

Medicines Australia Code of Conduct Quarterly Report January - March 2009

Medicines Australia Code of Conduct

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

The Medicines Australia Code of Conduct was introduced in 1960 and is currently operating under Edition 15 (Effective 6 December 2006).

This report covers all complaints finalised between January - March 2009. Complaints finalised during this period were in relation to materials or activities conducted under Edition 15 of the Code.

Quarterly Reports preceding this Report are available from the Medicines Australia website <http://www.medicinesaustralia.com.au/pages/page30.asp>

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How do I obtain a copy of the Code?

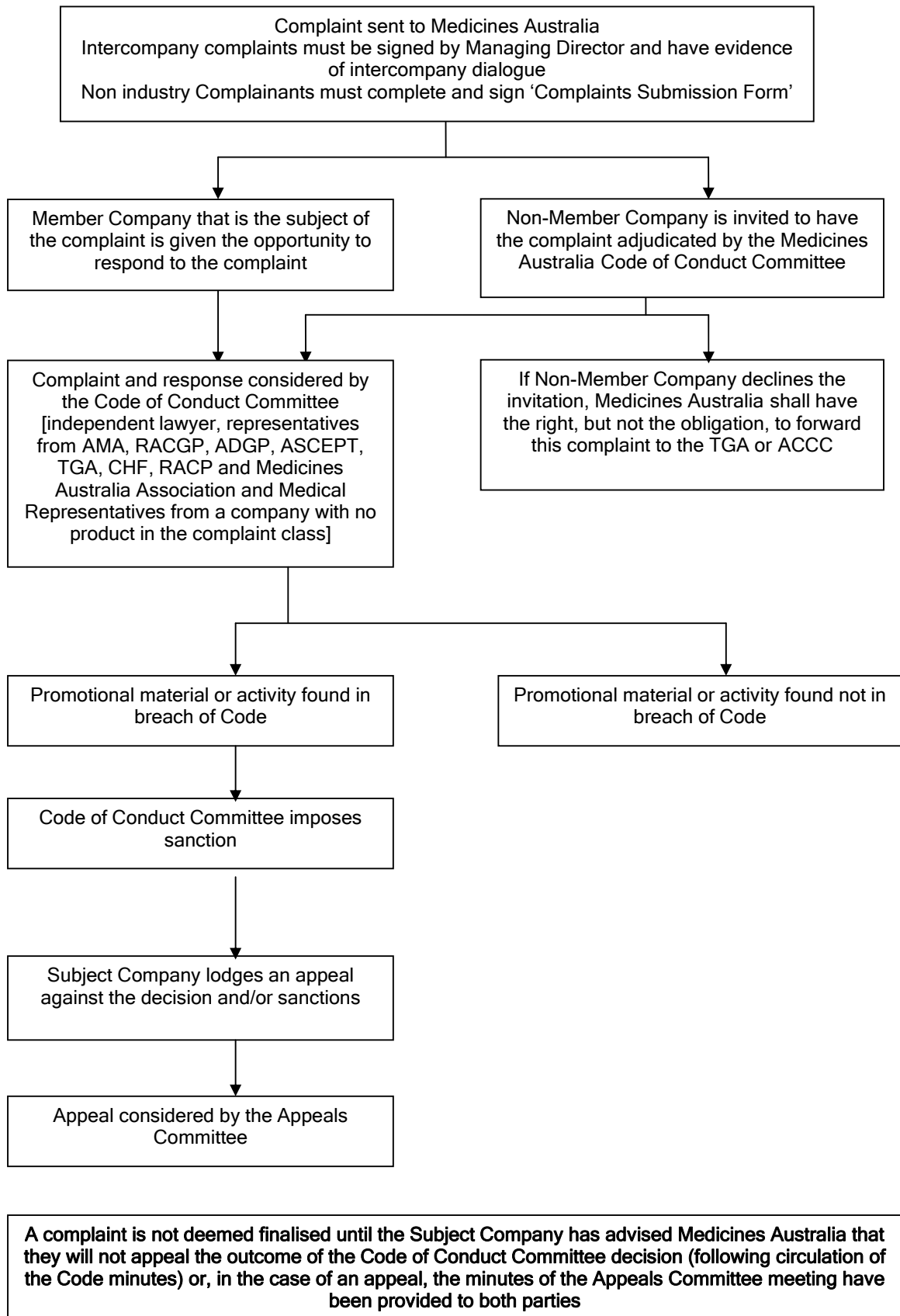
Hard copies of Edition 15 of the Code are available from Medicines Australia.

The Code of Conduct and the Guidelines that accompany the Code are available from the website (<http://www.medicinesaustralia.com.au/pages/page16.asp>).

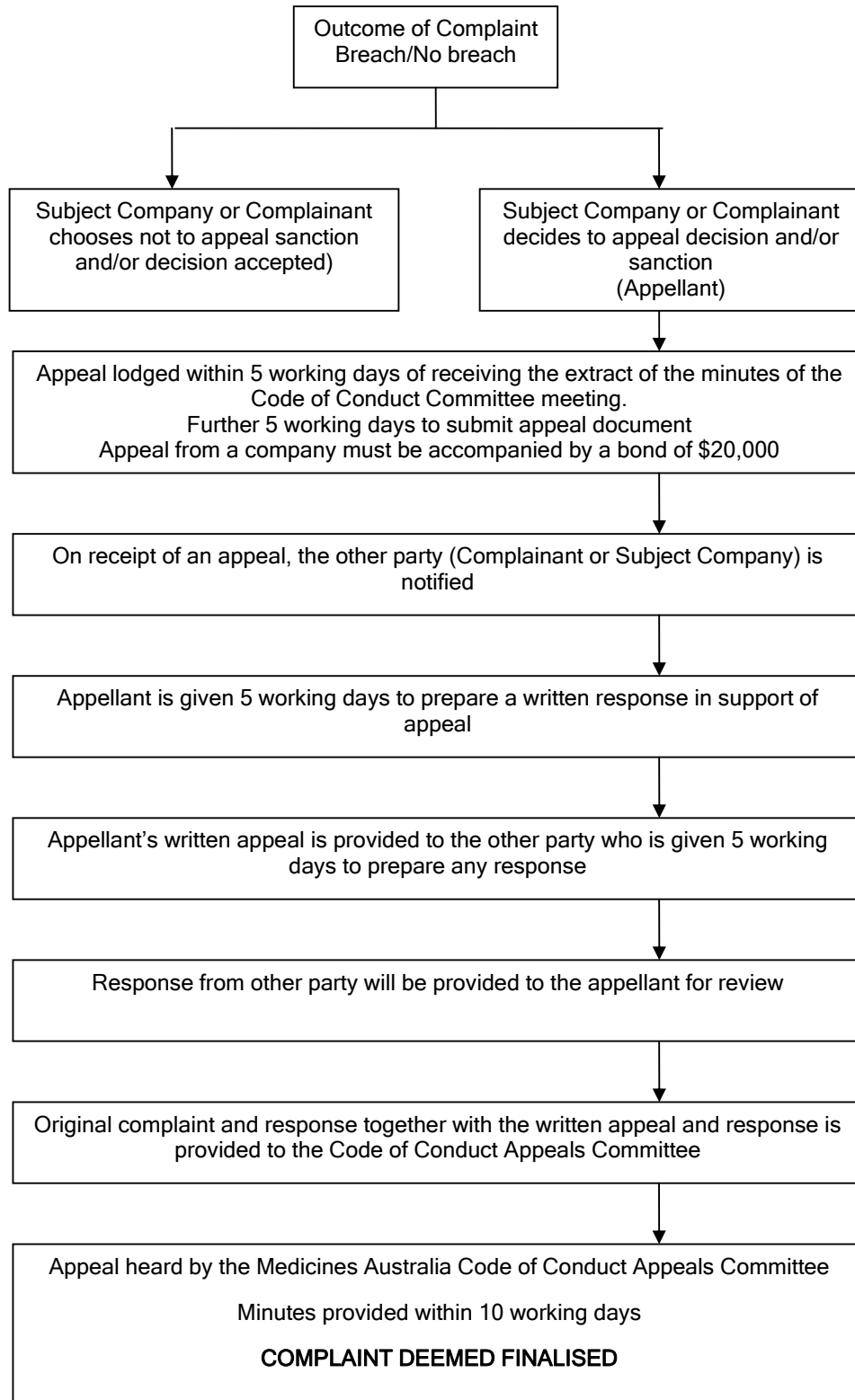
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Medicines Australia Code of Conduct Complaints Handling Process



Medicines Australia Code of Conduct Appeals Committee Procedures



Committees and Secretariat

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

Committee Member Biographies

Brief biographies for all Code, Appeals and Monitoring Committee members are available on the Medicines Australia website <http://www.medicinesaustralia.com.au/pages/page96.asp>

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of six trade practices lawyers
- *Representatives nominated by:*
- Australian General Practice Network (AGPN)
- Australian Medical Association (AMA)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Consumers Health Forum of Australia (CHF)
- Royal Australasian College of Physicians (RACP)
- Royal Australian College of General Practitioners (RACGP)
- Therapeutic Goods Administration (TGA)
- Medicines Australia Association Representatives (maximum 3)
- Medicines Australia Medical/Scientific Directors (maximum 2)

Observers (No voting rights)

- Medicines Australia member companies' employees (maximum 2)
- Observer nominated by Medicines Australia (maximum 1)

Advisors (No voting rights)

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

Appeals Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of six trade practices lawyers
- *Representatives nominated by:*
- The College and/or Society associated with the therapeutic class of the product subject to appeal
- The target audience to which the activity was directed eg: AMA, RACGP, AGPN
- Consumers Health Forum of Australia (CHF)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Medicines Australia Association Representatives (maximum 2)
- Medicines Australia Medical/Scientific Director (maximum 1)

Advisors (No voting rights)

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

Sanctions which can be imposed by the Code of Conduct Committee

Sanctions

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

Withdrawal of material or activity

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

Corrective letter

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

Corrective advertisement

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

Fine

Breach

Technical breach
Minor breach
Moderate
Severe breach

Fine

Maximum of \$100,000

Severe breach where activities have ceased
Breach repetitions
Repeat of previous breach

Maximum of \$200,000

Guidelines for determining Code sanctions can be found on the Medicines Australia website at <http://www.medicinesaustralia.com.au/pages/page16.asp>

Table of finalised complaints January - March 2009

No.	Subject Company	Material Activity	Product	Complainant	Outcomes*	Sanction
991	Bayer	Promotional Material	Levitra	Pfizer Australia	Breach 1.3, 1.7 No Breach 10.8	<ul style="list-style-type: none"> • Fine \$40,000 • Withdraw advertisements • Corrective advertisement
996	Allergan	Educational Event	Various	Monitoring Committee	No Breach 4.11, 6.2, 10.2, 10.8	N/A
1001	Bayer	Promotional Material	Yaz	Healthcare Professional via TGA	No Breach 1.3, 1.3.1, 1.9, 1.10, 3.10	N/A
1003	iNova	Media Release	Duromine	Healthcare Professional	No Breach 1.1, 1.2, 1.3	N/A
1004	AstraZeneca	Promotional Material	Crestor	Pfizer Australia	Breach 1.1, 1.2, 1.3, 1.7 No Breach 1.1, 1.2, 1.3, 1.7	<ul style="list-style-type: none"> • Fine \$100,000 • Withdraw materials & cease use • Corrective letter
1006	Servier	Promotional Activities	Micardis	Boehringer Ingelheim	Breach 1.1, 1.3, 1.7 No Breach 4.1, 4.3, 10.8	<ul style="list-style-type: none"> • Fine \$100,000 • Withdraw materials
1008	Novartis Pharmaceuticals	Promotional Material	Famvir	Healthcare Professional	Breach 9.4 No Breach 9.6, 9.10	<ul style="list-style-type: none"> • Fine \$5,000

Levitra 991

Subject Company: Bayer Australia (Bayer)

Complainant: Pfizer Australia (Pfizer)

Product: Levitra

Complaint

Pfizer alleged that advertisements comparing the prices of Viagra and Levitra were deceptive and a distortion of the true costs to patients of these medicines. The overall impression created by the advertisements and promotional material was that Viagra is significantly more expensive than Levitra. This impression was not corrected by the disclaimer in fine print stating "*Based on the maximum Arrow listed price for private scripts at participating pharmacies for Levitra 20mg 4 pack and Viagra 100mg 4 pack as at 1 July 2008*" as there is a lack of awareness of the Arrow script model based on feedback from healthcare professionals.

Sections of the Code

Materials alleged to be in breach of the following Section of the Code:

- 1.3 False and misleading claims
- 1.7 Comparative statements
- 10.8 Discredit to and reduction of confidence in the industry

Response

Bayer responded that the images and prices included in the advertisements were adequately explained and qualified by the inclusion of the disclaimer and the PBS listing information. Both were prominently displayed in a manner that complies with the requirements set out in the Code and Guidelines. Bayer further argued that doctors possess a sophisticated level of knowledge of the disclaimer and PBS claim as established by research conducted by Bayer (doctors independently surveyed and members of the Levitra Advisory Board).

Code Committee determination

- In a majority decision the Committee found a breach of Sections 1.3 and 1.7 of the Code. In a unanimous decision

the Committee did not find a breach of Section 10.8 of the Code.

Sanction

- Withdraw materials found in breach
- Publish a corrective advertisement
- Pay a fine of \$40,000

Consideration of the complaint

Some members of the Committee reported that they had researched a number of pharmacies to gauge the range of prices for both Levitra and Viagra. It was noted that these prices varied considerably (in most cases lower) from the advertised prices in the promotional material.

The Committee accepted that Bayer had provided a qualifying statement at the top of the page that the stated prices were based on 'the maximum Arrow listed price for private scripts at participating pharmacies'; however some members were of the view that the maximum Arrow listed price was not a realistic reflection of actual prices paid by consumers and was therefore misleading. A majority of Committee members were of the view that this price comparison was equivalent to not reflecting the body of evidence to support a claim. Other members thought that the advertisement was misleading by omission, by failing to clearly communicate that prices may vary and may be less than the stated prices.

Members were of the view that the advertisements were misleading by implication and omission. Some members expressed concern that Bayer was not marketing its product based on the quality use of medicines but focussing only on price. However, it was also noted that this therapeutic area was a market where price was important to the user, in consideration that the product was not listed on the PBS.

The Committee discussed the informal surveys reported by both Pfizer and Bayer regarding the Arrow private script pricing model. Some general practitioner members of the Committee agreed that there was a lack of awareness of the Arrow private script model and what it means.

The Committee noted that Section 1.7 of the Code in relation to comparisons between products requires that a comparison must

properly reflect the body of evidence and not mislead by distortion. In this case a majority of the Committee considered that the use of 'the maximum Arrow private script price' was not reflective of the price commonly paid for Viagra. The advertisements were misleading by the implication that there is a large difference in price that consumers are actually paying, which was not correct, and misleading by omission of some evidence of the actual prices commonly paid for the products.

In a majority decision the Committee found a breach of Sections 1.3 and 1.7 of the Code. It was a unanimous decision that no breach of Section 10.8 of the Code should be found.

Sanction

Having found several breaches of the Code the Committee considered what sanction should be imposed.

In a unanimous decision the Committee determined that Bayer should:

- Withdraw materials found in breach
- Publish a corrective advertisement in the same journals as the advertisements found in breach were published. The advertisements must be the same size and prominence as the advertisements found in breach of the Code.
- The corrective advertisement must be approved in writing by the Chairman of the Code of Conduct Committee. The text of the corrective advertisement must be in a font of no less than 12 point. Medicines Australia must receive documentary evidence of the publication of the advertisement. The corrective advertisement must be published within 30 calendar days of receipt of the minutes detailing the decision.
- Pay a fine of \$40,000.

Appeal

Bayer lodged an appeal stating that the Code Committee had erred in failing to accord procedural fairness and denying natural justice to Bayer.

Bayer asserted that the Code Committee had relied upon certain information not disclosed to Bayer, specifically:

- The personal *ad hoc* enquiries made by some members of the Committee of the

price of medications in certain pharmacies;

- The personal knowledge (or lack thereof) of some of the general practitioner members of the Committee; and
- Some supporting material to Pfizer's complaint (specifically, page 3 of the minutes of the Viagra Advisory Board meeting).

Furthermore, the Committee had failed to disqualify one general practitioner as a member of the Code Committee which heard the complaint. The general practitioner is related to one of the partners of Bayer's solicitors, Piggott Stinson.

Bayer further asserted that the Code Committee had erred by;

- Failing to consider the advertisements as a whole;
- Ignoring the target audience to which the advertisements were exclusively distributed;
- Failing to give proper weight to the evidence before the Committee, which established the high level of knowledge and understanding of that target audience; and
- Failing to have regard to prior decisions of the Code of Conduct Committee (and the Federal Court) in relation to price comparison advertising.

Response to the appeal

Pfizer responded that it agreed with the findings of the Code Committee and did not agree with Bayer's contentions. Pfizer considered there was no merit in the assertion that procedural fairness and natural justice had been denied to Bayer. Pfizer argued that members of the Code Committee had applied their individual knowledge and judgement in a fair and balanced manner. New evidence submitted by Bayer in its appeal did not overturn the basis of the Code Committee's finding of breaches.

Appeals Committee determination

- The Appeals Committee did not uphold the appeal in relation to breaches of Sections 1.3 and 1.7 of the Code and did not amend the sanctions imposed by the Code of Conduct Committee.

Consideration of the appeal

Prior to consideration of the appeal, the Chairman called for declaration of any potential conflicts of interest. Prior to the meeting a member of the Code Secretariat had contacted both Bayer and Pfizer seeking their advice on the participation of a company Associate Medical Director on the Appeals Committee. Bayer and Pfizer had stated that they had no objection to this persons participation.

The Chairman advised the Bayer and Pfizer representatives that when he was a partner at Minter Ellison solicitors prior to 1996 and had acted for Bayer. Pfizer and Bayer accepted that he had no current conflict of interest that should prevent him chairing the Committee.

There being no further declared conflicts of interest the meeting proceeded.

Members of the Committee were introduced to the company representatives.

The Chairman outlined the procedures for the meeting.

The following outlines the appeal presentation made by Bayer.

- Bayer contended that the Code Committee had erred in its decisions - the first errors were in lack of procedural fairness accorded to Bayer and secondly in the basis for the Committee's decisions. Thirdly Bayer submitted that the penalties imposed were harsh and excessive when compared to other breaches and the sanctions do not appear to have taken into account that during intercompany dialogue Bayer had offered to withdraw the advertisements.
- Bayer has not been accorded a fair and unbiased hearing on matters which affect it:
 - The personal enquiries made and relied upon by some members of the Code Committee;
 - The personal views of some general practitioner members; and
 - Bayer did not receive the full complaint from Pfizer (page 3 was missing from the record of the Viagra Advisory Board meeting at which Pfizer had sought responses

from Advisory Board members on the Arrow pricing model).

- The Code Committee had failed to allow Bayer to respond to these matters.
- Because the general practitioner, a member of the Code Committee, is the sister of a partner at Bayer's solicitors Piggott Stinson, she had a clear conflict of interest which should have disqualified her from adjudicating on Pfizer's complaint. In response to a question from the Chairman, Bayer explained that the general practitioner's brother is the managing partner at the firm of solicitors acting for Bayer in responding to the complaint. Bayer's response to the complaint included the name of its solicitors; therefore the general practitioner should have been aware of it. The Piggott Stinson partner was not responsible for running the particular matter for Bayer. However, Bayer argued that there may have been an apprehension of bias, not that there had been actual bias in the decision. Bayer did not intend any aspersions on the general practitioner's integrity rather that an impartial observer might have apprehended that her personal relationship might have caused her to apply a different standard to her consideration of the complaint than had she had no such relationship.
- A page missing from the Pfizer complaint had not been provided to Bayer until after the complaint had been determined. Therefore Bayer did not have the opportunity to consider it when making its response to the complaint. While Pfizer made reference to the comments by members of the Viagra Advisory Board in the body of its complaint letter this was not sufficient to allow Bayer to understand what questions had been asked of the Advisory Board members and the context of the discussion that led to the Board members advice. Pfizer had asked the Advisory Board members the wrong question and got the wrong answer.
- The application of transparency, objectivity, impartiality and lack of apparent bias is important for the operation of the Code. Bayer asserted that there was a reasonable

apprehension that the Code Committee chose not to apply the very procedural rules with which it is charged by the Code, which rules the ACCC and the Australian Competition Tribunal have accepted in granting and affirming authorisation of the Code.

- The sanctions were harsh and not consistent with other sanctions. Price comparisons are different from educational events and claims about efficacy or safety.
- The Code Committee had failed to take into account Bayer's offer made during intercompany dialogue to withdraw the advertisements.
- Pfizer had asked that Bayer withdraw the advertisements (this has been undertaken), distribute a corrective letter and never to engage in price comparisons again - this was unacceptable to Bayer.
- The decision by the Code Committee was by majority and made on a day when the Code Committee had a number of complaints to review. Bayer is of the view that the complaint may not have been given due consideration.
- The advertisement should have been considered as a whole and this did not appear to be the case.
- The Code Committee did not take into account the knowledge and understanding of the audience for the advertisements. The Code Committee appears to have ignored the audience and formed the view that it was not well informed about the Arrow Model. This was an error and contrary to the weight of evidence. Sigma has marketed the Arrow pricing model to general practitioners over a number of years; GPs should be very familiar with it.
- The PBS box on the advertisements advises the reader that Levitra is not listed on the PBS - as a private script is required, this informs the reader that prices may vary. The size and position of the PBS information complies with the Code.
- The asterisk next to the price alerts a reader that there is further information that should be read. The qualifying statement was placed in clear unpopulated space at the top left corner of the advertisements. In English a

reader will read from the top left corner and read down the page, finishing at the bottom right corner. The qualifying statement also complies with the Code in terms of type size.

- The qualifying statement makes reference to the maximum price at participating pharmacies. This is telling the reader that the price may vary between pharmacies.
- The additional evidence submitted by Bayer is not 'new'. It existed at the time of the complaint and should be considered by the Appeals Committee.

The following outlines the appeal presentation made by Pfizer.

- Pfizer agrees with the Code Committee's findings.
- Timeline of the complaint:
 - Advertisements published from 4 July - 5 September.
 - Pfizer first raised concerns with Bayer on 15 July.
 - Pfizer sent letter of complaint to Bayer on 6 August.
 - Intercompany dialogue was held on 2 September.
 - Complaint lodged with Medicines Australia on 19 September.
- In response to the allegations of lack of procedural fairness and natural justice.
 - The Code Committee is defined as a Committee of experts and should be allowed to bring their expertise to bear on complaints.
 - The Pfizer complaint included documentation that prices of Levitra and Viagra vary from pharmacy to pharmacy, which was consistent with the Committee members' investigations. Bayer does not dispute that product prices vary in the private market.
 - The advertisements omitted the fundamental information for prescribers that prices will vary and that Viagra may be cheaper than Levitra.
 - All documentation (including page 3 of the Viagra Advisory Board) was submitted to Medicines Australia.
- The alleged conflict of interest of a Committee member was rejected by Pfizer

- Bayer has provided no evidence that bias by the member was likely to have occurred. No reasonable observer would perceive a conflict of interest in a matter such as this complaint.
 - Whilst Bayer had offered to withdraw the advertisement, it had been running for two months. Pfizer considered it was inadequate just to stop using the advertisement; corrective action was required.
 - Pfizer did not ask Bayer never to advertise on the basis of price comparison again. It had sought undertakings that Bayer would not publish the same or similar price comparisons.
 - Errors in findings by the Code Committee.
 - It was clear that the Code Committee did view the advertisements as a whole. The advertisements were lacking because they omitted a number of facts.
 - The target audience (primarily GPs) would have little knowledge of the Arrow Model. This is borne out by the Code Committee members experience and the Viagra Advisory Board responses. The Code Committee did consider the target audience as evidenced by the minuted discussion on the level of knowledge of the pricing model amongst GPs.
 - New evidence presented in the appeal - If accepted, the new evidence:
 - Doesn't justify Bayer's position.
 - Shows that the price can vary from the maximum price stated in the advertisements and between pharmacies, and this is acknowledged by Bayer in its appeal, supporting Pfizer's position. What prescribers want to know is the price patients are likely to pay. Pfizer asserted that the new information submitted by Bayer on appeal indicated that pharmacists could increase or decrease the maximum price for products sold under the Arrow model.
 - Sanctions
 - If anything, the sanctions are lenient, not excessive.
- Bayer provided the following summary in response to the Pfizer presentation:
- Pharmacists participating in the Arrow Model agree to the maximum price. It is misleading for Pfizer to say that the maximum price can be raised. What can be varied is the actual price that the pharmacist sells the product to the patient up to the maximum agreed price.
 - The advertisements were not misleading. They convey the maximum price for Levitra and Viagra under the pricing model.
 - Bayer does not agree that the disclaimer, which has been previously found acceptable to the Code Committee for price promotion of a single product, is not acceptable for two prices in a single advertisement.
 - There were errors in the Pfizer chronology of the complaint:
 - The first communication to Bayer on 15 July was a complaint under the Trade Practices Act, not the Code; and
 - The 6 August letter was the first reference to the MA Code, with the request that Bayer not use comparative advertising in the future - that means never.
 - If the Committee fails to apply the principles of procedural fairness the Code Committee fails the test of the provisions in the Code and its authorisation by the ACCC.
 - Bayer accepted that there was a reference to the Viagra Advisory Board in the body of the Pfizer complaint, but it did not disclose the question asked or the context.
 - Previous advertising of price made reference to the Arrow Model and the Committee did not find a breach of the Code.
 - There is no prohibition in the Trade Practices Act or Code on price comparison.

The Chairman referred to a decision under the Trade Practices Act in relation to the use of an asterisk to draw attention to qualifying information in an advertisement:

Australian Competition and Security Commission v Signature Security Group Limited [2003] FCA 3 at [26] - [27]; [2003] FCA 3; (2003) ATPR 41 - 908

'While the Wonder White Case is an authority that an asterisk leading to a qualification of a representation may be effective to neutralise an otherwise misleading or deceptive advertisement, whether this is so is a matter for determination in the specific circumstances of any particular case. The qualifying material must be sufficiently prominent to prevent the primary statement being misleading and deceptive or likely to mislead or deceive.'

Bayer responded that whilst a reader may be initially directed to the middle of the page, on observing the asterisk a reader will be aware that further information is available on the page. The qualifying statement is close to the original statement in an uncluttered part of the page, the text is clear, the size complies with the Code and the wording is not misleading as it states that these are maximum prices at participating pharmacies.

Following questions from the Committee Bayer made the following comments:

- The qualifying statement was placed in the top left corner because research shows that a reader will read from the top left to bottom right. If the qualifying statement was at the bottom of the page with other text (for example with the prescribing information) it would be more difficult to identify and less clear.
- The offer to withdraw the advertisement was made in the spirit of the Code as there needs to be some compromise by each party. Pfizer did not offer any compromise on its positions.
- PDE5 treatments for erectile dysfunction are considered to be of relatively similar efficacy and are not listed on the PBS. Therefore price is relevant to differentiate between products.
- While acknowledging that the Code Committee members have a range of expertise and experiences, if a member

has undertaken investigations and produced information that the Committee is minded to take into account, but the Subject Company has not had the opportunity to respond to, this constitutes a lack of procedural fairness. It is not possible to say that no harm was done. A lack of procedural fairness is harm in itself. The Appeals Committee must consider this.

- If the Appeals Committee agrees that proper procedures had not been followed then the appeal must be allowed. The lack of procedural fairness has fed into the Code Committee decision and therefore the Committee erred in its determination. Having determined that there had been a lack of procedural fairness, the Appeals Committee should then consider the facts of the case and form its own view.

Following questions from the Committee Pfizer made the following comments:

- It agreed with the fine imposed by the Code Committee, although being of the view that it is lenient.
- Pfizer could not confirm whether the advertisements had an impact on market share between Viagra and Levitra. It was difficult to measure the market impact as the advertising period was too short.

The Chairman thanked representatives from Bayer and Pfizer for their presentations and asked that they leave the meeting to allow the Committee to deliberate on the matters before them.

Procedural fairness

The Appeals Committee considered all aspects of the Bayer appeal and Pfizer response in relation to issues of procedural fairness.

Conflict of Interest

Appeals Committee members noted advice from Bayer that the managing partner at Piggott Stinson (Bayer's solicitors) had not been aware that his sister was a member of the Medicines Australia Code Committee prior to this complaint and that he was not the instructing solicitor for Bayer in relation to this matter. Nevertheless, the general practitioner should have advised the Code Committee that her brother was a partner at

Piggott Stinson, since he had a financial interest in the way in which the firm conducted the matter for Bayer. It then would have been the responsibility of the Code Committee to determine that this constituted a conflict of interest because an impartial observer might have concluded that the general practitioner might have been influenced in her decision by matters other than the merits of the parties' arguments.

Personal enquiries made by some members of the Code Committee and relied on in the Code Committee's decision

Appeals Committee members noted the minutes of the Code Committee meeting stating that "Some members of the Committee reported that they had researched a number of pharmacies to gauge the range of prices for both Levitra and Viagra. It was noted that these prices varied considerably (in most cases lower) than the advertised prices in the promotional material."

Although Section 11.1.2 of the Code states (*inter alia*) "If the Code of Conduct Committee, after making such further inquiry as is necessary or desirable, meets and reaches a decision that a breach of the Code has occurred ..." where Committee members engage in investigations as occurred in relation to this complaint, this information should be provided to the Subject Company for its response before the complaint is determined. The Appeals Committee accepted that there was a lack of procedural fairness because Bayer had not been given the opportunity to respond to the Committee members' findings.

Personal views of some general practitioners

Appeals Committee members noted that members of all Committees are nominated for their specific knowledge and expertise which can be exercised when reviewing a particular complaint. This may be as a consumer or healthcare professional representative. The Appeals Committee did not accept Bayer's argument that Committee members bringing their personal knowledge and experience to bear resulted in a lack of procedural fairness.

Bayer did not receive the full Pfizer complaint

A member of the Code Secretariat advised that one of the 20 copies of the complaint submitted by Pfizer had been provided to Bayer and this copy evidently omitted one page, being the third page of the minutes of the Viagra Advisory Board meeting. This was not a deliberate attempt by Pfizer or Medicines Australia to withhold information from Bayer. It would appear to have been an error when compiling the documents. When Bayer contacted Medicines Australia advising that there appeared to be a page missing, Secretariat staff checked the file copy which was complete. Unfortunately Bayer did not receive the additional page at that time.

Conclusion on procedural fairness issues

The Chairman recommended to the Appeals Committee that there was a case for finding lack of procedural fairness, setting aside the Code Committee's decision and approaching the merits of the complaint afresh.

The Appeals Committee accepted that there may have been a lack of procedural fairness arising from the undisclosed conflict of interest by one member of the Code Committee; members' personal investigations of product prices to which Bayer was not given the opportunity to respond before a decision on the complaint was made; and the omission of one page from the complaint supplied to Bayer.

Substantive issues

The Appeals Committee then considered whether the price comparison advertisements for Levitra were in breach of Sections 1.3 and 1.7 of the Code. The Committee determined that the additional information supplied by Bayer concerning the Arrow pricing model should be taken into account.

The Appeals Committee came to the same conclusion as the Code of Conduct Committee in relation to the merits of the case. The Appeals Committee did not uphold the appeal against a breach of Sections 1.3 and 1.7 of the Code for the reasons outlined by the Code of Conduct Committee.

The Appeals Committee further stated that the advertisements were misleading and deceptive because:

- The eye of the reader would immediately be attracted to the prominent display of the prices of the two products in the middle of the page, which, unless effectively qualified, would be likely to convey to the target audience (doctors and pharmacists) the misleading representation that the products are generally available at those prices.
- Even taking the reference to the PBS into account (indicating that prices may vary), the disclaimer statement relating to the 'Arrow Private Script Model' was not sufficiently prominent to prevent the main comparative representation on product prices being misleading; many readers are likely not to see the disclaimer. The Appeals Committee confirmed that it was the overall impression left by the advertisement that was important, not just that the disclaimer statement was included somewhere on the page and was in a point size that complied with the Code.
- Those readers that would have found the disclaimer statement were not provided with sufficient information on how prices vary from the maximum prices and what the actual prices paid at pharmacies are likely to be. Having taken into account the additional information on the 'Arrow Pricing Model' supplied by Bayer in its appeal, the Committee was not satisfied that doctors would be sufficiently familiar with the Arrow model to avoid being misled by the advertisements into believing that the two products are generally available at the prices specified in the middle of the page.
- Even though doctors who were familiar with the 'Arrow model' would have been given insufficient information by the advertisement about the likely *real* price of these medicines to the patient to prevent them being misled.

Sanctions

Having not upheld all aspects of the appeal the Appeals Committee reviewed the sanctions imposed by the Code of Conduct Committee. The Committee discussed the fine and requirement for a corrective letter.

In a unanimous decision the Appeals Committee confirmed that Bayer should:

- Withdraw the advertisements found in breach.
- Publish a corrective advertisement in the same journals in which the advertisements found in breach were published. The advertisements must be the same size and prominence as the advertisements found in breach of the Code. The corrective advertisement must be approved in writing by the Chairman of the Code of Conduct Committee. The text of the corrective advertisement must be in a font of no less than 12 point. Medicines Australia must receive documentary evidence of the publication of the corrective advertisement. The corrective advertisement must be published within 30 calendar days of receipt of the minutes detailing the decision.
- Pay a fine of \$40,000.

Appeal Bond

Having confirmed the Code Committees decision to find the advertisements in breach of Sections 1.3 and 1.7 of the Code, the bond was retained by Medicines Australia.

Allergan Educational Event 996

Description of function including duration of educational content delivered	Venue	Professional Status of attendees	Hospitality provided	Total Cost of Hospitality	Number of attendees	Total Cost of Function
Product Clinical Training Workshop - 4 hours.	Dr Rooms-NSW	GPs, RNs, Ophthalmologists, Plastic Surgeons, Cosmetic Physicians, Dermatologists	Light refreshments	312.47	3	\$2957.37 - includes venue hire honoraria

Subject Company: Allergan Australia (Allergan)

Complainant: Monitoring Committee

Event: Educational Event AG_R2_59

Complaint

The Monitoring Committee had asked that Allergan provide justification for the following:

- Why a fee should be paid to the healthcare professional for use of their facilities for the purpose of product training.
- The appropriateness of the hospitality provided.

Sections of the Code

Conduct alleged to be in breach of the following Sections of the Code:

- 4.11 Company Representatives
- 6.2 Hospitality
- 10 (preamble)
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the Industry

Response

Allergan had responded that as it was appealing the Code of Conduct Committee's decision in relation to two closely similar educational event complaints. Allergan therefore requested that complaint 996 be deferred until after those appeals have been heard.

Code Committee determination November 2008

- The Committee agreed to defer Complaint 996 until the appeals in relation to Complaints 968 and 969 had been heard.

Code Committee Determination January 2009

- The Code of Conduct Committee in a majority decision determined that as complaint 996 pertained to the same activity as complaints 968 and 969, and to be consistent with the findings of the Appeals Committee no breach of Sections 4.11, 6.2, 10.2, or 10.8 should be found.

YAZ 1001

Subject Company: Bayer Australia (Bayer)

Complainant: Therapeutic Goods Administration (TGA) [Complaint submitted to the TGA by a healthcare professional]

Product: Yaz

Complaint

The TGA forwarded a complaint from a healthcare professional to the Code of Conduct Committee. The healthcare professional suggested two recent TV segments appear to advertise the prescription medication Yaz and therefore breaches the Code. The healthcare professional further alleges that the content of the segments is a 'consumer focused lobby effort to receive a PBS subsidy'.

The healthcare professional asserted that this medicine is being marketed using a label which is not accepted as a valid disorder, pathologises 'discomfort associated with the menstrual cycle', and is advertising in the guise of 'community interest'.

The TGA identified the sections of the Code which it considered to be in breach.

Sections of the Code

Materials alleged to be in breach of the following Section of the Code:

- 1.3 False or Misleading Claims
- 1.3.1 Unapproved Products and Indications
- 1.9 Medical Ethics
- 1.10 Distinction of Promotional Material
- 3.10 Restricted Access Television Advertising

Response

Bayer responded in the first instance by questioning 'serious issues' surrounding the fundamental procedure of this complaint. They suggest that the company has not received full information, nor an opportunity to address the individual's concern's prior to a formal complaint being lodged. Bayer further states that this complaint fails to

provide an explanation of the alleged breaches, and that the only reference to a breach of the Code of Conduct is made by the TGA, and not the healthcare professional who lodged the complaint with the TGA.

Notwithstanding, Bayer was not approached by Channel 7 at any time prior to the airing of this segment, and had no knowledge of the segment prior to it being aired. Bayer rejects the suggestion that either Channel 9 or Channel 7 TV segments contained promotional material or promotional claims. Bayer asserts that the information contained in the Channel 9 segment was current, accurate and balanced; does not mislead healthcare professionals either directly, by implication, or by omission. Bayer Australia has no connection with the website in question.

Code of Conduct Committee determination

- In a majority decision the Committee found no breach of Sections 1.3, 1.3.1, 1.9, 1.10, 3.10 of the Code.

Consideration of the complaint

Prior to giving consideration to the specifics of the complaint, the Committee discussed procedural issues as set out by Bayer.

Anonymous Complaint

Bayer referred to the Medicines Australia Guidelines for complaints which state that "*anonymous complaints will not be considered by the Code of Conduct Committee*". Members noted that if an individual lodges a complaint through the Medicines Australia process they must submit their name and a declaration in relation to any conflict of interest and they can request that their name is withheld from the subject company.

The Secretariat advised the Committee that contact had been made with the TGA to establish whether the healthcare professional complainant had provided their name to the TGA. The Head of the Advertising Unit advised that the healthcare professional had provided their name to the TGA but requested that it not be forwarded to Medicines Australia or the company.

The purpose in not accepting anonymous complaints is not to put up barriers for

complainants but to ensure the complaints process is transparent for all parties.

Some members were of the view that the TGA should direct complainants to the Medicines Australia website or ask that they complete the 'Complaints Submission Form' to ensure it is not an anonymous complaint and that the conflict of interest declaration is signed. Members also commented that the complainant should also be advised by the TGA that there is an opportunity to work with an independent facilitator in preparing their complaint and identifying sections of the Code that may be considered in breach

Bayer had no opportunity to provide an explanation or suggest a solution prior to lodgement of the complaint

Members noted that it is not compulsory for non-industry complainants to take up the offer of engaging in dialogue with the subject company or accessing the independent facilitator. The Committee was advised that no non-industry complainants have used the services of the independent facilitators. These documents are available on the Medicines Australia website.

Complaint lacks the required supporting data

The Committee noted that there is a different set of guidelines for lodging a complaint for industry complainants and non-industry complainants. Complaints from non-industry complainants are not required to identify sections of the Code. In this case the TGA identified what they considered to be relevant sections having reviewed the healthcare professional's complaint. These documents are available on the Medicines Australia website.

The Committee was of the view that a review of the complaint should proceed.

Pill for PMS relief on Today Show (Channel 9)

The Committee noted the advice provided by Bayer that they had no connection whatsoever with the segment. The company did not pay, conduct, support or provide any material to Channel 9 and Bayer was not approached directly by Channel 9. It was further noted that Channel 9 contacted the company's PR agency and was advised to contact the Family Planning Association (FPA). The healthcare professional who

participated in the show was an expert in sexual health and is a spokesperson for the FPA; and was not paid by Bayer and Bayer had no commercial or contractual or other relationship with her in relation to the Channel 9 segment.

As part of the launch of Yaz, Bayer instructed their PR agency to brief a number of Key Opinion Leaders in the field on this new treatment. The brief stated the approved indications and specifically the reference to *"treatment of symptoms of a severe form of PMS, premenstrual dysphoric disorder (PMDD) in women who have chosen an oral contraceptive as their method of birth control"*. The speaker on the Channel 9 segment was one of these experts. Members were also informed by the TGA representative that the TGA had in fact encouraged Bayer to develop a comprehensive education program in association with the launch of Yaz in Australia to ensure patient understanding and compliance.

Members noted that the healthcare professional had been a speaker at Bayer educational events (and may have also conducted training for other pharmaceutical companies); however this speaking engagement on Channel 9 had no relationship with these activities.

The Committee was of the view that as Bayer did not pay the speaker or have a contractual arrangement for her to present on behalf of the company there was no breach of the Code. Members were of the view that a healthcare professional is entitled to provide their expert opinion and clinical experience when contacted by a media outlet. As the Committee did not have a transcript of the program they were relying on the information provided by the Complainant and Subject Company. However members commented that as the speaker was acting independently there was no need to review a transcript.

One member of the Committee was of the view that the speaker had a relationship with the company by being briefed by the company before being quoted in the company's media release and was concerned that the company was using the

healthcare professional to promote on their behalf.

In a majority decision the Committee found no breach of Sections 1.3, or 1.3.1 of the Code. Members were of the view that Sections 1.9, 1.10 and 3.10 did not apply to this complaint.

In relation to the matter of disclosure it was noted that the Code of Conduct has no jurisdiction over healthcare professionals, however Committee members and Medicines Australia supports the disclosure of any sponsorship or funding of a healthcare professional by a pharmaceutical company when presenting on behalf of a company or for a company.

Members commented that from the information provided by the complainant and the subject company this was not an advertisement by a pharmaceutical company. If the information provided by an independent healthcare professional is misleading it is not the responsibility of the Code of Conduct Committee to make a finding.

New help for PMS on Sunrise (Channel 7)

On the basis of the information provided by Bayer that at no time prior to the production of this segment was Bayer or their PR agency approached by Channel 7 and that Bayer had no knowledge of the segment and had not heard of the presenter or had any contractual, commercial or other type of relationship with the speaker, the Committee found no breach of Sections 1.3, or 1.3.1 of the Code. Members were of the view that Sections 1.9, 1.10 and 3.10 did not apply to this complaint.

More information on Yaz, PMS & PMDD

Yaz website www.yaz-us.com

The Committee noted that the website was not referred to by Bayer in their media release and was not controlled by Bayer Australia.

In a unanimous decision the Committee did not find a breach of Sections 1.3, or 1.3.1 of the Code. Members were of the view that Sections 1.9, 1.10 and 3.10 did not apply to this complaint.

Allegation that Premenstrual Dysphoric Disorder (PMDD) is not included in the latest edition of Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)

Members of the Committee advised that PMDD is included in the manual and found no breach of Sections 1.3, or 1.3.1 of the Code. Members were of the view that Sections 1.9, 1.10 and 3.10 did not apply to this complaint.

Duromine 1003

Subject Company: iNova

Complainant: Healthcare Professional

Product: Duromine

Complaint

The complainant stated that a promotional piece for Duromine is misleading due to the omission of results from the comparable placebo group over the same period.

Sections of the Code

Materials alleged to be in breach of the following Section of the Code:

- 1.1 Responsibility
- 1.2 Substantiating Data
- 1.3 False or Misleading Claims

Response

iNova stated that the results are an accurate calculation and clinically meaningful and relevant to clinical practice that is consistent with the approved indication as a short term adjunct in combination with a 1000 calorie restricted diet.

Code of Conduct Committee determination

- In a unanimous decision the Committee found no breach of Sections 1.1, 1.2 or 1.3 of the Code.

Consideration of the complaint

In 12 weeks, patients on Duromine 30mg* achieved a mean weight loss of 9.2kg (*Plus 1000 calorie diet).

The Committee referred to the referenced paper and noted the results:

- 12.2kg - continuous treatment with phentermine (Duromine)
- 13.0kg - intermittent treatment with phentermine (Duromine)
- 4.8kg - placebo
- 9.2kg is the mean weight loss for patients on Duromine therapy and dietary restriction.

The Committee was of the view that the claim was not misleading and as the claim reflected the study outcomes and there was no requirement to subtract the weight loss

attributed to placebo. The material clearly indicated that the weight loss was in association with dietary restriction and was not making a comparison to any other treatment.

In a unanimous decision the Committee found no breach of Sections 1.1, 1.2 or 1.3 of the Code.

Crestor 1004

Subject Company: AstraZeneca

Complainant: Pfizer Australia (Pfizer)

Product: Crestor

Complaint

Pfizer stated that the promotional materials contain a number of misleading claims of efficacy and tolerability, and misleading and poorly supported comparisons with Lipitor. Pfizer expressed concern that there had been repeated attempts over several months to try and resolve the issues and obtain data from AstraZeneca.

Sections of the Code

Materials alleged to be in breach of the following Section of the Code:

- 1.1 Responsibility
- 1.2 Substantiating Data
- 1.3 False or Misleading Claims
- 1.7 Comparative Statements

Response

AstraZeneca stated that they had made every effort to engage with Pfizer to understand and address its concerns. In AstraZeneca's view, following the intercompany meeting Pfizer made no genuine effort to engage in further intercompany dialogue. AstraZeneca is of the view that Pfizer is asking the Committee to consider a complaint in circumstances where intercompany dialogue has been prematurely stopped and to bring a complaint in such an instance is arguably an abuse of the Code.

AstraZeneca believes that the data presented is an accurate representation of the study and that it is fundamental to the principles of the Quality Use of Medicines that healthcare professionals are able to compare the ability of low and commonly prescribed statins to achieve lipid targets.

Code of Conduct Committee determination

- *Inappropriate choice of Lipitor dose for comparison with Crestor 10mg* - In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 of the Code.

- *Inappropriate comparison between Crestor and Lipitor on a milligram per milligram basis* - In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 of the Code.
- *Selective citation of data* - In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 of the Code.
- *Misleading graphical presentation of data* - In a unanimous decision the Committee found a breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code.
- *Claim of superiority in contradiction of Crestor PI* - In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 and no breach of Sections 1.1 and 1.2 of the Code.
- *Unsubstantiated claim of efficacy* - In a majority decision the Committee found no breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code.
- *Failure to provide reference source* - In a majority decision the Committee found a breach of Section 1.2 of the Code.
- *Unsubstantiated and misleading claim of assurance* - In a majority decision the Committee found a breach of Section 1.1 and 1.3 of the Code and no breach of Section 1.7 of the Code.
- *Misleading safety claim of low potential for interactions for Crestor* - In a majority decision the Committee found a breach of Section 1.1 and 1.3 of the Code and no breach of Section 1.7 of the Code.
- *Misleading comparative table between Crestor and other statins* - In a majority decision the Committee found a breach of Section 1.1 and 1.3 of the Code and no breach of Section 1.7 of the Code.
- *Crestor raising HDL-C beyond LDL-C* - In a borderline majority decision the Committee found no breach of Sections 1.2 and 1.3 of the Code.
- *Crestor raising HDL-C beyond LDL-C and accompanying graph* - In a majority decision the Committee found a breach of Sections 1.1, 1.2 and 1.3 of the Code.

Consideration of the complaint

Prior to reviewing the individual claims alleged to be in breach of the Code the Committee considered the allegations by AstraZeneca that Pfizer is asking the Committee to consider a complaint in

circumstances where intercompany dialogue has been prematurely stopped and to bring a complaint in such an instance is arguably an abuse of the Code.

Members were of the view that the Code does not specify how many face-to-face meetings or teleconferences the two parties must undertake in an effort to resolve a complaint. The Code states *“Dialogue between the Subject Company and the Complainant should be meaningful with a willingness from both companies to consider each others position and concerns.... Medicines Australia will not accept a complaint from a company unless it has been clearly demonstrated that inter-company dialogue has taken place and that, despite every effort on the part of the Complainant and Subject Company, resolution of the matter has not been achievable.”* It is difficult for the Committee to resolve whether there has been a genuine attempt as they are not present at the meetings. While intercompany dialogue is a requirement members were of the view that it is not mandated how many meetings must occur and if one party is of the view that the other is attempting to draw out the process or it is not likely that there will be a resolution after two meetings it would be acceptable to bring the matter before the Code Committee. Members concurred that this complaint should proceed.

Inappropriate choice of Lipitor dose for comparison with Crestor 10mg

In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 of the Code for the following reasons.

- The comparison of Crestor 10mg to Lipitor 10mg and 20mg has the potential to mislead unless there is clear explanation about the basis of comparison. In this promotion, the basis for the comparison of Crestor 10mg with Lipitor 10mg and 20mg lacked adequate explanation and justification to the reader and was thus inappropriate. The evidence, as supported by the PBAC, is that the ratio of equi-effective doses of rosuvastatin to atorvastatin is of the order 1:3 (greater than 1:2 but probably less than 1:4). While rosuvastatin may be more potent on a mg per mg basis this does not establish that it is more effective than atorvastatin in doses

approved and recommended in clinical practice.

Inappropriate comparison between Crestor and Lipitor on a milligram per milligram basis

In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 of the Code for the reasons outlined above.

Selective citation of data

In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 of the Code for the following reasons.

- Referenced study - not pristine patients and patients were moved between therapies and the results were difficult to compare.
- Reference includes results at 8 weeks and 16 weeks. The selective use of the results (8 weeks only) does not provide the reader with a complete picture of the study outcomes and was therefore considered misleading.

Misleading graphical presentation of data

In a unanimous decision the Committee found a breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code for the following reasons.

- If the data are not designed for statistical comparison then it should not be presented in the form of a comparative graph.
- In one line a range of doses (for example 10 - 80mg or 5 - 40mg) are included therefore a reader cannot determine where the effect took place.
- In association with the claim the graph leads a reader to the view that Crestor has greater tolerability than other statins.

Claim of superiority in contradiction of Crestor PI

In a unanimous decision the Committee found a breach of Sections 1.3 and 1.7 and no breach of Sections 1.1 and 1.2 of the Code for the following reason.

- The manner in which the information is presented does not provide a true reflection of the increased incidence of adverse events with increasing dose.

Unsubstantiated claim of efficacy

In a majority decision the Committee found no breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code for the following reasons.

- The claim of tolerability with other statins and manner in which the information is presented is consistent with the literature.

Failure to provide reference source

In a majority decision the Committee found a breach of Section 1.2 of the Code for the following reasons.

- Where a company references data on file it should be accessible to a healthcare professional or complainant where these data may form part of the complaint.
- The Committee also stated that it would have been useful to them when considering this complaint.
- The data being too difficult to access is not acceptable once a breach of the Code has been raised.

Unsubstantiated and misleading claim of assurance

In a majority decision the Committee found a breach of Section 1.1 and 1.3 of the Code and no breach of Section 1.7 of the Code for the following reasons.

- While it may be correct that Crestor has a low potential for interactions with drugs metabolised via CYP 450 3A4; the way in which the information is presented is misleading as it is presenting a selective position of a complex area of clinical pharmacology.

Misleading safety claim of low potential for interactions for Crestor

In a majority decision the Committee found a breach of Section 1.1 and 1.3 of the Code and no breach of Section 1.7 of the Code for the following reasons.

- While it may be correct that Crestor has a low potential for interactions with drugs metabolised via CYP 450 3A4 the way in which the information is presented is misleading as it is presenting a selective position of a complex area of clinical pharmacology.

Misleading comparative table between Crestor and other statins

In a majority decision the Committee found a breach of Section 1.1 and 1.3 of the Code and no breach of Section 1.7 of the Code for the following reasons.

- While it may be correct that Crestor has a low potential for interactions with drugs metabolised via CYP 450 3A4 the way in which the information is presented is misleading as it is presenting a selective position of a complex area of clinical pharmacology.

Crestor raising HDL-C beyond LDL-C

In a borderline majority decision the Committee found no breach of Sections 1.2 and 1.3 of the Code for the following reasons.

- The Product Information notes in the Clinical Trials Section that Crestor not only reduces total cholesterol, LDL-C, ApoB, non-HDL-C and TG, but also increases HDL-C.
- HDL-C level of greater than 1.0mm/L is a treatment target recommended by the National Heart Foundation of Australia, achieving this target is clearly of benefit.
- For completeness, the members who were of the view that this was in breach of the Code commented that while raising HDL-C was important there was insufficient evidence to support a claim that the benefit is solely related to raising HDL-C.

Crestor raising HDL-C beyond LDL-C and accompanying graph

In a majority decision the Committee found a breach of Sections 1.1, 1.2 and 1.3 of the Code for the following reason.

- The claim and graphs are in breach as the Committee were of the view that the presentation was misleading and the heading did not have anything to do with the graph.

Sanctions

Having found several breaches of the Code the Committee considered what sanction/s should be imposed. The Committee determined that AstraZeneca should:

- Withdraw all materials containing claims found in breach of the Code and not use again or in a manner which conveys the same or similar meaning.
- Send a corrective letter to all general practitioners. The corrective letter to be approved in writing by the Chairman of the Code of Conduct Committee. The text of the corrective letter must be in a font of no less than 12 point. Medicines

Australia must receive documentary evidence of the distribution of the corrective letter and the Secretary of the Code Committee must be included on the mailing list for the letter. The corrective letter must be issued within 30 calendar days of receipt of the minutes detailing the decision.

- Pay a fine of \$100,000

Appeal

AstraZeneca lodged an appeal arguing that there is compelling corroborating material and independent expert evidence which, when considered, should confirm the validity of AstraZeneca's claims.

AstraZeneca also stated that Pfizer had artificially expanded the number of alleged breaches by subtle repetition of very similar claims in certain areas. This created false impressions and had led the Code Committee into error in both their assessment of the promotional material and in the sanctions imposed.

It was also reasserted that, contrary to the intention and spirit of the Code, Pfizer had prematurely curtailed intercompany dialogue.

Response to the appeal

Pfizer endorsed the determinations of the Code Committee and the sanctions imposed and noted that on two separate occasions in the last two years AstraZeneca had been found to have significantly misrepresented Crestor's efficacy and safety profiles compared to those of Lipitor.

Pfizer also asserted that no substantial new arguments had been advanced by AstraZeneca in its appeal to justify overturning the Code Committee's ruling.

Appeals Committee determination

AstraZeneca's appeals in relation to the findings of the Code of Conduct Committee were not upheld except for one aspect of the complaint. The complaint in relation to "*Inappropriate choice of Lipitor dose for comparison with Crestor 10 mg*" was found by the Appeals Committee, by a majority decision, not in breach of the Code. However, the promotional materials to which this claim related were confirmed as

being in breach of the Code by reason of the other complaints relating to the same materials.

The sanctions imposed by the Code of Conduct Committee (withdrawal of all materials containing claims found in breach of the Code and to not use them again or in a manner that conveys the same or similar meaning; pay a fine of \$100,000; issue a corrective letter to all GPs) were not changed.

Consideration of the appeal

Prior to consideration of the appeal, the Chairman asked the Committee members to disclose any potential conflicts of interest. There being no conflicts of interest declared the meeting proceeded.

Members of the Committee were introduced to the company representatives.

The Chairman outlined the procedures for the meeting. Company representatives were asked to keep their presentations to 30 minutes, concentrate on the salient points and respond to any questions from the Committee.

The Chairman noted that both companies had submitted new evidence in support of their positions - expert opinions that had been prepared since the Code Committee determined the complaint. The Chairman advised that the Committee would accept the new evidence and consider whether it should be taken into consideration when making their determination.

The Chairman asked that both companies briefly retire from the meeting to allow a closed session discussion of procedural issues by Committee members.

The following summarises the appeal arguments presented by AstraZeneca.

AstraZeneca appealed the Code Committee's decision on three main bases:

1. There were no findings by the Code Committee that any of the claims made in AstraZeneca's promotional material were false. AstraZeneca's promotional claims are current, accurate and balanced; do not mislead; properly reflect the body of scientific evidence;

and are factual, fair and capable of scientific evidence.

2. The alleged breaches were artificially inflated and multiplied by the use of subtle variations of the same complaint, giving the impression that AstraZeneca had breached the Code on more occasions than it actually had.
3. The complaint was forwarded to MA without a genuine attempt by Pfizer to resolve the issues at Intercompany Dialogue. AstraZeneca had offered concessions to Pfizer that were ignored.
 - 22 studies have compared Crestor 10 mg to Lipitor 10 mg and 20 mg and AstraZeneca has faithfully presented the results of these studies.
 - The intention of the Crestor promotional materials was to provide general practitioners with comparable information about commonly prescribed starting doses of statins and their relative success in getting a patient to achieve lipid targets.
 - The comparison between products is both appropriate and valid. It is fundamental to the Quality Use of Medicines that healthcare professionals are able to compare the ability of low and commonly prescribed starting doses to achieve established lipid targets. Two thirds of the general population commenced on statins are initiated on doses of Crestor 10 mg or Lipitor 10 mg and 20 mg. These starting doses are consistent with the Crestor and Lipitor Product Information.
 - AstraZeneca's promotional claims are not about the relative potency of the two products being compared. They are about the percentage of patients achieving lipid targets at low, commonly prescribed statin starting doses.
 - Pfizer's disparagement of AstraZeneca's independent experts' evidence is unfounded and inappropriate - all of AstraZeneca's experts are highly credentialed, eminent in their field and provided their opinion independently. These experts consider that the comparisons presented in the

Crestor promotional materials were relevant to general practice and consistent with the body of evidence.

- The Code Committee had relied on a dose relativity of 1:3 determined by the Pharmaceutical Benefits Advisory Committee (PBAC). While the PBAC has an important role in determining relative potency for pricing purposes, this relativity is not relevant to every day clinical practice. The materials are not about relative potency but the percentage of patients on commonly prescribed starting doses that achieve lipid targets. There is only one published study that compares Crestor 10 mg with Lipitor 40 mg whereas 22 of 25 published studies used Crestor 10 mg and Lipitor 10 mg and 20 mg. AstraZeneca asserts that the choices of comparator doses were appropriate and consistent with the body of evidence. The claims were not comparing Crestor and Lipitor on a milligram for milligram basis.
- The Schuster (Mercury 1) study was not selectively cited. AstraZeneca described the study methodology - a simple two arm study; the first 8 weeks was a head to head comparison of various statins in patients who had not previously taken a statin (the secondary endpoint - head to head comparison of monotherapy with different statins); in the second 8 weeks subjects were either switched to rosuvastatin or remained on their initial treatment (the primary endpoint - the proportion of patients who met their lipid targets at 16 weeks). Only the secondary endpoint was presented in the Crestor materials. An expert biostatistician has provided an opinion that the first 8 weeks of the study was a valid comparison of statin monotherapy. The study was not powered to make a comparison between statins at end of the 16 week study. AstraZeneca's presentation of the Schuster study data was not misleading.

- Pfizer has artificially inflated the number of alleged breaches by repetition. AstraZeneca agrees with Pfizer's acknowledgement that the complaints can be grouped into four main areas of complaint.
- Pfizer inappropriately truncated intercompany dialogue through its desire to submit a complaint before the cut-off date. Pfizer did not accept any of AstraZeneca's offers to withdraw the materials.
- AstraZeneca argued that the Appeals Committee should overturn the Code Committee's findings.

The following summarises the response to the appeal by Pfizer:

- Three independent experts have supported AstraZeneca's approach. However, their Key Opinion Leaders (KOL) are not experts in general practice. Other KOLs take opposing views, such as those cited by Pfizer. Expert opinion varies. Hence the low ranking of "opinion" in the hierarchy of evidence.
- Pfizer did not artificially expand the number of complaints. Previous experience suggests that small sub-points in a complaint tend to get ignored in corrective action. Graphs used by AstraZeneca in the latest Crestor materials have been found in breach before on four occasions but continue to be used. The dataset has not changed; the manner in which the data were presented has not changed.
- Pfizer did not prematurely stop inter-company dialogue
 - Pfizer submitted the complaint to Medicines Australia two and a half months after the initial letter to AstraZeneca - this was not premature.
 - AstraZeneca waited one month after the face to face intercompany meeting before responding - at 7pm on the day before cut-off for the December Code meeting. AstraZeneca's response did not answer Pfizer's concerns.
 - The effects of AstraZeneca's miscommunication about Crestor continue, five months later.

- In the past two years, AstraZeneca has been found to have breached the Code of Conduct on three occasions relating to its promotion of Crestor's efficacy and safety profile.
- Pfizer is most concerned that this repetitive pattern of breaches continues to disparage Pfizer's product, despite multiple Medicines Australia rulings against AstraZeneca.
- In the latest complaint (1004), 11 of 13 AstraZeneca claims were found to be in breach of the Medicines Australia Code of Conduct. All efficacy comparisons were found in breach by unanimous decision, as were all the complaints related to the comparable tolerability graphs.
- Pfizer maintained that misleading efficacy comparisons were drawn between the products on a mg for mg basis. The PBAC evaluates cost and effectiveness of drugs and has determined a dose relativity of 1:3 for the two products. The National Prescribing Service (NPS) also notes dose relativities of 1:3. This relativity was not used in AstraZeneca's comparative materials.
- Pfizer does not oppose dose comparisons, but believes appropriate doses should be compared. Crestor 10 mg should be compared with Lipitor 30 mg. If the comparison is about low starting doses, why are there no claims in relation to a dose of 5 mg Crestor, which is the lowest dose according to the Crestor PI?
- Pfizer considers that AstraZeneca's comparisons between Crestor 10 mg and Lipitor 10 mg and 20 mg exaggerate the efficacy of Crestor and mislead prescribers, to the detriment of patients. The Code of Conduct Committee findings should therefore stand.
- The data used in the tolerability comparative graph came from different studies, conducted over different time points, which is contrary to a basic scientific principle to compare "head to head". Combining data from separate studies on a single graph breaches scientific convention, is extremely misleading, is contrary to the Code of Conduct and is not permissible.

- Use of this graph with a different headline, claiming 'favourable risk benefit', was previously found in breach of the Code. Only at this appeal has AstraZeneca offered to 'replace the graph' however Pfizer believes these concessions are too little, too late. Detailed and specific information correcting the misleading information about Crestor tolerability needs to be communicated to GPs. Pfizer then proposed what should be included in a corrective letter.
- In response to a question from the Appeals Committee, Pfizer explained that it had considered whether the continued use of the tolerability graph was a repeat breach. It accepted that the previous ruling encompassed the graph and associated text and footnote; however the findings of the Code Committee remain relevant to the current use of the graph.

The following summarises the points made by AstraZeneca in its reply to Pfizer's presentation:

- The tolerability graph has never been found in breach of the Code; only when associated with certain claims, which have been changed in the current Crestor materials. There was debate about the data included in the graph. The therapeutic expert member of the Appeals Committee explained that the data presented was a cross-study comparison which was published in conference proceedings as a supplement. These data have not been published in a peer reviewed publication.
- In relation to the Schuster et al study, the presented data were those most relevant to general practice. The study was well designed; the primary end point was met; AstraZeneca presented the secondary endpoint results as these were most relevant to GPs. AstraZeneca continued to assert that the presentation was not false or misleading.

AstraZeneca tabled a meta-analysis comparing the risks and benefits of rosuvastatin and atorvastatin by Wlodarczyk et al. Pfizer argued that it had not been

provided with this publication nor had a chance to respond to it.

The Chairman thanked representatives from both companies for their presentations and asked that they leave the meeting to allow the Committee to deliberate on the matters before them.

The Committee noted that the Wlodarczyk et al paper was published in December 2008. As this was not published at the time the promotional material subject to the complaint was in use and Pfizer had not had the opportunity to respond to this paper the Appeals Committee determined to disregard it when making its determination.

The Appeals Committee then considered the substance of the complaint.

On the matter of the weight that should be given to the expert evidence submitted by both companies, the Appeals Committee noted that experts will have a range of experiences and may not all agree on an issue. While members agreed that healthcare professionals may provide their opinion on an issue, it is only opinion. The Committee must take into account all the evidence presented to it and not be overly persuaded by testimonial evidence.

Determination

Group 1: Efficacy of Crestor in reducing LDL-cholesterol, compared to Lipitor

Inappropriate choice of Lipitor dose for comparison with Crestor 10 mg

In a majority decision the Appeals Committee upheld the appeal, determining there had been no breach of Sections 1.3 and 1.7 of the Code in relation to the choice of starting doses for comparison.

The Committee accepted that the data presented by AstraZeneca on the usual starting doses of Crestor and Lipitor were consistent with the statin doses most commonly initiated by GPs. Members commented that the HIC data presented by Pfizer is likely to have been skewed by patients initiated on Lipitor 40 mg in hospital and continuing on this higher dose on discharge, the first prescription dispensed under the PBS. The Committee therefore accepted that a comparison between the

starting doses of Crestor 10 mg and Lipitor 10 mg and 20 mg may be appropriate.

However, the promotional materials to which this claim related were confirmed as being in breach of the Code by reason of the other complaints relating to the same materials.

The Committee agreed that the dose of 5 mg of Crestor was in special populations requiring a very low starting dose and was not commonly used.

Inappropriate comparison between Crestor and Lipitor on a milligram per milligram basis
In a majority decision the Appeals Committee did not uphold the appeal (breach of Sections 1.3 and 1.7 of the Code remain).

The Committee considered that, if a comparison were to be made, Crestor 10 mg dose should be compared with both the most commonly prescribed doses and equipotent doses. Rosuvastatin and atorvastatin are not equipotent. The PBAC has determined a relativity of 1:3 for Crestor: Lipitor. The Appeals Committee agreed with the reasoning of the Code Committee - there was insufficient explanation about the basis for the comparison of efficacy between Crestor 10 mg and Lipitor 10 mg and 20 mg in the promotional materials. It was not clear to a reader that the efficacy comparisons were not between the generally accepted equipotent doses of the two medicines. The promotional materials incorrectly gave the impression that it was reasonable to compare the efficacy of 10 mg Crestor with 10 mg or 20 mg atorvastatin, and were therefore misleading.

The Appeals Committee noted that the comparison between Crestor and Lipitor on a milligram per milligram basis appeared in five different promotional pieces, as detailed in the original complaint.

Selective citation of data

In a unanimous decision the Appeals Committee did not uphold the appeal (breach of Sections 1.3 and 1.7 of the Code remains).

The Appeals Committee agreed with the Code Committee that AstraZeneca had selectively presented the results of the

Schuster et al study. It had selectively chosen the data that suited its purpose in claiming that more patients reach target lipid levels with Crestor, but this comparison was not on the basis of equipotent doses. Although the Schuster study was designed to evaluate the proportion of patients reaching target on the starting doses, the study design and purpose were not clear to a reader and therefore a reader could not properly evaluate the basis for the claims. In the absence of an explanation of these matters the promotional materials were misleading.

In failing to communicate the primary endpoint, 16 week data and solely communicating the secondary endpoint, 8 week data the promotional materials were misleading. The difference between Crestor and atorvastatin at the 8 week study point was not maintained at the 16 week point, but this was not communicated to a reader. The Appeals Committee also noted that the promotional materials did not refer to the other statin treatments included in the study, which was also unbalanced in its presentation of the study.

Group 2: Safety and tolerability profile of Crestor

Misleading graphical presentation of data

In a unanimous decision the Appeals Committee did not uphold the appeal (breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code remains).

The Appeals Committee agreed with the reasoning of the Code Committee. The graphical presentation of the data, which are from different studies over different time periods, on a single graph is misleading. Although there was a qualifying statement below the graph that "the data are not designed for statistical comparison", this does not resolve the misleading comparative presentation. The Committee agreed that the validity of the comparison had not been peer-reviewed but had been presented by AstraZeneca to the US FDA. A similar graph had been published in peer reviewed journals but the original data have not been published or peer reviewed.

Failure to provide reference source

In a unanimous decision the Appeals Committee did not uphold the appeal (breach of Section 1.2 of the Code remains).

The Appeals Committee agreed with the Code Committee that the inability or unwillingness of AstraZeneca to provide sufficient source information to allow another company to evaluate the validity of the data and associated claim was a breach of Section 1.2 of the Code. As the graph was based, in part, on data on file, the company is expected to be able to provide the data to a person or company that requests it. "Data-on-file" was expressly mentioned in section 1.2.1 of the Code and, if a Company chose to rely on it, it must be prepared to make it available in accordance with that section.

Unsubstantiated and misleading claim of assurance

In a unanimous decision the Appeals Committee did not uphold the appeal (breach of Section 1.1 and 1.3 of the Code remains); and

Misleading safety claim of low potential for interactions for Crestor

In a unanimous decision the Appeals Committee did not uphold the appeal (breach of Section 1.1 and 1.3 of the Code remains).

The Appeals Committee agreed with the Code Committee. It considered that the claim "Crestor assurance through low potential for interactions" was misleading because it was based solely on metabolism by the CYP450 3A4 enzyme and did not take into account other mechanisms for drug interaction. The table presenting the comparison between Crestor, atorvastatin, simvastatin and pravastatin was an oversimplification of the complex area of drug metabolism.

Misleading comparative table between Crestor and other statins

In a unanimous decision the Appeals Committee did not uphold the appeal (breach of Section 1.1 and 1.3 of the Code remains).

In addition to the reasons stated above, in relation to the complaints concerning the drug interactions comparison, the Appeals

Committee considered that whilst the position stated in the table might be technically correct, the selective basis for the comparison in the context of a claim of 'assurance' of a low potential for interactions was misleading and in breach of the Code.

Group 3: Crestor's clinical benefits obtained by elevating HDL-cholesterol

Crestor raising HDL-C beyond LDL-C and accompanying graph - In a unanimous decision the Appeals Committee did not uphold the appeal (breach of Sections 1.1, 1.2 and 1.3 of the Code).

The Appeals Committee agreed with the Code Committee that the claim in association with the graph was misleading. It also agreed that the claim of clinical benefit in coronary heart disease from Crestor's effects on LDL-C on HDL-C could not be substantiated. The Committee noted that AstraZeneca had offered to not represent these data again in future, but AstraZeneca had not conceded that the graph and associated claims were in breach of the Code.

Sanctions

Having upheld only one aspect of the appeal and confirming the decisions of the Code Committee on all other aspects the Appeals Committee reviewed the sanctions imposed by the Code of Conduct Committee.

The Appeals Committee confirmed the sanctions imposed by the Code Committee and determined that AstraZeneca should:

- Withdraw all materials containing claims and graphs found in breach of the Code and not use them again or in a manner which conveys the same or similar meaning.
- Send a corrective letter to all general practitioners. The corrective letter to be approved in writing by the Chairman of the Code of Conduct Committee. The text of the corrective letter must be in a font of no less than 12 point. Medicines Australia must receive documentary evidence of the distribution of the corrective letter and the Secretary of the Code Committee must be included on the mailing list for the letter. The corrective letter must be issued within 30

calendar days of receipt of the minutes detailing the decision.

- Pay a fine of \$100,000.

Appeal Bond

Having not upheld the appeal, the full bond was retained by Medicines Australia.

Servier Campaign 1006

Subject Company: Servier Laboratories (Servier)

Complainant: Boehringer Ingelheim

Product: Coversyl detail aid and medical representatives' conduct in relation to Boehringer Ingelheim product Micardis

Complaint

Boehringer Ingelheim asserted that a coordinated campaign to discredit its product Micardis was being undertaken by Servier through the distribution of misleading and disparaging promotional information for Coversyl communicated to healthcare professionals.

Boehringer Ingelheim further asserted that despite lengthy and extensive communications with Servier, and despite Servier offering multiple changes and withdrawal of materials, Servier continued to contend that it had not breached the Code.

Sections of the Code

Materials and conduct alleged to be in breach of the following Sections of the Code:

- 1.1 Responsibility
- 1.3 False or Misleading Claims
- 1.7 Comparative Statements
- 4.1 Company Representatives
- 4.3 Company Representatives
- 10.8 Discredit to and reduction of confidence in the Industry

Response

Servier responded that it had acted promptly and appropriately in response to Boehringer Ingelheim's concerns and had taken a number of actions to clarify and withdraw relevant materials to eliminate any possibility of ambiguity and had sent a clarification mailing to all general practitioners who had been detailed with the Coversyl aid.

Servier rejected the assertion by Boehringer Ingelheim of a "co-ordinated campaign to disparage Micardis". Servier argued that the visual emphasis on Coversyl, whilst drawing attention to Micardis, does not encourage

inappropriate comparison between studies

in dissimilar populations or conducted with different agents.

Code Committee determination

- In a unanimous decision the Committee found a breach of Sections 1.1, 1.3 and 1.7 of the Code and no breach of Sections 4.1, 4.3 and 10.8 of the Code.

Sanction

- Withdraw materials found in breach of the Code
- Pay a fine of \$100,000

Consideration of the complaint

Issue 1: Page 1 of Coversyl detail aid: EUROPA/TRANSCEND

The Committee noted that the EUROPA and TRANSCEND studies were two separate studies conducted in different patient populations and the design, background therapy and endpoints were different in each study. The Committee also noted that an inclusion criterion for the TRANSCEND Study was patients who were intolerant to ACE inhibitors (such as Coversyl) and that this information had not been included in the detail aid.

While noting Servier's response that the presentation of the studies was not intended to be comparative but rather to provide healthcare professionals with information about recent studies, Committee members were of the view that the presentation in the detail aid, which included a tick for EUROPA/Coversyl and a cross for TRANSCEND/Micardis, invited comparison between the studies and outcomes for Coversyl and Micardis which was misleading because it implied that the two studies were comparable and failed to disclose that the TRANSCEND study was conducted in patients unable to tolerate ACE inhibitors such as Coversyl. This was further exacerbated by the prominent statement under the Micardis box "No significant effect".

The Committee also agreed with the Complainant that the heading "Only ACE inhibitors have benefits beyond BP lowering" was misleading, noting that the beta blocker class for example had demonstrated such benefits.

The Committee noted that during intercompany dialogue Servier had agreed to discontinue use of this page of the detail aid.

The Committee was unanimous in its decision that the information presented on page 1 of the Coversyl detail aid was selective, lacked sufficient clarity, was unfairly comparative and misleading and in breach of Sections 1.1, 1.3 and 1.7 of the Code.

Issue 2: Page 2 of Coversyl detail aid "The weight of evidence: trials involving Coversyl versus trials involving ARBs"

As discussed in relation to Issue 1, the presentation of trials was unarguably comparative, but importantly did not provide sufficient information to enable a reader to make an informed prescribing decision. Information such as patient inclusion criteria and study end points had not been included on the detail aid page. Committee members were also concerned that the detail aid implied that the cited studies "involved" Coversyl, whereas for four of the five studies the significant primary outcomes were achieved in patients on combination therapy (Coversyl with another agent - indapamide or amlodipine).

The Committee was unanimous in its decision that the information presented on page 2 of the detail aid was selective, lacked sufficient explanation that the results presented were not for Coversyl as a single therapy was unfairly comparative with other therapies including telmisartan (Micardis) and was misleading. The Committee unanimously determined that page 2 of the aid was in breach of Sections 1.1, 1.3 and 1.7 of the Code.

The Committee noted that Servier had prepared a revised version of page 2 of the detail aid but did not comment on this document as it was not the subject of the complaint.

In relation to the alleged conduct of Servier medical representatives, members were of the view that the conduct of the representatives themselves was not in breach of the Code; however, the information they were communicating to healthcare professionals in the Coversyl

detail aid was in breach. Representatives had been detailing with the item found in breach and the messages picked up in GP Monitor were expected to be part of their training. The Committee did not find a breach of Sections 4.1, 4.3 of the Code.

The Committee did not agree with the complainant that the Servier detail aid would bring the industry into disrepute. Rather it considered that the conduct reflected on Servier alone. The Committee unanimously found no breach of Section 10.8 of the Code.

Sanctions

Having found several breaches of the Code, the Committee considered what sanction/s should be imposed. The Committee considered that the breaches were moderate. The Committee unanimously determined that Servier should:

- Withdraw all promotional materials found in breach of the Code and not use the information again, or in a manner which conveys the same or similar meaning.
- Pay a fine of \$100,000.

The Committee considered whether to require a corrective letter to be sent to all general practitioners. Members were of the view that while Servier did not acknowledge any breach of the Code, it had distributed a clarification letter to healthcare professionals qualifying the information in the detail aid which had now been found in breach. Members were of the view that it may be confusing to GPs to receive a further letter. Members determined that no corrective letter should be required.

Famvir 1008

Subject Company: Novartis Pharmaceuticals

Complainant: Healthcare Professional

Product: Famvir

Complaint

The TGA had been contacted by a pharmacist who complained that a Consumer Medicine Information (CMI) for Famvir 500mg tablet had been published on the MIMS/MyDr website. It was alleged that the CMI included a statement *"Packs containing this dose can be purchased from a pharmacy without a doctor's prescription"*. This is inconsistent with the scheduling of this medicine, which is available only on prescription.

The TGA wrote to Novartis about this matter and submitted a complaint to the Code of Conduct Committee at the same time.

Sections of the Code

Materials alleged to be in breach of the following Section of the Code:

- 9.4 Promotion to the General Public
- 9.6 Use of the Internet
- 9.10 Discredit to and reduction of confidence in the Industry

Response

Novartis stated that the inaccurate statement in the Famvir CMI was an editorial error on the part of a Novartis employee. Novartis asserted that although the incorrect CMI was uploaded for public view onto the MIMS/MyDr website, the correct version had been made available on other websites and in hard copy.

Novartis also stated that it did not intentionally set out to provide an incorrect document or to promote access to the medicine over the counter. Novartis argued it had taken all reasonable steps to remove the incorrect CMI from the MIMS/MyDr website once it became apparent the incorrect document was still being distributed in February 2009.

Code Committee determination

- In a unanimous decision the Code Committee found a breach of Section 9.4

and no breach of Sections 9.6 and 9.10 of the Code.

Sanction

Pay a fine of \$5,000

Consideration of the complaint

The Code Committee reviewed the timeline of activities pertaining to this complaint.

10 November 2008

- The incorrect Famvir CMI was sent by Novartis to the Data Warehouse for distribution to third party publishers.

17 November 2008

- The incorrect statement in the CMI was identified by Novartis following an enquiry from a pharmacist.
- The error was immediately corrected by removing the statement.
- The incorrect CMI was removed from the Novartis website and replaced with the correct version.
- The corrected version of the CMI was sent to the Data Warehouse to replace the previous document.

19 November 2008

- The previous incorrect CMI (dated 5 November 2008) was released to the Healthlinks Data Warehouse by MIMS for on distribution.

2 December 2008

- The corrected CMI (dated 17 November 2008) was released by the Healthlinks Data Warehouse for on distribution.

11 February 2009

- Novartis contacted the editors of MIMS after discovering that the incorrect CMI had not yet been replaced on the MyDr website. Novartis staff were informed by the MIMS/MyDr editorial staff that the corrected CMI had missed the previous update due to tight deadlines associated with the Christmas holiday closures.

13 February 2009

- Novartis personnel contacted the Managing Editor of the MyDr website to request the immediate removal of the incorrect Famvir CMI document. At the same time the company initiated an

investigation into the extent of distribution of this document.

- The CMI containing the incorrect statement was removed from the MyDr site at approximately 5.23pm on Friday 13 February 2009.

17 February 2009

- Novartis confirmed that the corrected version of the CMI appeared on the MyDr website.

Having reviewed the timeline, the Committee was concerned about the time taken by Novartis to follow up on the removal of the incorrect CMI from the MyDr website (17 November 2008 - 11 February 2009). Members were of the view that a company must have internal procedures in place to ensure an error of this type does not occur and also has a responsibility to check that an error is immediately corrected. While acknowledging that a third party was involved in this distribution chain, Novartis was paying the supplier and the company should have identified the urgency of this matter requested immediate action and checked that it had been corrected within a few days (that is in November 2008) rather than wait until February 2009 to check if it had been updated.

Section 9.4 Promotion to the General Public

The Committee was of the view that Novartis should have sufficiently robust internal policies and procedures in place to ensure that a prescription medicine is not advertised as being available as an over-the-counter medicine. In the event of an inadvertent error, immediate action must be taken to correct or amend the activity and this should be followed up by the company to ensure the correction has taken place.

Members acknowledged that if a member of the public had tried to purchase the medicine without a prescription, a pharmacist would have advised that it was available by prescription only. However, it remains a breach of the Code that a prescription medicine was inappropriately promoted to the general public.

In a unanimous decision the Committee found a breach of Section 9.4 of the Code.

Section 9.6 Use of the Internet

The Committee noted that CMIs are provided to Data Warehouse which on-distributes them. Data Warehouse and not the company is responsible for third party's use. The Committee determined that while Novartis had provided the incorrect CMI to Data Warehouse it had not directly placed it on the MyDr website and therefore found no breach of Section 9.6 of the Code.

Section 9.10 Discredit to and reduction of confidence in the industry

The Committee was of the view that this apparently was a genuine error by a staff member and there was no deliberate action to promote a prescription medicine to the general public and therefore found no breach of Section 9.10 of the Code.

Sanction

Having found a breach of the Code, the Committee determined that Novartis should:

- Pay a fine of \$5,000