

# Medicines Australia Code of Conduct Quarterly Report April – June 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 April - June 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.

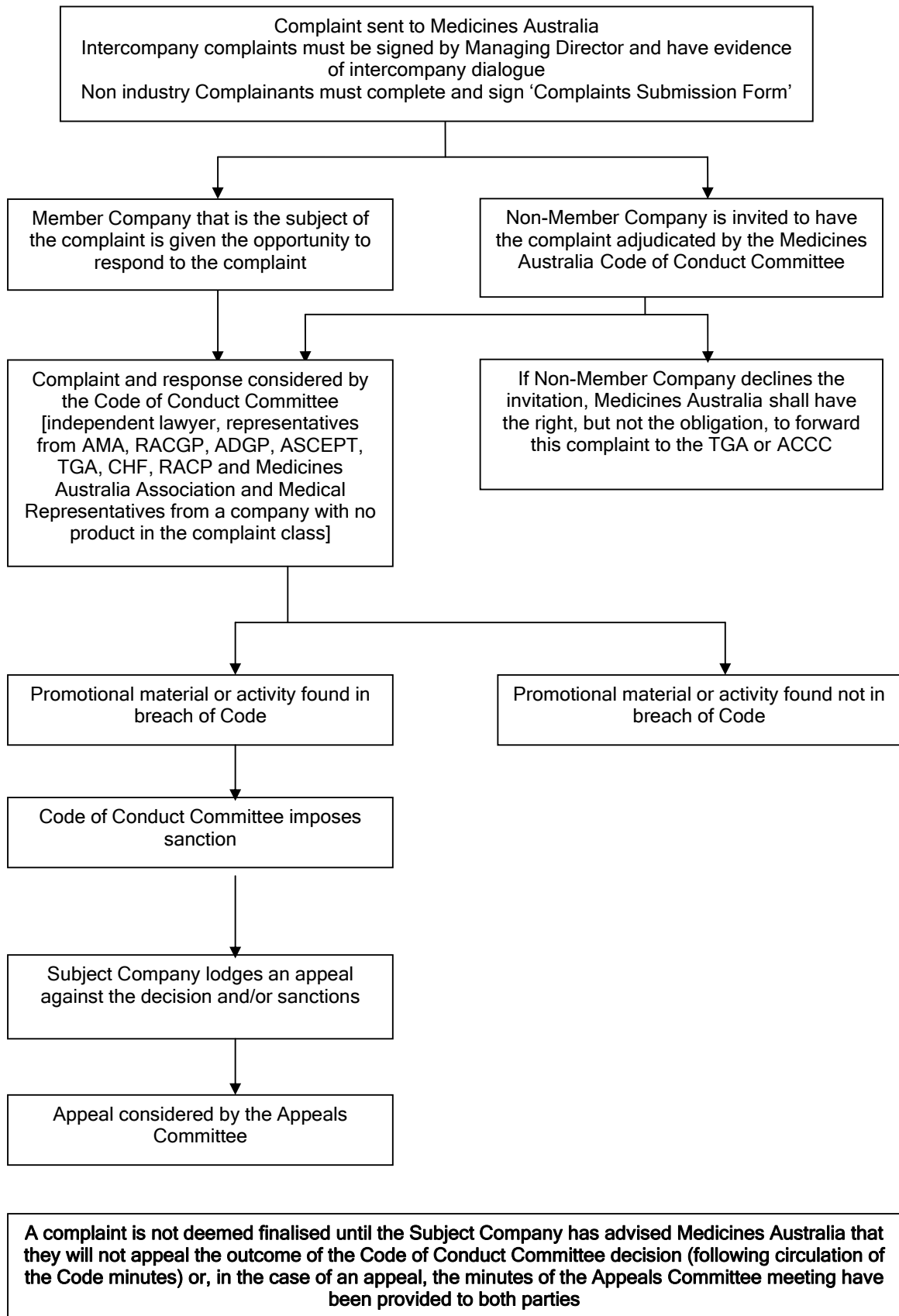
The Code of Conduct and the Guidelines that accompany the Code are available from the website (<http://www.medicinesaustralia.com.au/pages/page16.asp>).

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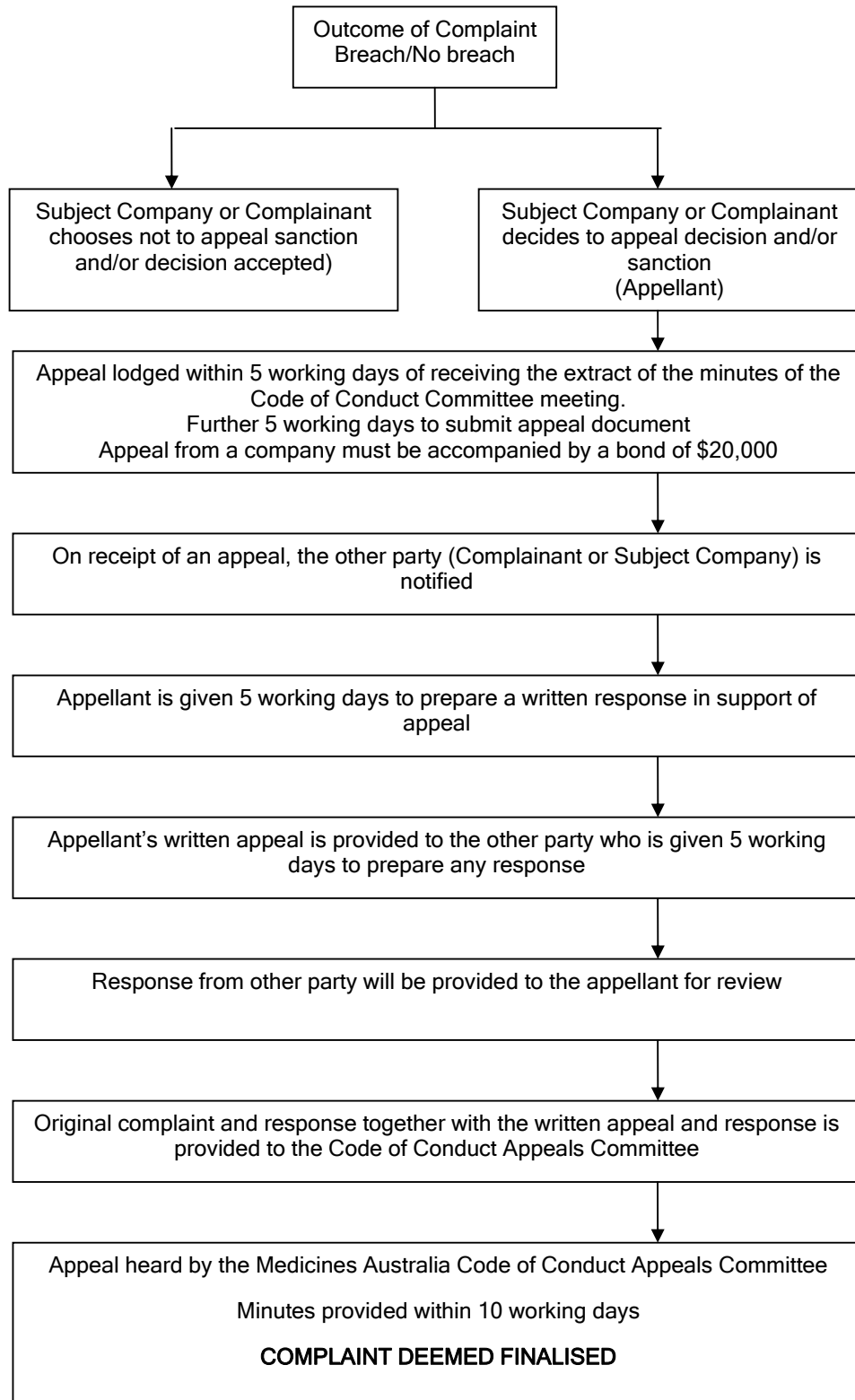
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*Medicines Australia Code of Conduct Complaints Handling Process*



*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 April - June 2009

No.	Subject Company	Material Activity	Product	Complainant	Outcomes*	Sanction
994	Baxter Healthcare	Representative Conduct	Desflurane	Healthcare Professional	1xNo Breach 10.8	
1002	Baxter Healthcare	Representative Conduct	Desflurane	Healthcare Professional	1xNo Breach 9.10	
1010	Sanofi Pasteur	Educational Events	Various	Healthcare Professional	1xNo Breach 6.2, 6.5, 6.8, preamble to 10, 10.2, 10.3, 10.6, 10.6.8, 10.6.11, 10.7, 10.8	
1011	sanofi-aventis	Representative Conduct	Various	Healthcare Professional	1xNo Breach 4.4, 5.1.2, 5.1.5, 5.1.7, 5.1.10, 10.8	
1012	Boehringer Ingelheim	Educational Event	Micare	Division of General Practice	1xNo Breach 6.6, 10.2, 10.8	
1013	AstraZeneca		Nexium	Nycomed	1xBreach 1.1, 1.2, 1.3, 1.5 1xNo Breach 10.8	<ul style="list-style-type: none"> <li>• Fine \$85,000</li> <li>• Withdraw materials</li> <li>• Corrective advertisement</li> </ul>
1014	Pfizer	Promotional Advertisement	N/A	Health Consumers' Council WA	1xNo Breach 9.4, 9.5, 9.10	
1015	sanofi-aventis	Sponsorship	Plavix	Healthcare Professional	1xBreach 7.1.2 1xNo Breach 10.8	<ul style="list-style-type: none"> <li>• Fine \$25,000</li> <li>• Cease promotion of sponsorship</li> </ul>

## Baxter Representative 994 and Baxter Representative 1002

**Subject Company:** Baxter

**Complainant:** Healthcare Professional

**Product:** Desflurane

### **Complaint 959**

The complainant had alleged that a Baxter Representative was observed entering the operating theatre at a Queensland Hospital. The hospital had implemented a policy which does not allow representatives to enter theatres unless there is a clear patient care purpose. This policy was communicated to Baxter prior to this incident. The complainant alleged that the Baxter representative did not have a clear patient purpose and was seeking access to patients. Further it was alleged that the Baxter representative had a responsibility to ensure patient consent had been obtained prior to the representative entering the operating theatre but this did not occur. Therefore Baxter was breaching hospital policy.

### **Code Committee determination pertaining to 959**

In a unanimous decision the Code of Conduct Committee found no breach of Sections 4.4, 4.5 or 10.8 of the Code.

### **Appeal pertaining to 959**

The complainant lodged an appeal in relation to the outcome of complaint 959. Prior to the appeal being determined the healthcare professional lodged a new complaint in relation to the Baxter response to his appeal submission (complaint 994, below).

### **Appeal Committee determination pertaining to 959**

In a unanimous decision the Appeals Committee did not uphold the appeal and confirmed the findings of no breach of Sections 4.4, 4.5 or 10.8 of the Code.

### **Complaint 994**

The complainant alleged that any demonstration or education involving desflurane in a real use setting is an

unlawful activity and any policies to circumvent these laws must be conducted likely to bring the drug industry into disrepute.

### **Sections of the Code**

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

- 10.8 Discredit to and reduction of confidence in the Industry

### **Response**

Baxter referred the Committee to the information provided previously to the Code Committee and Appeals Committee under Complaint 959.

### **Code Committee determination**

In a unanimous decision the Committee found no breach of Section 10.8 of the Code.

### **Consideration of the complaint**

The Committee noted that this complaint had been filed before the appeal in relation to Complaint 959 had been heard and finalised. This new complaint is in relation to the same occasion on which a Baxter representative had attended the hospital and would more appropriately have been put forward as part of the appeal. Members were of the view that the conduct of the representative had already been considered under Complaint 959 and no new issues or evidence had been submitted to the Code Committee in this complaint. The arguments put forward by the complainant in the new complaint do not go further in raising issues that have not already been addressed in complaint 959. The Committee determined that there was no case for finding a breach of Section 10.8 of the Code.

### **Complaint 1002**

The complainant had submitted a new complaint under Section 9.10 of the Code. The complainant asserted that the Baxter representative's presence in the operating theatre was a threat to patient safety. The complainant further asserted that the Baxter representative had failed to respect patient privacy whilst in the operating theatre and had not received appropriate consent from patients who are anaesthetised.

## Response

Baxter had responded to the complaint by referring the Code Committee to the information previously provided to the Code of Conduct and Appeals Committees in relation to complaint 959 and the Code of Conduct Committee in relation to complaint 994.

## Sections of the Code

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

- 9.10 Discredit to and reduction of confidence in the Industry

## Code of Conduct Committee determination

In a unanimous decision the Code Committee found no breach of Section 9.10 of the Code.

## Consideration of the complaint

In relation to the factual scenario that has been presented that a representative entered the operating suite the Committee finds no breach of the Code.

The Committee was of the view that this matter has been the subject of several Code of Conduct Committee meetings and has received exhaustive consideration by the members on each occasion. Although a new section of the Code has been raised on this occasion, the Committee was of the view that when applied to the same fact scenario, no new issues in relation to the Code have occurred for the Committee's consideration. The Code of Conduct Committee has determined that in relation to the set of facts the subject of complaints 959, 994 and 1002, this matter has been finalised. No further correspondence will be entered into on this matter.

Members were of the view that if the complainant has an issue with hospital policy he take this up directly with Hospital Administration.

## Appeals pertaining to complaints 994 and 1002

The complainant lodged appeals in relation to the Code of Conduct Committee's decisions concerning complaints 994 and 1002. The complainant argued that the Code of Conduct Committee had failed to take all aspects of complaint 994 into consideration. In relation to complaint 1002,

the complainant argued that the Code Committee had not undertaken a full and exhaustive review of the complaint.

In its response to the appeals, Baxter Healthcare rejected all statements by the complainant and particularly that Baxter had made a deliberate incorrect statement.

## Appeals Committee determination pertaining to complaints 994 and 1002

In a unanimous decision the Appeals Committee confirmed the decisions of the Code of Conduct Committee to find no breach of Sections 10.8 or 9.10 of the Code.

## Consideration of the appeals

The Appeals Committee heard a short statement from Baxter reiterating the substance of the responses they had made to complaints 994, 1002 and 959. The Chairman thanked the Baxter representative for his attendance and asked that he leave the meeting to allow the Committee to deliberate on the matters before it.

The Appeals Committee reviewed and considered all the correspondence and documentation put before it and the Code of Conduct Committee by both parties, including the letter from the complainant dated 27 March 2009 which was considered to be within the scope of the appeals in relation to complaints 994 and 1002. Having considered all of the evidence the Appeals Committee was not persuaded that the Code Committee's decisions involved an error on the basis of which its decisions in relation to complaints 994 or 1002 should be set aside or varied.

The Committee accepted the explanation that there was no purpose by Baxter Healthcare in any way to administer the drug desflurane to a patient. The two different explanations provided in correspondence from the Baxter Healthcare Managing Director and another Baxter staff member regarding the purpose of the Baxter representative's attendance at the hospital were not mutually exclusive and did not involve any dishonesty by Baxter Healthcare.

The Appeals Committee was satisfied that the subject matter of these complaints had been fully investigated and appropriately

considered and that by way of this appeal this matter is now finalised.

In a unanimous decision the Appeals Committee confirmed the decisions of the Code of Conduct Committee to find no breach of Sections 10.8 or 9.10 of the Code.

## Sanofi Pasteur Travel Medicines Educational Events 1010

**Subject Company:** Sanofi Pasteur

**Complainant:** Healthcare Professional

**Product:** Not applicable

### Complaint

The complainant alleged that Sanofi Pasteur had provided inappropriate travel to a speaker and his family when presenting at Sanofi Pasteur educational events. The complainant had identified that the relevant educational events were a series of meetings on travel medicine held around Australia, including in Newcastle in September 2008.

The complainant also made allegations that Sanofi Pasteur had provided confidential emails to another healthcare professional without the permission of the original author.

Medicines Australia had requested Sanofi Pasteur address the following issues:

- Provide the educational event listing details of all the events described as "Australians Visiting Friends and Relatives Medical Advisory Group" in the period July - December 2008;
- The names of the presenters at each event;
- The speaker costs associated with each event - itemised per event (fee or honorarium paid to speakers; travel costs; accommodation costs);
- The hospitality costs associated with each event for delegates in attendance;
- Respond to the allegation that the speaker's family's travel and accommodation was paid for or subsidised by Sanofi Pasteur;
- Did Sanofi Pasteur provide any emails from the Complainant to Sanofi Pasteur to another healthcare professional; or any other materials or correspondence between the Complainant and the company to the other healthcare professional? Did Sanofi Pasteur consider that such correspondence was confidential between the Complainant and Sanofi Pasteur?

- Was any fee paid or consideration given to the other healthcare professional in respect of his complaint to the NSW Medical Board?

### Sections of the Code (identified by the Secretariat)

- Section 6.2 Hospitality
- Section 6.5 Sponsorship of healthcare professionals
- Section 6.8 Travel
- Section 10 preamble Relationship with healthcare professionals
- Section 10.2 Hospitality
- Section 10.3 Travel
- Section 10.6 (specifically 10.6.8 and 10.6.11) Consultants and Advisory Boards
- Section 10.7 General remuneration; and
- Section 10.8 Discredit to and reduction of confidence in the industry

### Response

Sanofi Pasteur noted that this was the second complaint from this Complainant, with the first being found not in breach of the Code.

The subject of the educational meetings subject to the complaint was travel medicine, particularly in connection with a group of travellers defined in the prevailing medical literature as "visiting friends and relatives" (VFRs). While the meeting was sponsored by Sanofi Pasteur, it had been conducted under the auspice of the Australian Visiting Friends and Relatives Medical Advisory Group (AVMAG) as part of a series of meetings held across Australia to educate healthcare professionals whose patients may seek pre-travel healthcare advice. Current medical opinion is that VFR travellers are generally at higher risk than most other groups of travellers on contracting certain vaccine-preventable diseases.

All remuneration, hospitality, travel and accommodation costs were appropriate and not extravagant and no costs for partners or family were paid for by Sanofi Pasteur.

### Code Committee determination

In a unanimous decision the Committee found no breach of Sections 6.2, 6.5, 6.8, 10

(preamble), 10.2, 10.3, 10.6.8, 10.6.11, 10.7 or 10.8 of the Code.

### **Consideration of the complaint**

The Committee considered the detailed Sanofi Pasteur response in relation to each aspect of the complaint and the accompanying papers, namely:

- Extract from The Australian Immunisation Handbook 9th Edition 2008 (page 75 “Vaccination for International Travel”);
- Visiting Friends and Relatives - A Travel Medicine Resource Kit for GPs (published by AVMAAG and Sanofi Pasteur) and the list of AVMAAG members;
- *Curriculum vitae* for the three presenters;
- National Travel Medicine Conference August 2008 Delegate’s Handbook;
- Emails between Sanofi Pasteur and the presenters; and
- Summary of “Australians Visiting Friends and Relatives” meetings with detailed information pertaining to hospitality and function costs.

### ***Complaint to the NSW Medical Board***

Members stated that matters pertaining to a complaint to the NSW Medical Board were not relevant to the considerations of the Code of Conduct Committee and were not be taken into consideration in this matter.

### ***Confidentiality***

The Committee noted the Sanofi Pasteur reference to “common law obligations of confidentiality are only imposed on a person receiving information if they know, or ought to have known, that the information was being imparted to them in confidence and in respect of which the law would regard as confidential”.

The Committee was of the view that the allegation of a breach of confidentiality was not made out as the complainant had voiced the views expressed in this complaint in public forums, had made these complaints through a public website, and had not requested confidentiality in any correspondence to Sanofi Pasteur. No communication had been sent to people other than the members of the AVMAAG or

presenters, who had been informed of issues arising from the complaint.

### ***Relationship with healthcare professionals*** **Speakers**

Having noted the educational component of the educational events and the *curriculum vitae* of the speakers the Committee unanimously was of the view that there was no breach of Section 6.5 of the Code as there was no evidence that they were not qualified or had sufficient experience to present on this topic.

### **Remuneration**

Members were of the view that the presenters were suitably qualified and experienced and that there was no evidence of any inducement to the speakers to present at educational events sponsored or held by Sanofi Pasteur.

The Committee reviewed the summary table and noted that the honoraria for speakers ranged from \$500 - \$1000 for 1.5 to 3 hour presentations.

The Committee unanimously was of the view that these payments were commensurate with the work performed and found no breach of Section 10 preamble or Sections 10.6, 10.6.8 or 10.6.11 of the Code.

There was also no fee paid to the other healthcare professional in relation to the lodgement of a complaint to the Medical Board of NSW or any involvement by Sanofi Pasteur in this healthcare professional’s complaint to the Medical Board of NSW.

### ***Hospitality***

#### **Provision of food & beverages**

The Committee reviewed the summary table and the hospitality provided to attendees and speakers at the series of educational events. The food and beverage component of the 1.5 - 3 hour educational events ranged from \$37 - \$68 per head with a \$72 per head all day package (morning tea, lunch and afternoon tea) for the 6 hour educational event.

Members were unanimously of the view that the cost of food and beverages was not excessive or lavish and found no breach of Sections 6.2 or 10.2 of the Code.

### Travel

The Committee also noted that, where required, all speakers were provided with economy travel from their city of origin to the city where they were presenting.

Members unanimously were of the view that the travel provided to speakers was consistent with the Code and found no breach of Sections 6.8 or 10.3 of the Code.

### Accommodation

Accommodation costs for speakers ranged from \$174 to \$264 per night depending on the city in which the educational event was held.

Members unanimously were of the view that the cost of accommodation provided to the speakers was not excessive or lavish and found no breach of Sections 6.8 or 10.3 of the Code.

### Partner and family costs

Members also noted the Sanofi Pasteur advice that the company did not pay for any travel or accommodation costs for any family members (extended or otherwise) of any speakers or attendees at any educational events.

The Committee unanimously was of the view that there was no evidence that Sanofi Pasteur had paid or subsidised any costs pertaining to family members of speakers and found no breach of Section 10.7 of the Code.

### Discredit to the industry

Having reviewed the complaint and the response from Sanofi Pasteur, and having found no breach of the Code had occurred; the Committee determined that there was no evidence that Sanofi Pasteur's conduct had brought discredit to the industry. In a unanimous decision no breach of Section 10.8 of the Code was found.

### **Appeal**

The complainant lodged an appeal stating that for Sanofi Pasteur to suggest that they were not aware of any confidential letters concerning the complainant was both preposterous and a poor attempt to hide the truth. The complainant asserted that Sanofi Pasteur had planned and launched a revenge attack on the complainant through a

third party (a complaint lodged with the Medical Board).

The complainant also stated that the spreadsheet of expenditures provided by Sanofi Pasteur was inadequate proof of the company's adherence to the Code. The company should have provided invoices and information from the travel agent describing who travelled and what the costs were.

The complainant also noted that as a non-company complainant the Committee cannot find a breach of the code in relation to a vexatious complaint.

### **Response to appeal**

Sanofi Pasteur rejected all allegations made by the complainant. Specifically the speaker at the educational event has extensive expertise in the field of travel medicine; the member of the AVMAAG wrote to the NSW Medical Board of his own volition; there was no breach of confidentiality; and all expenses pertaining to the educational events has been accurately detailed in the spreadsheet submitted to the Appeals Committee.

### **Appeal Committee determination**

In a unanimous decision the Appeals Committee did not uphold the appeal. The findings by the Code Committee of no breach of Sections 6.2, 6.5, 6.8, 10 (preamble), 10.2, 10.3, 10.6.8, 10.6.11, 10.7 or 10.8 of the Code were confirmed.

### **Consideration of the appeal**

It was noted that the appellant, who is the complainant, had been invited to attend the Appeals Committee meeting and the meeting had been scheduled to accommodate her availability. Subsequently the appellant had advised Medicines Australia that she would not be in attendance. The appellant had submitted an additional written submission to the Appeals Committee, which had also been provided to Sanofi Pasteur.

The following summarises the additional submission from the appellant to the Appeals Committee:

- The person who submitted the original complaint was the practice manager who is also the complainant's husband

who is authorised to respond on her behalf.

- The speaker at the educational event does not seem to have any merit as a speaker on vaccines, infectious diseases or travel medicines. He has no post graduate qualification on his CV and none whatsoever in travel medicine, vaccines or infectious diseases. He flies around the country at high expense to merely read out what Sanofi Pasteur has written for him.
- The receipts for travel expenses do not have the name of any passenger on them and therefore are illegal and not tax office compliant.
- The complainant stated that she wished to appeal the unethical nature of the complaint about her made by Sanofi Pasteur to the NSW Medical Board by paying another healthcare professional to do the dirty work for them. Sanofi Pasteur had released to the speaker and the Medical Board confidential emails sent by the complainant and her husband to Sanofi Pasteur.

The following summarises the appeal arguments presented by the Sanofi Pasteur representative:

Sanofi Pasteur takes its responsibilities under the Medicines Australia Code of Conduct very seriously. It has demonstrated these responsibilities in the following ways:

- Through the thorough and comprehensive manner by which it responded to two complaints lodged against it, as well as this current appeal against the findings for the second complaint.
- Through the presence here today, as Managing Director of Sanofi Pasteur, Australia-New Zealand
- Through his direct involvement and oversight of the estimated 70-80 man hours that has been devoted to preparing the responses.
- By doing all of the above despite the vexatious, groundless, and slanderous accusations that have been asserted by the Complainant; complaints that contain not a shred of truth (as has been borne out by the Code of Conduct Committee on two occasions now);

Sanofi Pasteur further stated that in the additional paper provided to the Appeals Committee the Complainant essentially repeated the same groundless accusations for which the Code of Conduct Committee has already ruled there was no breach of the Code:

- The Complainant alleged that Sanofi Pasteur breached obligations of confidentiality - the Code Committee ruled that no such breach had occurred;
- The Complainant alleged that Sanofi Pasteur had "planned and launched a revenge attack against her" by urging and paying another healthcare professional to lodge a complaint against the Complainant to the NSW Medical Board. This is completely untrue. Sanofi Pasteur neither paid nor urged the healthcare professional to lodge his complaint to the Medical Board;
- The Complainant alleged that Sanofi Pasteur had paid exorbitantly for a healthcare professional and extended family members to travel with him when delivering presentations. Sanofi Pasteur did not pay for family members to accompany the speaker. The accusation is made without any evidence whatsoever. Sanofi Pasteur has provided substantial evidence of expenses incurred in its response to the second complaint, and the Code of Conduct Committee found no breach of the Code. Further evidence of the expenses incurred was submitted in the written response to the Appeal.

In relation to the further accusations raised by the Complainant in her additional correspondence:

- The healthcare professional speaking at the travel medicine educational events is eminently qualified to speak on these topics, as evidenced by his extensive body of work and experiences including:
  - Dozens of presentations at various congresses, during the past twenty years, from the 13th International Congress on Tropical Medicine and Malaria in Dec 1992 in Thailand, to his role as Chair of an International Conference on Travel Medicine in February 2008.

- He is widely published on the topic in peer-reviewed journals and in the lay media.

The Sanofi Pasteur representative left the meeting following this presentation.

The Appeals Committee considered the substance of the appeal.

1. This is an appeal which the Complainant seeks to make against a decision of the Code of Conduct Committee. It appears from a chronology set out in a letter dated 15 January 2009 by a healthcare professional to the New South Wales Medical Board that the Complainant made the initial complaint on the Sanofi Pasteur website shortly after attending a presentation sponsored by Sanofi on 16 September 2008 in Newcastle. The Complainant subsequently sent an email to Medicines Australia which was the foundation of her first complaint (complaint 992). A further email from the Complainant (7 February 2009) was treated as a second complaint and was the subject of the decision from which the appeal is sought to be brought.
2. Sanofi Pasteur expressed concern that the appellant and Complainant were not the same person. The day before the hearing of the appeal, an email was received from the Complainant advising that she had authorised her Practice Manager to make the appeal on her behalf. Further, the letter from the Practice Manager seeks to agitate new issues as well as seeking a review of the decision, or part of the decision, of the Code of Conduct Committee.
3. The second basis on which Sanofi Pasteur seeks to resist the appeal is that it is out of time. It appears that the last date for notification of an appeal by the Complainant would have been 6 April 2009. On this basis, were the appeal otherwise in order, while on a strict view a delay of 2 days would render the appeal incompetent, it might not otherwise stand in the way of the Appeals Committee giving the matter consideration, particularly if the appeal had some prospects of success. It does not appear that Sanofi Pasteur has

incurred any additional prejudice as a result of the 2 day delay and the company has chosen to address the substance of the matters raised by the Complainant in any event. The Code Secretariat advised that due to delays with Australia Post the original Sanofi Pasteur response to the complaint did not reach the complainant for several days. Medicines Australia agreed to an extension to the response time for the complainant.

4. The first matter raised in the appeal is that of confidentiality. The original complaint dealt with by the Code Committee was that Sanofi Pasteur had provided confidential emails, written by the Complainant, to another healthcare professional without the Complainant's permission. It is suggested that Sanofi Pasteur's motivation for doing so was to prevail on the other healthcare professional to make a complaint about the Complainant to the Medical Board. It is not in dispute that on 15 January 2009 the other healthcare professional made such a complaint. Sanofi Pasteur has from the outset denied that they instigated the complaint or that they made any payments to him in connection with it. The Code Committee considered, correctly in the Appeals Committee's view, that matters pertaining to that complaint were not relevant to its considerations. It found that there had been no breach of confidence because the views expressed in the emails were not imparted by the Complainant to Sanofi Pasteur in confidence and had in fact been raised by her in public forums.
5. The appeal does not take issue with this decision. Rather, it takes issue with a submission made by Sanofi Pasteur to the Code Committee that the company was not aware of any confidential letters concerning the Complainant addressed to its Managing Director. The letters in question, which have now been supplied by Sanofi Pasteur are from two individual doctors, addressed to the Managing Director of Sanofi Pasteur. Both doctors were present at the 16 September 2008 meeting (one of these

doctors was the speaker) and the letters provide the doctors' description of what occurred at that meeting relevant to the Complainant's complaint, which in part was critical of the speaker who addressed the meeting. Sanofi's response to the complaint in the appeal is that neither letter contains any information that had been imparted in confidence by the Complainant and that as the speaker was named in the first complaint and two other healthcare professionals, as participants in the series of meetings at which the presentation was being made, had an interest in the matter, it was in order for its Managing Director to make them aware of the Complainant's complaints. The letters were their response to the complaints.

6. The appeal letter seeks to draw a conclusion that Sanofi Pasteur prevailed upon the other healthcare professional to lodge the complaint with the Medical Board. While it is true that a Sanofi Pasteur representative's email to the three doctors invites them to indicate what they propose to do, there is nothing to suggest that, by making that inquiry, Sanofi Pasteur was urging them to make a complaint about the Complainant. The presentations were continuing, and it would be natural for those involved to discuss among themselves the sort of serious allegations about the presentation that the Complainant had made, in order to satisfy themselves whether they had any foundation. It is clear from the two letters that this is what occurred. There is no evidence to suggest that when, some months later, the other healthcare professional made his complaint, he did so at the behest of Sanofi Pasteur. Such a conclusion is denied by Sanofi Pasteur and the correspondence referred to above does not provide any substantiation for the allegation.
7. The matters raised by the appellant therefore provide no basis for disturbing the Code of Conduct Committee's decision that there was no breach of confidentiality by Sanofi Pasteur in relation to the Complainant.
8. The second matter raised in the appeal is that Sanofi Pasteur has not provided adequate proof of its adherence to the Code in relation to travel and accommodation expenditure for the other healthcare professional's attendance at the presentations and to verify that, contrary to the Complainant's allegation, members of the healthcare professional's extended family were not provided with travel and accommodation by the company. The Code of Conduct Committee proceeded on the basis of a summary of speakers' costs in the format specified in the Medicines Australia Code of Conduct Guidelines. Members of Medicines Australia are required to prepare these records and provide them on a periodic basis. This information is then made publicly available on Medicines Australia's website. The form of reporting is that specifically approved by the Australian Competition and Consumer Commission. The Appeal Committee considers that, there being no evidence provided by the Complainant to support her allegations, the summary provided an adequate basis for the Code of Conduct Committee's determination. The company has now provided the supporting invoices which verify the summary. In response to the issues raised in the Complainant's additional information to the Appeals Committee, the Sanofi Pasteur Managing Director tabled tax invoices relating to travel and accommodation for speakers at the educational events. Accordingly, there would be no basis to uphold this part of the appeal.
9. It is clear that Sanofi Pasteur has been required to apply considerable effort and resources to address the original complaint and the matters raised in the appeal letter. The Committee notes that this is not the only complaint against the company by this complainant. The Complainant and her practice manager had originally indicated that they would be present at the appeal, which had been scheduled to accommodate their availability, but in the end had elected not to be present. However, a further email had been admitted from the

Complainant in lieu of her being present at the appeal.

In a unanimous decision the Appeals Committee did not uphold any aspect of the appeal. The findings by the Code Committee of no breach of Sections 6.2, 6.5, 6.8, 10 (preamble), 10.2, 10.3, 10.6.8, 10.6.11, 10.7 or 10.8 of the Code were confirmed.

## sanofi-aventis Representative 1011

**Subject Company:** sanofi-aventis

**Complainant:** Healthcare Professional

**Product:** Panadeine Forte

### Complaint

The Complainant asserted that a sanofi-aventis Medical Representative had arrived uninvited and without any notice at the Medical Practice where she was working. Despite the Complainant's objections, she allegedly signed a sample request form for an unidentified quantity of Panadeine Forte and other samples.

The Complainant alleged that the Medical Representative told her he would return with the samples immediately, however he did not return. After attempting to contact Sanofi-aventis with concerns about a theft of narcotics, the Complainant lodged an incident report with the NSW Police.

### Sections of the Code

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

- 4.4 Company Representatives
- 5.1.2 Product Starter Packs
- 5.1.5 Product Starter Packs
- 5.1.7 Product Starter Packs
- 5.1.10 Product Starter Packs
- 10.8 Discredit to and reduction of confidence in the Industry

### Response

Sanofi-aventis asserted that it is not possible, given their multiple procedures and auditing requirements for starter pack supply to doctors, that the Medical Representative could have stolen any medicines as had been alleged.

Sanofi-aventis also stated that after investigation into this alleged incident, the order for starter packs had been cancelled by the Complainant because it could not be delivered immediately. Sanofi-aventis alleged that no communication from the complainant in relation to this alleged matter had been recorded by the company.

### Code Committee determination

In a unanimous decision the Committee found no breach of Sections 4.4, 5.1.2, 5.1.5, 5.1.7, 5.1.10 or 10.8 of the Code.

### Consideration of the complaint

#### *Blank starter pack request allegedly signed by complainant under duress*

The Committee reviewed the Sanofi-aventis Standard Operating Procedure in relation to the provision of starter packs to healthcare professionals and noted that any requests for starter packs allocated to the representative must be recorded on a starter pack 'order form' in triplicate.

Representatives do not have starter packs in their possession but must submit the request form to their manager, who forwards the orders to a distribution provider which dispatches the samples ordered directly to the GP's surgery address.

The Committee considered that sanofi-aventis' standard procedures for supply of starter packs would mean that the Medical Representative could not offer to immediately supply any starter packs at the time of their visit. The Committee determined, on the information available to it, that the complaint had not been made out.

The Committee unanimously found no breach of Sections 4.4, 5.1.2, 5.1.5, 5.1.7, 5.1.10 or 10.8 of the Code.

#### *Alleged theft of narcotics*

The Committee unanimously found no breach of Sections 4.4, 5.1.2, 5.1.5, 5.1.7, 5.1.10 or 10.8 of the Code as the Medical Representative did not have any starter packs in his possession. In addition, sanofi-aventis has audit procedures in place for the third party distributor which is accountable for its distribution of starter packs against the orders.

#### *Report of alleged theft of Panadeine Forte to police*

The Committee noted the timeline of events in relation to this matter

- Medical Representative's attendance on the complainant was on 5 January 2009
- Complaint lodged with Medicines Australia on 7 February 2009
- Report to police by complainant on 24 February 2009

- Sanofi-aventis Sales Manager spoke with police on 24 February 2009. This was the first and only call from police to discuss this matter.

The Committee stated that any investigation by the police is outside the jurisdiction of the Code Committee. However, based on the information presented in the complaint and sanofi-aventis response, the Code Committee unanimously found no breach Sections 4.4, 5.1.2, 5.1.5, 5.1.7, 5.1.10 or 10.8 of the Code.

***Sanofi-aventis did not return calls or make return numerous calls from the complainant***

The Committee considered the sanofi-aventis advice that the Medical Information Group had not logged, nor triaged to any other part of the business, a call from the complainant since 11 December 2006. The Committee unanimously found that this aspect of the complaint was not made out and found no breach of Section 10.8 of the Code.

**Appeal**

The Complainant lodged an appeal seeking an examination of what happened to the starter pack request form signed by the Complainant and to produce a document listing all Panadeine Forte supplied to doctors since 5 January 2009 to date on requests initiated by the sanofi-aventis representative concerned. The existence of a standard operation procedure (SOP) and audit system doesn't guarantee in itself that it is working properly and not being abused by a representative.

**Response to appeal**

Sanofi-aventis stated that they had conducted a search of Panadeine Forte samples requested by the representative during 2009 and that search confirmed that no Panadeine Forte starter packs have been requested by that person on behalf of the Complainant at any time. Panadeine Forte was not "allocated" with the electronic distribution system to this representative at the time of the visit to the Complainant's clinic and therefore it would not be possible for him to request the supply of this product due to the constraints imposed by the electronic ordering system.

The original signed starter pack request form was discarded by the representative upon realising that the Complainant had requested product starter packs, which the representative was unable to process since those products were not "allocated" to the representative.

Sanofi-aventis representatives do not have in their possession any starter packs. The request forms are processed and starter packs delivered by courier.

**Appeals Committee determination**

In a unanimous decision the Appeals Committee did not uphold the appeal. The findings by the Code Committee of no breach of Sections 4.4, 5.1.2, 5.1.5, 5.1.7, 5.1.10 or 10.8 of the Code were confirmed.

**Consideration of the appeal**

As neither the Complainant nor Subject Company was present at the Appeals Committee meeting no presentations were made to the Committee. In lieu of attendance the appellant had submitted some additional information to the Appeals Committee. The Committee proceeded to consider the substance of the appeal.

1. This appeal relates to the handling of a complaint originally made by the appellant in relation to the conduct of a medical representative of Sanofi-aventis. He seeks to have the Code of Conduct Appeals Committee review the Code Committee's determination dated 16 March 2009.
2. The substance of the original complaint was that a person claiming to be a representative of sanofi-aventis visited the healthcare professional, who practices from the same rooms as the appellant, and "insisted" that she sign a blank samples request pad without specification of quantity for Panadeine Forte and other drugs, stating that he would bring them back from his car, together with the doctor's copy of the request form. The healthcare professional, who provided further details of the allegations in an email to Medicines Australia, claims to have been concerned that a theft of narcotics was involved and reported the matter to Police. She also claims that she

endeavoured to report the matter to sanofi-aventis but that they did not return her calls. The Code Committee had addressed a number of provisions of the Code and unanimously found no breach by sanofi-aventis.

3. In its original response, sanofi-aventis conceded that the sales representative did visit the healthcare professional's surgery at the time complained of and provided a summary of the representative's recollection of the meeting. Among other things sanofi-aventis made the point that its sales representatives do not carry samples with them in their cars and are only able to comply with requests for starter packs with respect to drugs allocated to particular representatives. There is then a strict protocol in relation to provision of the starter packs directly to the GP's surgery, which does not involve the ordering representative. The company indicated that it had no record of any calls received from the healthcare professional although it accepted that it had been contacted by the Police and had provided information in relation to the distribution protocol.
4. The substance of the appeal appears to be that the representative left his business card with the healthcare professional on which there had been written the names of 3 products which included Panadeine Forte. The appeal appears to proceed on the basis that this is evidence of the fact that the representative accepted an order from the healthcare professional to provide starter packs of Panadeine Forte, perhaps with a view to using the request form as a basis for himself obtaining the drug from the company for some other purpose than its supply to the healthcare professional. On the basis that such an inference might be drawn it is suggested the company has an obligation to establish "beyond reasonable doubt" that the postulated events did not occur.
5. In response the company has stated that it has conducted a search of its requests register which confirms that no Panadeine Forte starter packs were requested by the representative on behalf of the healthcare professional. The company repeats its statement that Panadeine Forte was not allocated to the sales representative and it was therefore not possible for him to request the supply of this product. In any event the delivery protocol would preclude the representative receiving the drugs. It further states that the original signed starter pack request form was discarded by the sales representative when he realised that the healthcare professional had requested only products which the representative was unable to process, since they were not allocated to him. The representative denies that he used "duress" to obtain the healthcare professional's signature to the form, or that he said he would obtain the drugs from his car. Under standard procedures if a starter pack request were to be processed, the form would need to be completed in triplicate, with the healthcare professional inserting the quantity required and signing the form. One copy would be retained by the healthcare professional, one copy is retained by the representative and the third copy is forwarded to the distribution provider.
6. The company has provided Medicines Australia with the copy of the request form which remained in the representative's order book, which is dated 7 January 2009, and on which the names of a number of drugs have been written. These and the printed name of Panadeine Forte are marked with a cross. Some figures which appear to be single numerals appearing opposite the drugs have been written over or crossed out. The form appears to have been signed. The form has had two parallel lines drawn across its face between which the hand written words "CANCELLED not required" appear.
7. The Code does not impose on the Subject Company any obligation to provide evidence which might satisfy a Court of law "beyond reasonable doubt" (the criminal rather than the civil standard) that certain conduct postulated by a complainant has not occurred. The Code Committee can only proceed on the basis of persuasive

evidence in support of a complaint, which is then evaluated against the response provided by the subject company. In this case the explanation originally provided by the Subject Company is consistent with the evidence, namely that the markings referring to Panadeine Forte appearing on the request form were added by the healthcare professional, but that the usual procedure of leaving a copy of the form with the ordering doctor was not followed because the representative was not authorised to place an order for any of the drugs requested by the Complainant. (The healthcare professional has not contended that a copy of the form was left with her.) The company has further explained that its delivery protocol is such that representatives cannot themselves obtain drugs by completing starter pack requests for GPs. The Code Committee was entitled to accept this explanation, which disposes of the complaint, since it would make it impossible for a representative to obtain product by abuse of the system of requesting drugs on behalf of doctors.

8. The appellant has provided no evidence to suggest that the delivery protocol is otherwise than as described by sanofi-aventis. In light of this the dispute about the completion of the request form does not need to be resolved, since a resolution of that matter cannot affect the outcome. The only "evidence" (which was not before the Code Committee) is the representative's card and the writing on it, and the cancelled order form referred to above. It is not disputed that the representative called on the healthcare professional. The representative was asked to provide starter packs for drugs for which he was not the appointed representative. He appears to have written their name on the card, and an order form was completed and signed by the healthcare professional on which the names of three drugs were handwritten and the reference to Panadeine Forte highlighted. There is a dispute as to who made the markings on the form. That is as far as the evidence provided by the complainant goes. In face of the

conflicting accounts by the complainant and the representative as to what was said at their meeting, the Code Committee was correct to proceed on the basis that it did. The complainant now says there were witnesses to the conversation, but has not provided any evidence to support that claim. On that basis there can be no requirement for the company to establish affirmatively (let alone according to the criminal standard) that the representative did not obtain drugs illicitly. It also appears that the NSW Police did not regard the matter as warranting further investigation. The Appeals Committee was satisfied that the Code Committee was not in error in deciding that the original complaint lacked any proper foundation. It therefore dismissed the appeal.

#### **Appeals Committee decision**

In a unanimous decision the Appeals Committee did not uphold the appeal. The findings by the Code Committee of no breach of Sections 4.4, 5.1.2, 5.1.5, 5.1.7, 5.1.10 or 10.8 of the Code were confirmed.

## Micare 1012

**Subject Company:** Boehringer Ingelheim

**Complainant:** Division of General Practice

**Product/Activity:** Micare Educational Event

### Complaint

The Complainant stated that the educational event was inappropriately advertised and delivered. The Complainant also asserted that the event was held in an open restaurant which had approximately 20 members of the public present within hearing and viewing distance of the education being delivered.

### Sections of the Code

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

- 6.6 Venue Selection
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the Industry

### Response

Boehringer Ingelheim responded to allegation of inappropriate advertising of the event by referring to the invitation for the event, which did not suggest the venue would be used exclusively for this event.

Boehringer Ingelheim stated that no complaints had been received on the evening or since the event. In contrast, praise had been received from participants and the presenter to have such an event in a rural area.

The only suitable venue available was the identified restaurant. It has been standard practice in rural towns, often with only single venues to divide off an area of a larger restaurant in order to separate the event from the general public as much as possible. It is not always possible to book out the restaurant exclusively at a reasonable cost in order to keep within expenditure levels deemed acceptable to Medicines Australia.

The local Boehringer Ingelheim representative had tried to book out the restaurant exclusively at a reasonable cost, however was told it was not possible to guarantee exclusivity without confirmed

numbers. The restaurant had offered to organise a separate, partitioned area of the restaurant and that few other diners were expected who would be seated well away from the company function.

### Code Committee Determination

- In a majority decision the Code Committee found no breach of Sections 6.6 or 10.2 of the Code.
- In a unanimous decision the Committee found no breach of Section 10.8 of the Code.

### Consideration of the Complaint

Members agreed that the choice of suitable venues in rural areas may be more difficult than in regional centres or a city. A company must make every effort to identify a venue that has a private room or obtain sole use of the venue in which to hold an educational meeting.

Companies should document the venue options considered and the rationale for the selection of a particular venue, which must be made available to the Code Committee if a complaint is lodged. Members noted that any complaint about an educational event would be considered on a case by case basis.

Where a company cannot have sole use of the venue, the company must discuss options with the venue management for segregating the area from that used by members of the general public.

The Committee noted that it is important for rural doctors to have access to education in their local area. Members noted that the program delivered at this educational event was an RACGP and ACRRM accredited program.

### Reasons for determination

- Boehringer Ingelheim had attempted to divide the area for the educational meeting from the general public with screens and a banner.
- There was no evidence that there had been an intention to promote to the general public.
- The program was on the broad area of cardiovascular medicine with little or no reference to specific products.

- There was no general thoroughfare to the public.
- It is important for rural healthcare professionals to be offered educational meetings, and it was understood that the choice of venue is more limited in rural areas.

The Committee reiterated the view that companies should hold educational meetings in a private room or have exclusive use of the venue wherever feasible. On this occasion the Committee did not find a breach of Sections 6.6, 10.2 or 10.8 of the Code.

## Nexium 1013

**Subject Company:** AstraZeneca

**Complainant:** Nycomed

**Product:** Nexium

### Complaint

Nycomed stated that the promotional claims made in the material subject to complaint were misleading, inaccurate and created expectations of proton pump inhibitors that have brought the industry into disrepute. Through intercompany dialogue, resolutions regarding several issues have been achieved. However Nycomed considered that the misrepresentation of data was a severe breach and it had been unable to resolve the matter with AstraZeneca.

Nycomed also alleged negligence by AstraZeneca in failing to comply with agreed resolutions achieved at intercompany dialogue and its prolonged use of unsubstantiated claims in promotional advertisements and leave behinds. AstraZeneca had agreed to remove the materials subject to complaint on 21 January 2009 however they were still in use in March 2009.

Nycomed asserted that the unresolved claim *"Heals more patients, regardless of severity"* represents an extensive and sustained campaign of misinformation which gave the illusion of enhanced efficacy and superiority.

### 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
- 1.5 Unqualified Superlatives
- 1.7 Comparative Statements

### Response

In its response to the complaint AstraZeneca stated that at intercompany dialogue on 20 November 2008 it had agreed to cease using the phrase *"regardless of severity"*. All relevant materials were withdrawn from circulation on 25 November 2008. However, Nycomed now alleged that the expression *"Heals more patients"* referred to absolute

patient number rather than the percentage of patients as the rationale for complaint. AstraZeneca alleged that Nycomed's interpretation of the data is flawed and against accepted convention.

In relation to the timeframe for withdrawal of materials using the claim *"Live life with heartburn ... or love life with Nexium"*, agreement with Nycomed was reached on 21 January 2009 that the claim would be removed from materials that go into development and placement in the medical media by early April 2009. AstraZeneca had abided by its undertakings.

### Code Committee Determination

#### Heals more patients regardless of severity

- Unanimous breach of Sections 1.1, 1.2, 1.3, 1.5 and 1.7 of the Code

This was considered to be a moderate breach.

#### Agreement between Nycomed and AstraZeneca on the withdrawal of materials

- Unanimous no breach of Section 10.8 of the Code

#### Sanctions

- Withdraw materials found in breach of the Code
- Publish a corrective advertisement
- Pay a fine of \$85,000

### Consideration of the Complaint

#### *"Heals more patients regardless of severity"*

The Committee was cognisant of the issue raised by AstraZeneca in relation to the change in Nycomed's complaint. The initial complaint had been in relation to the use of *"...regardless of severity"*. AstraZeneca had agreed to cease using this phrase and withdrew the relevant materials from circulation on 25 November 2008. AstraZeneca was of the view that this matter had been resolved. The subsequent complaint alleged a breach in relation to the claim *"Heals more patients"* because it was alleged this comparison was based on absolute numbers of patients rather than the percentage of patients.

Having considered the alleged procedural fairness issues, the Committee was of the view that in relation to the claim *"Heals more*

*patients regardless of severity*” AstraZeneca had had sufficient opportunity to respond to the allegations made by Nycomed to the Code Committee. There was no issue of lack of procedural fairness to be answered.

The issue of whether AstraZeneca had delayed withdrawing materials following an agreement formulated during intercompany dialogue was also considered. No other matters would be taken into consideration by the Code Committee.

The Committee considered that the claim “*regardless of severity*” was too broad and went beyond what the clinical data could support:

- In mild cases (Grade A), there had been no significant difference demonstrated between treatments. Thus, it would be inappropriate to extrapolate these data to imply that there would be equivalent healing rate regardless of severity.
- The claim is only referenced to one study which compared esomeprazole 40mg and pantoprazole 40mg. Members noted that there had been a qualifying statement associated with the claim, however this qualifier was not sufficient to support the broad generalisation of the claim from the more narrowly defined study population in a single study.

By unanimous decisions the Committee made the following determinations:

- Items AST1757 and AST1758 - breach of Sections 1.1, 1.2, 1.3, 1.5 and 1.7 of the Code.
- Item 05/08 AST1760 and AST1674 - no breach of Sections 1.1, 1.2, 1.3, 1.5 and 1.7 of the Code.

In relation to the claim “Heals more patients” and the alleged presentation of data using absolute numbers rather than percentages the Committee noted:

- The Nexium Product Information states “In the healing phase of the EXPO Study, a randomised, double blind, multi-centre study (n=3,170), esomeprazole 40mg had significantly more patients healed on endoscopic assessment at 4 and 8 weeks compared to pantoprazole 40mg. (results were presented as percentages in Table 6:

The Healing of reflux oesophagitis by baseline LA classification grade)

- Referenced study Labenz et al Figure 1 (page 742) used percentages and ‘intent to treat population’ numbers.

Members were of the view that it is acceptable to use percentages to express the efficacy rate and noted that the title of the graph in the promotional item was % of patients healed at week 4: Nexium 40mg vs Somac 40mg.

#### Agreement between Nycomed and AstraZeneca on the withdrawal of materials

The Committee noted the extensive intercompany dialogue between AstraZeneca and Nycomed. Members considered that the minutes and agreed actions between companies must be clearly documented and followed up immediately where there is disagreement or there is a lack of clarity. Definitive dates for actions must be identified and agreed to in a timely manner by both parties.

Members were of the view that the processes in this complaint (such as agreement on timeframes for withdrawal of materials and what materials would be withdrawn), should have been determined. It was incumbent on companies not to ‘game’ the system and/or to be proactive in defining any agreed action. It was not the role of the Code Committee to advocate on behalf of any party to a complaint.

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

#### **Sanctions**

Members were of the view that this was a moderate breach of the Code.

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

- In a unanimous decision, withdraw all materials containing the claim found in breach of the Code.
- In a majority decision, publish a corrective advertisement in the front half of *Australian Doctor Weekly and Medical Observer*.

- In a majority decision, pay a fine of \$85,000

## Pfizer advertisement 1014

**Subject Company:** Pfizer Australia

**Complainant:** Health Consumers' Council WA

**Product:** not relevant

### Complaint

The complainant expressed concern at the advertisement placed by Pfizer Australia in *The West Australian* on Friday 17 April 2009. The advertisement encouraged patients to talk to their doctor about combination medicine options for conditions such as high blood pressure or high cholesterol. The complainant suggested that although no medicine name is mentioned in the advertisement, it constitutes direct to consumer advertising and is therefore in breach of the Medicines Australia Code of Conduct.

### Sections of the Code

Pfizer Australia was asked to respond to the complaint with reference to the following Sections of the Code:

- 9.4 Promotion to the General Public
- 9.5 Patient Education
- 9.10 Discredit to and reduction of confidence in the Industry

### Response

Pfizer Australia responded by stating that the advertisement does not mention a prescription product by name, nor does it direct patients to a single product. Pfizer therefore was of the view that the advertisement does not breach the Medicines Australia Code of Conduct.

The advertisement in question is intended to encourage patients to "talk to their doctor". The ultimate goal of the campaign was to increase compliance which has been shown to improve clinical outcomes. Pfizer further contended that the advertisement makes a positive contribution to the quality use of medicines by informing patients that they may be able to reduce the number of medicines they need to take.

### Code Committee Determination

In a majority decision the Code Committee found no breach of Sections 9.4, 9.5 or 9.10 of the Code

### Consideration of the Complaint

The Committee noted that there were two dimensions to the advertisement. On one hand the advertisement was directed to the public with a message about reducing the number of medicines they take for particular conditions by considering combination products. The second dimension was a message to doctors through the clipboard image on the tear off 'notice' which continues the theme of advertisements to health professionals for Pfizer's product Caduet. The Committee considered that members of the general public would not be aware of this linkage to the advertising campaign to doctors associated with a particular medicine.

The Committee understood that there are a range of combination products available for the treatment of hypertension and hypercholesterolemia. Encouraging patients to have their treatment reviewed and potentially improving compliance by simplifying a treatment regimen and lowering the cost of prescriptions is consistent with the quality use of medicines. There was no particular product identified in the advertisement to the general public.

A minority view was expressed that the advertisement was directly advertising a prescription medicine to consumers. The advertisement prompts a member of the public to take the tear off notice to their doctor who would make the link to a particular product, Caduet. Further, the co-location of the company name with 'a combination heart pill' and the 'Take one' clipboard made a link to a particular prescription medicine.

In discussing the complaint, the TGA member advised that any determination by the TGA would likely consider aspects that include whether the advertisement is an advertisement for therapeutic goods within the meaning of the Therapeutic Goods Act 1989, as well as the advertising offences under Section 42 DL of the Act, regarding references to therapeutic goods in Schedules 3, 4 or 8 to the Poisons Standard,

and whether the advertisement makes reference to a restricted representation about therapeutic goods. The TGA representative undertook to inform Medicines Australia of TGA's further considerations of such matters.

By a majority decision, the Code Committee determined that the advertisement did not encourage a member of the general public to seek a prescription for a particular prescription medicine and was therefore not in breach of Section 9.4 or 9.5 of the Code. The Committee further determined, by a majority decision, that the advertisement did not bring the industry into disrepute and was not in breach of Section 9.10 of the Code.

## Plavix 1015

**Subject Company:** sanofi-aventis

**Complainant:** Dr Ken Harvey

**Product:** Plavix

### Complaint

The Complainant alleged that the arrangement between sanofi-aventis and a private Research Institute, which provides the Institute with 25 cents for each prescription dispensed for Plavix, interferes with the independence of the prescribing doctor, and is therefore a breach of Section 7.1.2 of the Code of Conduct. The Complainant further alleged that behaviour such as the sponsorship arrangement brings discredit to and a reduction of confidence in the industry and is in breach of Section 10.8 of the Code.

### Sections of the Code

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

- 7.1.2 Sponsorship
- 10.8 Discredit to and reduction of confidence in the Industry

### Response

Sanofi-aventis responded that the arrangement with the private Institute complies with the Code and would withstand public and professional scrutiny and was not in breach of the Code.

Sanofi-aventis argued that the intent of 'sponsorship', referred to in Section 7.1.2 of the Code, was in the context of the prescribing or dispensing healthcare professional being the recipient or beneficiary of that sponsorship. Sanofi-aventis stated that there was no direct or indirect benefit to a prescriber or dispenser in the donation arrangement with the private Institute and therefore was not an incentive to a prescriber to prescribe Plavix.

Sanofi-aventis rejected the claim that the unconditional donation to one of Australia's leading research institutions for the sole purpose of supporting medical research brings discredit to or reduces confidence in the industry. Sanofi-aventis asserted that the donation to the Baker Institute is ethical

and transparent and did not bring the industry into disrepute.

### Code Committee Determination

- By majority decision a breach of Section 7.1.2 of the Code was found
- By majority decision no breach of Section 10.8 of the Code was found

### Sanctions

- Cease promotion of the sponsorship of the Baker Institute in any manner that links the sponsorship to prescriptions written or dispensed for a particular prescription medicine, or may otherwise interfere with the independence of a healthcare professional's prescribing or dispensing practices
- Pay a fine of \$25,000

### Consideration of the Complaint

#### Consideration of whether the sponsorship of the Institute is an incentive to prescribe or dispense Plavix

The Committee discussed the nature of the arrangement to provide a donation of 25 cents to the Baker Institute for each prescription dispensed for Plavix. It was noted that there is an alternative brand that contains the same active ingredient, clopidogrel.

The Committee reviewed Section 7.1.2 of the Code, and particularly this section in the context of the introductory paragraphs to Section 7. The second paragraph in the introductory provisions to Section 7 states:

*The provisions of this Section cover the sponsorship of any activities involving healthcare professionals by a company (emphasis added).*

The first sentence of Section 7.1.2 states that

*No sponsorship should be conditional upon any obligation to prescribe a particular product" (emphasis added).*

The Committee therefore understood that 'sponsorship' in Section 7.1.2 should be read widely and is applicable to sponsorship of healthcare professional activities broadly and should not be restricted to sponsorship of an individual. Further, the second

sentence of Section 7.1.2, in particular, states:

*Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing or dispensing practices.*

The Committee accepted that there was no direct pecuniary benefit to a doctor or a pharmacist for prescribing or dispensing Plavix. However, a majority of the Committee considered that the structure of the sponsorship and its promotion to health professionals, directly linking the sponsorship to prescriptions written and dispensed for a particular prescription medicine, was an inducement to choose to prescribe or dispense Plavix in preference to the alternative product or products. The Committee by a majority decision determined that the promotion of the sponsorship of the Baker Institute to healthcare professionals by linking the sponsorship to prescriptions for Plavix was in breach of Section 7.1.2 of the Code. It could also be argued that the prescribing or dispensing of Plavix and its link to sponsorship of the Baker Institute may lead to indirect benefits of a qualitative nature for a doctor or pharmacist that would be difficult to measure but a benefit nonetheless.

The Committee noted that the sponsorship of an independent medical research institute to support research in Australia is a laudable objective. However, the linkage of the sponsorship to a promotional purpose by encouraging selection of Plavix when prescribing or dispensing was in breach of the Code.

#### Consideration of bringing the industry into disrepute

The Committee noted that there had been some coverage of the sponsorship of the Baker Institute and its linkage to Plavix prescriptions in the general media.

The promotion of the sponsorship of the Baker Institute differed from the usual marketing of a prescription medicine whereby a prescriber is provided with information about the comparative efficacy, safety and overall quality of a product. In the present case the health professional is

encouraged to choose Plavix on the basis of the company investing in independent Australian clinical research. There was no evidence that doctors were being encouraged to inappropriately prescribe Plavix, which is an authority drug under the Pharmaceutical Benefits Scheme. There was no likelihood of patient harm arising from the conduct.

The Committee determined by a narrow majority that there was no breach of Section 10.8 of the Code.

#### **Sanctions**

A majority of members were of the view that this was a minor breach of the Code arising from the linkage of the sponsorship to an inducement to prescribe or dispense a particular medicine. The untied sponsorship of independent Australian clinical research ameliorated the severity of the breach found.

Having found a breach of Section 7.1.2 of the Code, the Committee determined that sanofi-aventis should:

- Cease promotion of the sponsorship of the Baker Institute in any manner that links the sponsorship to prescriptions written or dispensed for a particular prescription medicine, or may otherwise interfere with the independence of a healthcare professional's prescribing or dispensing practices
- Pay a fine of \$25,000, by a unanimous decision.