committee Membership

The following is the composition of the Code of Conduct and Appeals Committees:

## Code of Conduct Committee

### Full Members

- Independent lawyer (Chair)
- Representative of the Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Representative of the Royal Australian College of General Practitioners (RACGP)
- Representative of a Patient Support Group
- Representative of the Australian Medical Association (AMA)
- Representative of a Consumers Organisation
- Up to three APMA Association Representatives
- Up to two Medical/Scientific Directors from APMA Member Companies

### Observers

- Representative of the Therapeutic Goods Administration (TGA)
- Member of APMA's Marketing Committee
- APMA Member Company observers

### Advisors

- Chief Executive Officer, APMA
- Manager, Scientific and Technical Affairs, APMA
- Code of Conduct Secretary, APMA

## Code of Conduct Appeals Committee

### Full Members

- Independent lawyer (Chair)
- Representative of the Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- One representative from the target audience to which the promotional activity has been directed eg RACGP or AMA
- One representative from the Colleges and/or Societies from the therapeutic class of the product
- Two APMA Association Representatives
- One Medical/Scientific Director from APMA Member Companies

### Advisors

- Chief Executive Officer, APMA
- Code of Conduct Secretary, APMA

## 1. Pfizer Pty Ltd Viagra (618)

**Newspaper articles entitled:**  
"Funding drives the big chase"  
"Firms defend a seat at the table"

### Complaint

A complaint was received from a medical practitioner alleging that two articles included in a special newspaper report sponsored by Pfizer Pty Ltd were in breach of the Code of Conduct. The complaint alleged that statements in the article "Funding drives the big chase" in relation to Viagra promoted an unapproved indication to the general public and were in breach of Section 1.3.1 of the Code. It was also alleged that statements on Viagra were in breach of Section 1.1 of the Code, as they were unbalanced. The complaint stated that Pfizer Pty Ltd had initiated the article with the aim of promoting Viagra to the general public and was thus in breach of Section 9.3 of the Code. It was also alleged that the article "Firms defend a seat at the table" was in breach of Section 1.1 of the Code as it was considered misleading and unbalanced by omission.

### Response

A response was received from Pfizer Pty Ltd in which any breaches of the Code of Conduct were denied. Pfizer Pty Ltd advised that the article had been written by the newspaper and that Pfizer Pty Ltd had been given limited opportunity to review the text of the article.

### Committee ruling

The Code of Conduct Committee found that statements regarding Viagra in the article "Funding drives the big chase" were in breach of Section 1.3.1 of the Code as they were promoting an unapproved indication. The Committee found no breach of Section 1.1 of the Code in relation to unbalanced statements.

The Committee ruled a minor breach of Section 9.3 of the Code in relation to promoting to the general public, as Pfizer Pty Ltd had initiated the special newspaper feature by the placement of a half-page advertisement and had some editorial input into the content of the articles.

### Sanction

The Committee resolved that Pfizer Pty Ltd should ensure that any future general media articles initiated by the company should not include any inference of

promotion of an unapproved indication and that Pfizer Pty Ltd should ensure that the activity found in breach should not occur again.

### Appeal

Pfizer Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Pfizer Pty Ltd argued that it was not their intention to promote Viagra or an unapproved indication. Pfizer Pty Ltd maintained that they were not responsible for the editorial content of the articles. Apart from minor factual or typographic errors, Pfizer Pty Ltd advised that it had not been permitted to substantially change any text prior to the publication of the articles.

### Committee Ruling

The Code of Conduct Appeals Committee resolved that the decision of the Code of Conduct Committee to find a breach of Section 1.3.1 should be overturned as the statement in question was not made by the company or the company's representative and that it was not promotional. In relation to Section 9.3, in consideration of the new material presented in the Pfizer Pty Ltd appeal, the Committee resolved that the decision on the breach of Section 9.3 of the Code should be overturned.

### Sanction

The Committee resolved that as the appeal had been upheld the sanction imposed by the Code of Conduct Committee should be removed.

## 2. Lundbeck Australia Pty Ltd Cipramil (620)

**Promotional material entitled:**  
"The most selective SSRI"

### Complaint

A complaint was received from GlaxoSmithKline Australia alleging that a promotional item for Cipramil by Lundbeck Australia Pty Ltd was in breach of Sections 1.3.1 of the Code. GlaxoSmithKline Australia alleged that the claim "The most selective SSRI" was based on unreferenced in vitro animal data and, when used in the context of this promotional piece, created the impression that the selectivity of Cipramil correlated with superior efficacy and/or tolerability when compared with other SSRIs.



### **Response**

A response was received from Lundbeck Australia Pty Ltd in which any breach of the Code of Conduct was denied. Lundbeck Australia Pty Ltd maintained that the intention of the promotional piece was to discuss individual patient responses that may differ between SSRIs, and that secondary binding characteristics may provide the rationale for those observed differences in individual patient.

### **Committee ruling**

The Committee resolved that the statement "most selective Serotonin Reuptake Inhibitor (SSRI)" used in the context of this promotional item was potentially misleading and therefore in breach of Section 1.3 of the Code of Conduct. The Committee also resolved that as the statement inferred clinical superiority over other SSRIs that could not be substantiated, it was in breach of Section 1.7 of the Code. The Committee also resolved that the statement "Purest SSRI" was potentially misleading and was in breach of Section 1.3. It was also considered a hanging comparative and therefore in breach of Section 1.7 of the Code.

The Committee concluded that the presentation of a table of reports of suspected adverse drug reactions in the promotional item, with the heading "Cipramil ... see the difference", was unbalanced and potentially misleading. The Committee resolved that the use of the table in this context was in breach of Sections 1.3 and 1.7 of the Code of Conduct.

### **Sanction**

It was noted that Lundbeck Australia Pty Ltd had already withdrawn the promotional item. The Committee resolved that Lundbeck Australia Pty Ltd should permit no further appearance of the material found in breach in its present form. The statements and diagrams found in breach of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.

In addition, the Committee resolved that Lundbeck Australia Pty Ltd should send a corrective letter to all doctors who had received or viewed the promotional material stating that it had been found in breach of the Code of Conduct, providing an explanation of why the material had been found in breach and correcting any misleading messages that may have been conveyed.

### **Appeal**

Lundbeck Australia Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Lundbeck Australia Pty Ltd maintained that it had not been its intention to mislead physicians by implying superiority of Cipramil over other SSRIs.

### **Committee ruling**

The Code of Conduct Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Committee resolved to uphold the decision of the Code of Conduct Committee relating to the claims as no evidence had been provided to justify overturning its decision.

### **Sanction**

Having found breaches of the Code of Conduct, the Committee considered the sanction determined by the Code of Conduct Committee. The Code of Conduct Appeal Committee resolved that the sanction imposed by the Code of Conduct Committee should remain.

## **3. Aventis Pharma Specialist Symposium (622)**

### **Invitation to a Specialist Symposium**

#### **Complaint**

A complaint was received from a medical practitioner alleging that an invitation to a Specialist Symposium to be held by Aventis Pharma was in breach of the Code of Conduct. It was alleged that the invitation to the Symposium gave the impression that the educational content of the meeting was secondary to the entertainment, as no information was provided on the content of the scientific sessions. Aventis Pharma was invited to respond to Sections 7 and 10 of the Code of Conduct.

#### **Response**

A response was received from Aventis Pharma in which any breach of the Code of Conduct was denied. Aventis Pharma advised the Code of Conduct Committee that the Symposium had been cancelled, however they did not agree that if the event had gone

ahead it would have been in breach of the Code of Conduct.

#### **Committee ruling**

The Committee ruled that the invitation to the Specialist Symposium was in breach of Section 10 of the Code of Conduct, as it could not successfully withstand public or professional scrutiny. The Committee also expressed concern that the hospitality offered at the Symposium was not in proportion to the educational content of the Symposium.

#### **Sanction**

The Committee resolved that Aventis Pharma should take immediate action for the prompt withdrawal of the Symposium invitation found in breach of the Code and should permit no further appearance of it in its present form. The Committee considered that a fine of \$10,000 should be imposed on Aventis Pharma for the breach found.

#### **Appeal**

Aventis Pharma lodged an appeal against the findings of the Code of Conduct Committee in relation to the breach of Section 10 of the Code. Aventis Pharma maintained that the brochure in question did not contain any detailed educational content as it was a preliminary program, and they had considered it inappropriate to specify speakers and topics before the program had been finalised. Aventis Pharma considered the proposed program had been well constructed and entirely appropriate.

#### **Committee ruling**

The Code of Conduct Appeals Committee found that based exclusively on the first invitation to the Specialist Symposium and how the content of the Symposium was portrayed to doctors, it agreed with the Code of Conduct Committee's decision. The invitation to the weekend Symposium, which included reference to specific entertainment events but little information about the educational content, could not withstand public and professional scrutiny.

#### **Sanction**

The Appeals Committee resolved that the sanction determined by the Code of Conduct Committee was appropriate and did not require amendment.

## 4. CSL Ltd Vaqta (623)

#### **Promotional advertisement entitled:**

"The hepatitis vaccine with the speed and power to deliver clinically proven 100% early protection"

#### **Complaint**

A complaint was received from GlaxoSmithKline Australia alleging that an advertisement for Vaqta by CSL Ltd was in breach of Sections 1.2, 1.3, 1.5 and 1.7 of the Code of Conduct. The complainant alleged that statements made by CSL Ltd in the advertisement were potentially misleading and unsubstantiated.

#### **Response**

A response was received from CSL Ltd in which any breach was denied. CSL Ltd maintained the view that the complaint was unjustified and that the claims made in the advertisement were appropriate and could be substantiated.

#### **Committee ruling**


The Committee resolved that the claims "100% protection" and "early protection" were potentially misleading and therefore in breach of Section 1.3 of the Code of Conduct.

The Committee resolved that the use of "the" in the context of "the hepatitis vaccine" was neither an unqualified superlative nor disparaging of other products. No breaches of Sections 1.5 or 1.7 were found.

The Committee resolved that the claim "vaccine with the speed" had not been adequately substantiated and was therefore in breach of Section 1.2 of the Code of Conduct.

#### **Sanction**

The Committee resolved that CSL Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach of the Code and should permit no further appearance of it in its present form. The claims found in breach should not be used again in their present form or in a manner that conveyed the same or similar meaning.



The Committee unanimously resolved that CSL Ltd should undertake corrective advertising to address the potentially misleading information conveyed by the Vaqta advertisement.

A majority of members of the Committee considered the breaches of the Code moderate breaches as the claims for "100% protection" and "early protection" may have an effect on how the medical profession might prescribe the product. The Committee also resolved to impose a fine of \$20,000.

## 5. Merck Sharp & Dohme (Australia) Pty Ltd Propecia (626)

### **Website entitled:**

"www.seeyourdoctor.com.au"

### **Complaint**

A complaint was received from a medical practitioner alleging that a website [www.seeyourdoctor.com.au](http://www.seeyourdoctor.com.au) made available by Merck Sharp & Dohme (Australia) Pty Ltd was in breach of the Code of Conduct. The complaint alleged that the inclusion of a list of doctors names on the website was in breach of Section 1.9 of the Code of Conduct, as the website promoted the services of selected doctors. The complaint also stated that the website made no mention that hair loss was a normal variation for which drug treatment was not appropriate.

### **Response**

A response was received from Merck Sharp & Dohme (Australia) Pty Ltd in which any breach was denied. Merck Sharp & Dohme (Australia) Pty Ltd maintained that the website did not promote its product Propecia, but provided information about male pattern hair loss, its causes and treatments and encouraged men who wanted more information to see a doctor.

### **Committee ruling**

The Code of Conduct Committee resolved that no breaches of the Code of Conduct should be found. The Committee recommended that Merck Sharp & Dohme (Australia) Pty Ltd should consider revising its website so that the basis for the selection of doctors who were up to date on hair loss treatments was evident and that it did not imply that doctors not listed as members of the Hair Loss Interest Group

were less interested or able to treat men with concerns about hair loss.

The Committee ruled that the treatment for hair loss was not inappropriate, and agreed that hair loss was of sufficient concern to some men that they would seek treatment. It was also noted that the website discussed a number of alternative methods of treatment, including cosmetic and surgical treatments and use of wigs.

The Committee considered that the information on the website was informative, educational and encouraged men to seek treatment for hair loss and that this information did not fall within the definition of promotion under the Code of Conduct, as it did not promote a particular product for the treatment of hair loss.

## 6. Wyeth Australia Pty Ltd Educational Meeting (629)

### **Educational Meetings entitled:**

"Generalised Anxiety Disorder Workshop" held at the ANA Hotel  
"Gastroenterology update" at Forty One restaurant

### **Complaint**

A complaint was received from the Australian Consumers Association (ACA) alleging that hospitality offered to doctors by Wyeth Australia Pty Ltd was in breach of the Code of Conduct. The ACA identified a videotape of the Channel 9 Sunday Program as the basis of their complaint. Two meetings sponsored by Wyeth Australia Pty Ltd had been identified in the Sunday Program - one at the ANA Hotel and one at "Forty One" restaurant. The complaint alleged that Wyeth Australia Pty Ltd was in breach of Section 7.3 of the Code. In addition Wyeth Australia Pty Ltd was invited to respond to Sections 7.4, 10 and 10.1 of the Code.

### **Response**

A response was received from Wyeth Australia Pty Ltd in which any breach was denied. Wyeth Australia Pty Ltd maintained that the focus of the meeting was on the education of general practitioners in the diagnosis and management of Generalised Anxiety Disorder. The function was accredited by the RACGP and the facilitator was a recognised expert in the non-

drug treatment of anxiety disorders. There was no entertainment at the event, and the only hospitality was a hotel meal.

#### **Committee ruling**

The Code of Conduct Committee reviewed the program for the Generalised Anxiety Disorder (GAD) Workshop, noting that the workshop had been allocated a total of 4 CME points by the RACGP. Members advised that the allocation of 2 CME points per hour was higher than average and that this reflected the educational content of the workshop. Members also noted that the hospitality offered to workshop participants was a meal of 45 minutes duration.

The Committee considered that the hospitality provided at the GAD workshop was not the core focus of the meeting, but was secondary to the educational content and could withstand public and professional scrutiny. The hospitality was not considered excessive or lavish but consistent with what a doctor might pay for himself or herself. The Committee determined that there was no breach of Section 10 or of the spirit of Section 7.3 of the Code of Conduct.

The Committee noted that no CME points had been allocated to the "Forty One" restaurant meeting, whereas 4 CME points had been allocated to the workshop at the ANA Hotel. Although no CME points had been allocated, some members considered that the educational component provided at the "Forty One" restaurant was appropriate.

The Committee determined by a majority decision that the meeting at Forty One restaurant was in breach of Section 10 of the Code of Conduct as the hospitality provided would not be able to withstand public and professional scrutiny and because the educational component could be perceived to be secondary to the hospitality provided. The Committee considered that on the evidence provided to it, it was able to differentiate between the GAD Workshop at the ANA Hotel and the meeting at Forty One restaurant in terms of compliance with the Code of Conduct.

#### **Sanction**

The Code of Conduct Committee determined that Wyeth Australia Pty Ltd should take immediate action to ensure that the activity found in breach should not occur again in the same or similar form.

## 7. Pfizer Pty Ltd Medical Representative Behaviour (630)

#### **Complaint**

A complaint was received from a healthcare professional alleging that conduct by a medical representative employed by Pfizer Pty Ltd was in breach of the Code of Conduct. The complaint alleged that the medical representative's manner was unprofessional, overly familiar and overtly intrusive. Pfizer Pty Ltd was asked to repond in terms of possible breaches of Sections 1.3, 1.7, 4.1, 4.3, 4.4 and 4.6 of the Code.

#### **Response**

A response was received from Pfizer Pty Ltd in which any breach was denied. Pfizer Pty Ltd maintained that although the medical representative may have been persistent, his manner was professional, not overly familiar or overtly intrusive. Pfizer Pty Ltd advised that both written and verbal apologies had been made to the healthcare professional for any inconvenience caused.

#### **Committee ruling**

The Committee ruled that as Pfizer Pty Ltd had provided an explanation of the representative's behaviour, had written an apology to the healthcare professional and had undertaken to ensure that the representative would make no further contact with the healthcare professional, that adequate resolution of the situation had occurred. No breach of the Code of Conduct was found.

## 8. GlaxoSmithKline Australia Seretide (632)

#### **Promotional material entitled:**

"Switch from Budesonide Turbuhaler to Seretide Accuhaler"

"Switch to Seretide for asthma control at 1/3 of the steroid dose"

#### **Complaint**

A complaint was received from AstraZeneca Pty Ltd alleging that two items of promotional material for Seretide by GlaxoSmithKline Australia were in breach of the Code of Conduct. The complaint alleged that

statements made by GlaxoSmithKline Australia were potentially misleading and in breach of Section 1.3 of the Code.

#### **Response**

A response was received from GlaxoSmithKline Australia in which any breach was denied. GlaxoSmithKline Australia maintained that the promotional material was a switching guide not a comparative claim and that the claims were referenced with supporting materials.

#### **Committee ruling**

The Committee found that the promotional item did not contain misleading information, but was offering a guide on how to switch from a corticosteroid to combination therapy and that there was no breach of Section 1.3 of the Code. In addition the guide was consistent with the Approved Product Information for Seretide.

The Committee considered that the statement "Switch to Seretide for asthma control at 1/3 the steroid dose" was potentially misleading as it was unclear how this statement would be interpreted. The Committee unanimously resolved that a breach of Section 1.3 should be found as it confused two concepts (dose by weight in micrograms and equivalent steroid dose) and was therefore misleading.

The Committee found that the statement "The Accuhaler provides more consistent drug delivery across a wide range of inspiratory flow rates than the Turbuhaler" was not misleading as there was sufficient evidence to support the claim. No breach of Section 1.3 was found.

#### **Sanction**

The Code of Conduct the Committee resolved that GlaxoSmithKline Australia should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. Further, the claims or statements found in breach should not be used again in their present form or in a manner that conveyed the same or similar meaning.

The Committee resolved that GlaxoSmithKline Australia should send a corrective letter to all general practitioners and specialists who received the promotional item found in breach. If GlaxoSmithKline Australia was unable to identify who had received

the promotional item, it should send the corrective letter to all general practitioners and specialists.

#### **Appeal**

GlaxoSmithKline Australia lodged an appeal against the findings of the Code of Conduct Committee. GlaxoSmithKline Australia alleged that the Code of Conduct Committee had erred in their interpretation within the context of misleading having regard to the audience to whom the promotional material was directed and that insufficient evidence was provided by the Committee on how the statement in question would be interpreted. GlaxoSmithKline Australia also contended that all statements were based on accurate and balanced information.

#### **Committee ruling**

The Code of Conduct Appeal Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Committee resolved to uphold the decision of the Code of Conduct Committee relating to the claims as no evidence had been provided to it to justify overturning these decisions.

#### **Sanction**

The Code of Conduct Appeal Committee resolved that the sanction imposed by the Code of Conduct Committee was appropriate and should remain.

## **9. GlaxoSmithKline Australia Lamictal (633)**

#### **Promotional mailer entitled:**

"A Valentines Wish"

#### **Promotional material entitled:**

"Helping Women keep their balance"

#### **Complaint**

A complaint was received from Sanofi Synthelabo Australia Pty Ltd alleging that two items of promotional material for Lamictal by GlaxoSmithKline Australia were in breach of Sections 1.3.1, 1.3, 1.4, 1.7, 1.10 and 9.4 of the Code of Conduct. The complaint alleged that statements made by GlaxoSmithKline Australia were potentially misleading, unsubstantiated, promoting an unapproved

indication, were disparaging, could not be identified as promotional material and were promoting a prescription product to the general public.

#### **Response**

A response was received from GlaxoSmithKline Australia in which any breach was denied. GlaxoSmithKline Australia maintained that the mailer was an attempt to highlight to medical practitioners the issues women had felt important in the management of their epilepsy. GlaxoSmithKline Australia indicated that the Time magazine, which contained the promotional material, was mailed to a select list of neurologists and that it was clearly indicated that the cover of the material should be removed prior to placement of the magazine in the patient waiting room.

#### **Committee ruling**

The Committee unanimously agreed that the Valentine's Day mailer was not in poor taste and was unlikely to cause offence to professional recipients. No breach of Section 1.4 was found.

The Committee considered that the statements in the other mailer, and particularly the statement "I wish I could control my epilepsy without all this", implied that medicines other than Lamictal caused the side effects mentioned. The Committee considered that the cited reference was inadequate to support the claims or to allow readers to make a judgement as to whether Lamictal had less effect on weight gain, menstrual irregularities, contraceptive effectiveness and hair loss.

The Committee concluded that the promotional mailer was in breach of Section 1.3 of the Code of Conduct as it was potentially misleading and Section 1.7 as it made comparative claims that had not been adequately substantiated.

The Committee did not agree that the promotional item made claims for unapproved indications or implied that Lamictal could treat obesity, regulate menstrual cycles, provide contraception or improve hair quality. No breach of Section 1.3.1 was found in relation to these aspects of the complaint.

Several members of the Committee considered that by placing the warning to remove the cover within the publication this was inadequate to prevent the possible promotion of a prescription product to the general public. Further, these members of the

Committee considered that GlaxoSmithKline Australia should have predicted that there would be a risk that the cover would not be removed and therefore should have undertaken measures to ensure that the cover would not be available to members of the general public.

By a majority decision the Committee determined that no breach of Section 9.4 should be found as a warning had been printed that this information should not be provided to members of the general public. However, it was unanimously agreed that the concerns of the minority regarding the inadequacy of the warning be provided to GlaxoSmithKline for its consideration.

By a majority, the Committee found that in relation to the inclusion of the word "ADVERTISEMENT" on the Time magazine cover and the advice to remove the cover, this adequately distinguished the item as promotional material, and ruled that there was no breach of Section 1.10 of the Code.

#### **Sanction**

The Committee resolved that GlaxoSmithKline Australia should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. Further, the claims or statements found in breach should not be used again in their present form or in a manner that conveyed the same or similar meaning.


The Committee further resolved that GlaxoSmithKline Australia should send a corrective letter to all general practitioners and specialist neurologists who received the mailer found in breach to correct the misleading claims made.

## **10. Baxter Healthcare Pty Ltd Suprane (634)**

**Promotional advertisements entitled:**  
"Imagine the Possibilities"

#### **Complaint**

A complaint was received from Abbott Australasia Pty Ltd alleging that an advertisement for Suprane by Baxter Healthcare Pty Ltd was in breach of the Code of Conduct. The complaint raised three issues in relation to the Suprane advertisement: whether the unqualified use of the word "superior" was in breach



of Sections 1.3 and 1.7, whether the advertisement was in breach of the requirements for advertising a new chemical entity and whether the advertisement was in breach of Section 3.1.1.3 that related to journal advertising.

#### **Response**

As a non-member of the APMA, Baxter Healthcare Pty Ltd agreed to have this complaint considered by the Code of Conduct Committee. Baxter Healthcare Pty Ltd advised that they had already agreed to send a new advertisement to all anaesthetists who had received the original registration booklet for the Australian Society of Anaesthetists (ASA) National Scientific Congress along with a letter advising that this new advertisement should replace the original. Baxter Healthcare Pty Ltd had also undertaken not to supply Suprane until after the Australian Society of Anaesthetists National Scientific Congress to ensure that the information in the original advertisement had been replaced and would not have any influence on prescribing practices.

#### **Committee ruling**

The Code of Conduct Committee considered that the use of the term "superior" in the statement "a superior volatile anaesthetic agent" was a hanging comparative and therefore in breach of Section 1.7 of the Code. The Committee also considered that the statement implied general superiority of Suprane over other anaesthetic agents, which was unable to be adequately substantiated. The statement was therefore considered to be misleading and in breach of Section 1.3 of the Code of Conduct.

In relation to the requirements of the Code of Conduct for advertising new chemical entities, the Committee noted that Baxter Healthcare Pty Ltd was apparently not aware of the requirements of the Code for use of the full Product Information for the promotion of all new chemical entities for 24 months from the date of first advertising of the product. The Committee determined that the Suprane advertisement was in breach of Section 3.3.1.3.

#### **Sanction**

The Committee noted that Baxter Healthcare Pty Ltd had acknowledged that the Suprane advertisement did not comply with all requirements of the Code of Conduct and had sent a replacement advertisement to all anaesthetists who had received the original advertisement in the conference programme booklet and to all registrants at the Australian Society of

Anaesthetists conference.

The Code of Conduct Committee determined that Baxter Healthcare Pty Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. Further, the statement found in breach should not be used again in its present form or in a manner that conveyed the same or similar meaning.

The Committee further determined that Baxter Healthcare Pty Ltd should be required to send a corrective letter to all anaesthetists who had received the original advertisement and all registrants at the ASA National Scientific Congress.

## 11. Pfizer Pty Ltd Zeldox (635) (638)

### **Promotion at Trade Display**

#### **Complaint**

A complaint was received from Eli Lilly Australia Pty Ltd as well as a similar complaint from AstraZeneca Pty Ltd alleging that the promotion of Zeldox to medical professionals at the 3rd Australian Early Psychosis Conference was in breach of Sections 1.3.1, 2.1.1, 6 and 6.4 of the Code of Conduct. It was alleged that Pfizer Pty Ltd was promoting an unapproved product and did not have an Approved Product Information available at the trade display stand.

#### **Response**

A response was received from Pfizer Pty Ltd in which any breach was denied. Pfizer Pty Ltd maintained that the promotional activities complied with the Code as it was an Australasian Congress and there was a notice advising participants that the product was not currently registered in Australia.

#### **Committee ruling**

The Committee did not accept Pfizer Pty Ltd's explanation that the 3rd Australian Early Psychosis Conference could be classified as an Australasian Congress.

The Committee also noted that final Australian registration of Zeldox had not been achieved at the time of the meeting and did not accept Pfizer Pty

Ltd's argument that a positive ADEC recommendation and near resolution of outstanding Product Information issues was sufficient to meet the requirement of the product being registered in Australia.

The Code of Conduct Committee unanimously determined that the promotion of Zeldox at the 3rd National Early Psychosis Conference was in breach of Section 1.3.1 as Zeldox was not approved for registration in Australia at the time of the conference. Breaches of Sections 2.1.1 and 6.4 were also found as an unapproved product had been promoted at a trade display at an Australian conference.

#### **Sanction**

The Code of Conduct Committee determined that Pfizer Pty Ltd should take immediate action to ensure that the promotional activity found in breach should not occur again.

In addition the Committee determined that a fine of \$15,000 should be imposed.

## 12. Pfizer Pty Ltd Educational Meeting (636)

#### **Education Meeting entitled: "Experts on Vessels"**

#### **Complaint**

A complaint was received from the Australian Consumers Association (ACA) alleging that hospitality offered to doctors by Pfizer Pty Ltd was in breach of the Code of Conduct. The ACA identified a videotape of the Channel 9 Sunday Program as the basis of their complaint. A meeting "Experts on Vessels" sponsored by Pfizer Pty Ltd had been identified in the Sunday Program. The complaint alleged that Pfizer Pty Ltd was in breach of Section 7.3 of the Code. Pfizer Pty Ltd was also invited to respond to Sections 7.4, 10 and 10.1 of the Code.

#### **Response**

A response was received from Pfizer Pty Ltd in which any breach of the Code was denied. Pfizer Pty Ltd maintained that the invitation was sent to medical practitioners to attend an expert presentation on recent developments in the understanding of pathological processes affecting blood vessels. Any entertainment or hospitality was secondary to the

prime purpose of the meeting which was education.

#### **Committee ruling**

The Committee noted that the duration of the educational component should not be the only measure of the quality of education provided. However, the inclusion of spouses or partners at an evening meeting at which entertainment was provided suggested that the educational component was secondary to the entertainment component.

Members noted that the speaker was a well-recognised international expert and did not express concern about the educational content of the meeting. However, members were concerned that the entertainment, especially the style of entertainment, was inappropriate in the context of an educational meeting and would not withstand public or professional scrutiny. Members also considered that the meeting appeared to have been promoted to participants on the basis of the entertainment rather than the educational content.

By a unanimous decision the Committee determined that the meeting sponsored by Pfizer Pty Ltd was in breach of Sections 10 and 10.1 of the Code of Conduct as it would not withstand public and professional scrutiny and the educational content appeared to be secondary to the entertainment provided at the meeting.

No breach of Section 7.3 was found, given that this event could not be described as a Symposium as defined by the Code.


#### **Sanction**

The Code of Conduct Committee determined that Pfizer Pty Ltd should take immediate action to ensure that the activity found in breach should not occur again in the same or similar form.

By a majority decision the Committee determined that Pfizer Pty Ltd should be required to issue a letter to all participants at the "Experts on Vessels" meeting advising of this breach. In addition, it was agreed that APMA should prepare an article for publication in Australian Doctor Weekly and Medical Observer, discussing this complaint.

Given the fulsome discussion of the appropriate interpretation of Section 10 of the Code, the Committee requested that its discussions be referred to the APMA's Code of Conduct Review Panel and





Strategic Market Directions Working Group in order that some guidance be developed for members.

#### **Appeal**

Pfizer Pty Ltd lodged an appeal against the findings of the Code of Conduct Committee. Pfizer Pty Ltd alleged that the complaint had been based on hearsay evidence and that the depiction of the educational event by the Sunday Program was not fair, unbiased or factual. Pfizer Pty Ltd also alleged that the producers of the program had designed a program that was controversial. Pfizer Pty Ltd had not been offered an opportunity to view the program before it was aired although a written statement had been submitted by Pfizer Pty Ltd to the program's directors.

#### **Committee ruling**

The Code of Conduct Appeal Committee discussed the position taken by the ACA and its reliance upon international material that had yet to be published and may not accurately reflect the Australian environment. The Committee agreed that this material would be of value to the APMA in its current review of the Code of Conduct but did not assist the Committee in its consideration of this appeal given there was no prohibition on entertainment in the current edition of the Code. The decision as to whether the entertainment offered at the event was inappropriate was a value judgement that would be assisted by the information provided by Pfizer Pty Ltd that may not have been clearly communicated on the Sunday Program.

The Committee discussed in detail the cost of the event, the substantial educational component, the world-class nature of the speaker in attendance and the timing of the education component compared to the entertainment. The Committee also noted that the entertainment had been viewed by members of the general public and was not subject to any restrictions. Pfizer Pty Ltd advised the Committee that the cost per head had been \$64. Pfizer Pty Ltd had charged parters attending the event \$20 per head. The Committee also noted that there had been no complaints regarding this event by participating health care professionals.

The Committee then discussed the findings of the Code of Conduct Committee to find breaches of Sections 10 and 10.1. The Committee having been informed of the specifics of the event including its cost, educational component and details of the

entertainment could not agree with the Code of Conduct Committee's findings that this event could not withstand public and professional scrutiny. The Committee acknowledged that a decision to find breaches of the Code may have been influenced by the way in which the event had been portrayed in the Sunday Program. The Committee also acknowledged the subjective nature of the current Code provisions and encouraged the APMA to consider reviewing these sections during its current review of the Code. The Committee referred to the written submission by the ACA as a useful resource to be used by the APMA.

It was unanimously agreed that the discussion of this complaint and appeal had added to the review process for the Code of Conduct and that the ACA should be thanked for its submission.

Having considered the appeal, the Committee were of the view that Pfizer Pty Ltd was not in breach of Sections 10 and 10.1 of the Code of Conduct and that their appeal should be upheld.

The Committee reiterated the Code of Conduct Committee's request that this area of the Code be scrutinised as part of the current review process.

#### **Sanction**

Having upheld the appeal the Code of Conduct Appeals Committee resolved that the sanction imposed by the Code of Conduct Committee should be removed.

## **13. Smith & Nephew Pty Ltd Sponsorship (637)**

### **Sponsorship for general practitioner attendance of conference**

#### **Complaint**

A complaint was received from the Australian Consumers Association (ACA) alleging that free conference registrations offered to doctors by Smith & Nephew Pty Ltd was in breach of the Code of Conduct. The ACA identified a videotape of the Channel 9 Sunday Program as the basis of their complaint. Smith & Nephew Pty Ltd were invited to respond to Sections 7.3, 7.4, 10 and 10.1 of the Code.



### **Response**

A response was received from Smith & Nephew Pty Ltd in which any breach of the Code was denied. Smith & Nephew Pty Ltd maintained that the company was assisting general practitioners with their education and that hospitality had not been provided.

### **Committee ruling**

The Committee unanimously determined that the provision of one three-day registration and one hundred one or two day registrations was not in breach of Sections 7.3, 7.4 or Section 10 of the Code of Conduct as the conference and exhibition was focussed on scientific and medical matters, would be able to successfully withstand public and professional scrutiny and that no hospitality had been offered in association with the conference.

## 14. AstraZeneca Pty Ltd Oxis Turbuhaler (639)

### **Promotional material entitled:**

"Faster Relief"

### **Complaint**

A complaint was received from GlaxoSmithKline Australia alleging that promotional material pertaining to Oxis Turbuhaler contained claims about safety and use that were not in accord with the Approved Product Information. GlaxoSmithKline Australia alleged that the promotional material contained breaches of Sections 1.1, 1.3 and 1.5 and 1.7 as well as technical breaches of Sections 1.1, 1.3, 1.3.1 and 1.5 of the Code.

### **Response**

A response was received from AstraZeneca Pty Ltd denying any breach of the Code. AstraZeneca Pty Ltd maintained that the material was in accord with the Approved Product Information and that all claims had a qualifying symbol referring to appropriate footnotes.

### **Committee ruling**

By a majority decision, the Committee considered that the claim "No safety issues associated with the Oxis PRN use were identified" was in breach of Sections 1.1 and 1.3 of the Code as it had the potential to mislead prescribers regarding the safety of Oxis Turbuhaler. The Committee did not consider that the claim was an unqualified superlative and no

breach of Section 1.5 was found.

The Committee unanimously determined that no breach of Section 1.1 or 1.3 should be found as "Who benefits from Oxis PRN?" and the associated text and picture were not misleading and were consistent with the Approved Product Information for Oxis Turbuhaler.

The Committee considered that the statement "Faster relief" was a hanging comparator as it implied comparison with another product or Oxis itself, but this was not identified in the promotional material. The Committee determined that the claim "Faster relief" was in breach of Section 1.7 of the Code.


In relation to the qualifying statement "For patients over the age of 18 years and on regular corticosteroid and regular eformoterol treatment" linked to the claim "Faster relief", the Committee considered that the use of the symbol in the promotional material was confusing. The Committee determined that the qualifying statement was in breach of Section 1.3 as the font size was less than 2mm as required by the Code.

By a majority decision, the Committee resolved that the claim "fast acting for fast relief" was in breach of Section 1.3 of the Code of Conduct as it may mislead prescribers to infer that Oxis Turbuhaler is appropriate as a relief medication for acute severe exacerbations of asthma. The Committee resolved that this claim was not in breach of Section 1.1 of the Code as the statement was consistent with the Approved Product Information with respect to being fast acting. The Committee also resolved that the claim was not in breach of Section 1.5 as the statement was not an unqualified superlative.

The Committee unanimously determined that the reference to a 4.5µg dose did not imply that Oxis was effective at lower doses and was therefore not in breach of Section 1.3.1 of the Code of Conduct.

### **Sanction**

The Code of Conduct Committee determined that AstraZeneca Pty Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. The statements found in breach of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.



The Committee further determined that AstraZeneca Pty Ltd should require the company's medical representatives to immediately recover the promotional material from all medical practitioners who had received it.

## 15. Aventis Pharma Rulide (640)

### **Doctor Mailer:**

"Rulide Right on target"

### **Complaint**

A complaint was received from GlaxoSmithKline Australia alleging that a letter to doctors issued by Aventis Pharma was in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct. GlaxoSmithKline Australia alleged that the mailer aimed to mislead doctors regarding the relative incidence of atypical pathogens in acute exacerbations of chronic bronchitis and encouraged them to prescribe Rulide first line in these patients.

### **Response**

A response was received from Aventis Pharma denying any breach of the Code of Conduct. Aventis Pharma maintained that the letter was consistent with the body of published evidence and that there was no intention to mislead prescribers.

### **Committee ruling**

The Committee determined that the letter was misleading, as the clinical study on which the promotional claims were based, was inadequate to support such broad claims. The letter was therefore found in breach of Section 1.3 of the Code. The Committee further determined that the letter was in breach of Section 1.1 of the Code as the claims were unbalanced and inadequately supported by the available data. As the promotional claims for Rulide included comparisons with other products which were unable to be adequately substantiated, the Committee also concluded that the letter was in breach of Section 1.7 of the Code of Conduct.

### **Sanction**

The Code of Conduct Committee resolved that Aventis Pharma should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. In addition, the claims found in breach should not be used again in their present form or in a

manner that conveyed the same or similar meaning.

The Committee further resolved that Aventis Pharma should be required to send a corrective letter to all general practitioners. In addition, the Committee resolved that a fine of \$20,000 should be imposed on Aventis Pharma.

### **Appeal**

Aventis Pharma lodged an appeal against the findings of the Code of Conduct Committee. Aventis Pharma claimed that the letter was designed to provide information regarding the results of a recent Australian study looking at causative pathogens for acute exacerbations of chronic bronchitis. Aventis Pharma claimed that the letter accurately presented the results of the study and that the results were not at odds with the body of current clinical knowledge.

### **Committee ruling**

The Code of Conduct Appeal Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeal Committee resolved to uphold the decision of the Code of Conduct Committee relating to the claims as no evidence had been provided to justify overturning its decision.

### **Sanction**

The Code of Conduct Appeal Committee agreed with the decision of the Code of Conduct Committee that this material should be withdrawn and not used again in the same or similar appearance. In addition, it was considered appropriate that a corrective letter, as required by the Code of Conduct Committee, should be sent to all general practitioners. In relation to a fine, the Appeal Committee agreed that a fine of \$10,000 should be imposed rather than the \$20,000 proposed by the Code of Conduct Committee as Rulide was indicated for the treatment of AECB.

## 16. Pharmacia Australia Pty Ltd Somac (641)

**Promotional material entitled:**  
"Somac: Eclipse reflux without hassles"

### **Complaint**

A complaint was received from AstraZeneca Pty Ltd alleging that promotion of Somac by Pharmacia Australia Pty Ltd was in breach of Sections 1.3, 1.5 and 1.7 of the Code of Conduct. AstraZeneca Pty Ltd alleged that the promotional material used by Pharmacia Australia Pty Ltd contained hanging comparatives and disparaging claims.

### **Response**

A response was received from Pharmacia Australia Pty Ltd denying any breach of the Code of Conduct. Pharmacia Australia Pty Ltd maintained that they had shown willingness to discuss the complaint with AstraZeneca Pty Ltd at all times and had offered resolution of the complaint prior to it being submitted to the Code of Conduct Committee.

### **Committee ruling**

The Code of Conduct Committee considered that whilst there was some evidence that Somac 40mg daily was equivalent to omeprazole 20mg to 40mg daily, there was no published clinical evidence sufficient to demonstrate equivalence between Somac 40mg daily and omeprazole 40mg daily. The Committee concluded that the claim was in breach of Section 1.3 as it was misleading and Section 1.7 as the comparative claim was unable to be adequately substantiated.

The Code of Conduct Committee considered that it was inappropriate to claim superior efficacy at day four of treatment in a disease state that requires long term treatment. Further, the Committee considered that the single study on which this claim was based was inadequate to support the comparative claim. The Committee considered it was inappropriate to generalise on the basis of the single cited study and concluded that the claim was in breach of Section 1.3 as it was misleading and in breach of Section 1.7 as the comparative claim was inadequately substantiated.

The Committee noted that the claim "Superior acid suppression compared to omeprazole" had previously been found in breach of Section 1.3 of the

Code as the qualifying statements regarding the clinical significance of the claim were not sufficiently prominent. The Committee considered that the statement "Reduce hassles by prescribing Somac. Somac has demonstrated superior acid suppression to omeprazole during both day and night" inferred a clinical benefit that had not been established. The Committee considered that both promotional claims were in breach of Section 1.3 of the Code and that these constituted a repeat breach of the Code of Conduct in each case.

The Committee considered that the claim implying absolute clinical benefits for Somac had not been substantiated and was therefore in breach of Section 1.5 and 1.3 of the Code of Conduct. The Committee did not consider that the claim was comparative and no breach of Section 1.7 was found.

The Committee considered that the claim "reduce hassles by using Somac" was a hanging comparative and was therefore in breach of Section 1.7 of the Code of Conduct. The Committee also considered that the statement was misleading by the lack of any reference to a comparator product or products had not been substantiated. It was therefore found in breach of Section 1.3.

The Committee considered that the statement "Somac offers a low incidence of adverse events which may mean improved patient compliance and satisfaction" lacked any scientific content and was a poor choice of words. The Committee considered that although lacking in meaning, the claim could not be described as a "hanging comparator" and therefore no breach of Section 1.7 was found.


### **Sanction**

The Committee resolved that Pharmacia Australia Pty Ltd should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of them in their present form. In addition, the claims found in breach should not be used again in their present form or in a manner that conveyed the same or similar meaning.

A fine of \$15,000 was imposed for each of the two repeats of a previous breach and \$5,000 for each of the other four breaches, making a total fine of \$50,000.

### **Appeal**

Pharmacia Australia Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct



Committee. Pharmacia Australia Pty Ltd argued that there was no evidence that a repeat breach occurred, that the body of evidence supported the claims and that errors of fact and interpretation of statistical and clinical outcomes had been made by the Committee.

The Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

In relation to the claim "Acid suppression. Reduce the hassles by using Somac. Somac has demonstrated superior acid suppression to omeprazole during both day and night" the Appeals Committee considered that the Code of Conduct Committee appeared not to have considered the date of its previous decisions when finding that this claim represented a "repeat breach". As the original decision was greater than 24 months before the second decision to find a breach of the Code, the Committee resolved to uphold this aspect of the appeal and overturned the finding of a "repeat breach". However, the Committee did agree with the findings of the Code of Conduct Committee that the inappropriate qualification for this claim represented a breach of Section 1.3.

In relation to other claims the Committee resolved to uphold the decision of the Code of Conduct Committee relating to the claims as no evidence had been provided to justify overturning its decision.

#### **Sanction**

The Code of Conduct Appeal Committee agreed with the requirement that the promotional material in question be withdrawn from use and not used again in the same or similar format or in a manner that conveyed the same or similar meaning.

In relation to the proposed fine, the Committee resolved to look at an appropriate cumulative fine for the breaches found. During the discussion of an appropriate fine, the Committee noted that while the appeal in relation to a repeat breach had been upheld, the breach found should not be considered as purely technical. The Committee considered that this breach should be considered as a moderate breach having regard to the number of times this matter had been considered by the Code of Conduct Committee on previous occasions. The Committee discussed an appropriate sanction that would ensure that the

requirements of the Code are complied with and to prevent a similar breach re-occurring.

The Committee resolved that a total fine of \$50,000 was appropriate for the breaches found.

## **17. Bristol-Myers Squibb Australia Pty Ltd Pravachol (642)**

#### **Promotional brochure**

##### **entitled:**

"Reasons to choose Pravachol"

#### **Letter to doctors**

#### **Complaint**

A complaint was received from Pfizer Pty Ltd alleging that a brochure and letter to doctors seriously misrepresented recent information on the withdrawal of cerivastatin from the market and were in breach of Sections 1.1, 1.3, 1.5 and 1.7 of the Code. It was further alleged that there was potential for harm to patients as doctors may have been misled by the materials.

#### **Response**

A response was received from Bristol-Myers Squibb Australia Pty Ltd denying any breach of the Code. Bristol-Myers Squibb Australia Pty Ltd maintained that the claims were based on information from the Approved Product Information or peer reviewed journal articles.

#### **Committee ruling**

The Committee considered that the part of the brochure discussing the withdrawal of cerivastatin was factual and a fair summary of the rationale for this product's withdrawal. As the two statements regarding the cerivastatin withdrawal and Pravachol's low potential for drug interactions were factual and not misleading, the Committee found no breach of Sections 1.1 or 1.3 of the Code.

However, the Committee concluded that in totality the brochure was misleading as it inferred that there is an increased risk of rhabdomyolysis for atorvastatin, cerivastatin and simvastatin due to drug interactions related to metabolism by the CYP 450 3A4 isoenzyme which had not been substantiated. The messages

conveyed by the flow diagrams and conclusions were conflicting, confusing and misleading. The flow diagrams for pravachol were also misleading by providing incomplete information about the risk of rhabdomyolysis. The Committee resolved that the brochure was in breach of Section 1.3 of the Code and Section 1.7 as the comparison between pravachol and other statins was disparaging and had not been adequately substantiated. No breach of Section 1.5 was found as the promotional material did not claim uniqueness for pravachol or use an unqualified superlative.

The Committee considered that similar messages to that contained in the Pravachol promotional brochure were contained in the letter to doctors, suggesting a link between differences in drug interactions between the statins and the risk of rhabdomyolysis. However, there were statements in the letter that identified that the mechanism underlying muscle weakness and rhabdomyolysis was unclear. Also, the letter acknowledged that the risk of rhabdomyolysis with pravachol did exist, although it was very rare. By a majority decision, the Committee concluded that the letter was not in breach of Sections 1.3 or 1.5 of the Code as it was not misleading and did not claim uniqueness or special merit for Pravachol.

#### **Sanction**

The Code of Conduct Committee resolved that Bristol-Myers Squibb Australia Pty Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. In addition, the claims found in breach should not be used again in their present form or in a manner that conveyed the same or similar meaning.

The Committee resolved that Bristol-Myers Squibb Australia Pty Ltd should be required to send a corrective letter to all medical practitioners who had received the Pravachol brochure. The Committee considered that the breaches of the Code of Conduct were moderate as the promotional material may influence how the medical profession may prescribe Pravachol or other statins. The Committee resolved that a fine of \$40,000 should be imposed on Bristol-Myers Squibb Australia Pty Ltd.

#### **Appeal**

Bristol-Myers Squibb Australia Pty Ltd lodged an appeal against the findings of the Code of Conduct Committee. Bristol-Myers Squibb Australia Pty Ltd contended that it had presented factual, accurate and balanced information for the benefit of physicians.

#### **Committee ruling**

The Code of Conduct Appeals Committee reviewed the decision of the Code of Conduct Committee to find a breach of Sections 1.3 and 1.5 to determine whether it had been persuaded to overturn this decision based on the material presented to them.

Based on this information, it was the view of the Committee, that there was some evidence to support a possible linkage between CYP450 3A4 and the risk of myopathy or rhabdomyolysis. In addition, the Committee was satisfied that the clinical evidence and the Approved Product Information indicated differences in the statins relating to this risk. Although agreeing with the Code of Conduct Committee that the brochure had been unbalanced in the manner in which these issues had been presented, the Committee did not agree with the severity of the criticism expressed by the Code of Conduct Committee. The Committee considered that the brochure could have been enhanced by the addition of qualifiers such as "possible" or "potential" increased risk rather than the inference of a definite linkage.

Having considered the appeal, the Committee was of the view that the decision of the Code of Conduct Committee to find a breach of Sections 1.3 and 1.7 should remain and that the appeal should not be upheld.

#### **Sanction**

Having been provided with further evidence regarding the current scientific research in this area and having undertaken a review of the relevant statin's Product Information, the Code of Conduct Appeals Committee considered that an appropriate sanction for the breaches found should be \$20,000 rather than the \$40,000 determined by the Code of Conduct Committee.