# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report from the Chairman and Chief Executive</td>
<td>5</td>
</tr>
<tr>
<td>Executive Summary</td>
<td>8</td>
</tr>
<tr>
<td>Governance</td>
<td>10</td>
</tr>
<tr>
<td>Communications</td>
<td>16</td>
</tr>
<tr>
<td>Continuing Education Program</td>
<td>18</td>
</tr>
<tr>
<td>Code Review</td>
<td>25</td>
</tr>
<tr>
<td>Educational Event Reporting</td>
<td>28</td>
</tr>
<tr>
<td>Complaints Process</td>
<td>30</td>
</tr>
<tr>
<td>Analysis of Complaints</td>
<td>32</td>
</tr>
<tr>
<td>Definitions</td>
<td>40</td>
</tr>
<tr>
<td>Complaint determinations</td>
<td>43</td>
</tr>
<tr>
<td>Monitoring Committee Report</td>
<td>118</td>
</tr>
</tbody>
</table>
It is with great pride in the work of Medicines Australia over the last twelve months that we present the 2010 Code of Conduct Annual Report.

The Code in its new edition 16 continues to provide an exemplary ethical framework for companies when they interact with health professionals and consumers. Medicines Australia members have continued to demonstrate their commitment to ensuring their conduct remains of the highest ethical standards and that their self-regulatory Code sets the benchmark for the industry.

**Highlights**

- Code of Conduct new edition authorised by the Australian Competition and Consumer Commission (ACCC) and is deserving of its reputation as a world leader in codes of conduct for the pharmaceutical industry.
- Medicines Australia has delivered on its commitment that, once administrative costs of the Code program have been covered, surplus revenue from fines would be put to a worthy cause. This has allowed Medicines Australia to donate
  - $1m to the Jimmy Little Foundation to help improve indigenous health outcomes in remote communities.
  - The Uncle Jimmy “Thumbs Up!” campaign will deliver healthy eating messages to Indigenous communities, to encourage children and parents to make more nutritious food and drink choices.
  - The establishment of a mobile renal dialysis unit to be managed by the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation based in Alice Springs.
  - $150,000 to sponsor two young indigenous students to study medicine at the University of New South Wales.

**Global and Australian Context**

**Global**

Globally the pharmaceutical industry has committed to greater transparency in interactions with healthcare professionals and health consumer organisations. European Codes of Conduct require pharmaceutical companies to make public their sponsorship of health consumer organisations by including details of these relationships on company websites. We have incorporated this into the new edition of the Medicines Australia Code.

Transparency about the nature of the relationship between the industry and healthcare professionals remains an important issue of interest and debate globally. Reforms in Europe and the United States demonstrate that the community expects ongoing evolution of standards of transparency. The ACCC has also indicated a desire for the Australian industry to work towards greater transparency. External commentators have criticised the fact that industry interacts with health professionals at all, despite this being a legitimate and, in fact, necessary activity to...
encourage the quality use of medicines. It will remain a challenge for the industry to better communicate the legitimacy and value of the services we provide to support the ongoing clinical education of healthcare professionals and clinical research into new and improved medicines.

US companies have also prohibited the distribution of brand name reminders and service items to healthcare professionals. The British Pharmaceutical Industry Code of Practice for the Pharmaceutical Industry 2008 permits the provision of inexpensive promotional aids that are relevant to the recipient’s work but prohibited the provision of items that are for use in the home or car. Consistent with international changes to industry Codes and recommendations from submissions, the Medicines Australia’s Code now prohibits giving health professionals items with product branding that are likely to be used outside the work environment, such as items of general utility that can be used in the home, car or socially. These are no longer acceptable as brand name reminders in Australia.

**Australia**

**Changes to the Australian Code of Conduct**

There is no logical reason for there to be one standard of ethical conduct for Medicines Australia members and another, lesser, standard for non-member companies supplying prescription medicines. We believe that there must be a consistent ethical standard for all companies when they interact with health professionals and consumers and we are encouraged by the Government’s commitment to pursue a level playing field for promotional activities within the prescription medicines sector and more broadly in the therapeutic goods industry. Medicines Australia cannot require generic or other companies to become Medicines Australia members. However, we very firmly believe that every prescription medicine company should adhere to the high ethical standards embodied in the Medicines Australia Code of Conduct.

**Social Responsibility**

Medicines Australia’s donations to projects to improve indigenous health have been funded by fine revenue from companies found in breach of the Medicines Australia Code of Conduct. Medicines Australia made a commitment to the community that once administrative costs of running the Code had been covered, any fine revenue would be put to a worthy cause.

As Medicines Australia Chairman and Chief Executive we are proud of our sponsorship of the Jimmy Little Foundation and the Shalom Gamarada Indigenous Scholarship Program. This sponsorship reflects the pharmaceutical industry’s commitment to ensuring practical, on-the-ground initiatives to improve the lives of Indigenous Australians to make a real, long-term difference. While this is a relatively modest contribution compared with the vast challenge we all face in closing the gap between indigenous and non-indigenous Australian’s health and life expectancy, it is a positive and responsible step forward in effecting change.

If this donation can encourage young Indigenous Australians to choose more nutritious food, and if Indigenous Australians on renal dialysis in the western desert can travel home and have treatment while they are there with their family, this money will have been put to great use.

We were also pleased to provide sponsorship to two talented young Indigenous Australians to realise their dreams and become qualified and successful medical practitioners. Medicines Australia recognises the urgent need to improve Indigenous health outcomes and fully supports the recruitment and training of more Indigenous doctors. We have a chronic shortage of GPs in Australia but in training the next generation of doctors, it is very important that we train and support more
Indigenous doctors. Indigenous Australians are severely underrepresented in the medical profession
and schemes like the Shalom Gamarada Scholarship program do an excellent job in redressing that
imbalance.

People

The effective and equitable implementation and administration of the Code of Conduct relies on the
commitment, skill and professionalism of the Medicines Australia staff and members of the Code,
Appeals and Monitoring Committees. We take this opportunity to thank them for their energy in
pursuing these objectives and for their belief and support of a first class industry Code of Conduct.
We would also like to thank the many people who took the time to make submissions and attend
workshops, make written and oral submissions as part of the Code Review Panel. Medicines
Australia listened carefully to their suggestions and recommendations and we have acted upon them
in implementing the 16th edition of the Code.
Executive Summary

This year has seen the achievement of authorisation of the new Code, its implementation and an increased level of compliance by member companies.

Code of Conduct Edition 16

The ACCC’s authorisation of Edition 16 of the Code was a very pleasing outcome from the 18-month long consultation process during which Medicines Australia and the ACCC sought input from industry, patient groups, consumer organisations, healthcare professionals, colleges and societies, professional associations, academics and other stakeholders.

Medicines Australia is proud of its achievements in reviewing, revising and reporting under the Code. Areas in which the Code has been strengthened include:

- Brand name reminders: a ban on brand name reminders that are ordinarily used outside the surgery (eg pens, coffee mugs, notepads etc)
- Prescribing software: a ban on advertisements for prescription medicines in prescribing software used by doctors
- Transparency of support for consumer groups: any support provided by consumer groups must be disclosed on a company’s website
- Fines: the maximum fine for breaching the Code is increased to $300,000

During the review of the Code and implementation of the newly authorised edition 16, the Code Secretariat provided education sessions to 640 individuals at 50 events to ensure pharmaceutical companies, suppliers to industry and stakeholders were informed of the changes to the Code and how the new provisions should be interpreted and actioned.

Edition 16 of the Code can be found on the Medicines Australia website at www.medicinesaustralia.com.au

Educational Event Reports

Pharmaceutical companies take their responsibility to provide doctors with current, accurate and balanced information very seriously and provide a wide variety of educational opportunities throughout the year. These engagements are legitimate, appropriate and, in the case of Medicines Australia members, transparent. Doctors continue to ‘vote with their feet’ by attending these events because they derive genuine professional benefit from their engagement with pharmaceutical companies. It is also very evident from the reports that member companies also support a wide range and large number of independently organised educational meetings for health professionals.

Member companies continue to report their educational events, which are published on a six-monthly basis on the Medicines Australia website. There continues to be a high level of transparency and compliance with the Code requirements for the provision of high quality education and
appropriate hospitality. Details on the Monitoring Committee’s review of educational events in 2009/2010 can be found on pages 121 and 126 in this report.

How we performed

I am pleased to report an increased level of compliance by member companies with respect to adherence to the Code. In 2009-2010 39 new complaints were received, which is a decrease from 2008-2009 when 59 complaints were submitted to Medicines Australia. Of the 22 new complaints finalised in 2009-2010, 45% were not found to be in breach of the Code. Details of the complaints considered in 2009-2010 and the outcomes can be found on page 33.

The Monitoring Committee continued to provide extensive reviews of company promotional material and activities. In 2009-2010 the Committee reviewed 548 different items and 18,300 educational events with 11 matters referred to the Code of Conduct Committee for their consideration (6 educational events, 4 media releases and 3 disease education activities). Of the 5 educational events referred to the Code Committee, 4 were found in breach of the Code. This demonstrates a continued high level of compliance of at least 99.9 percent for educational events. Details of the Monitoring Committee reviews can be found on page 119.

Looking ahead

Medicines Australia will continue to work with industry and stakeholders to take up the ACCC’s challenge to continuously enhance transparency of our activities. The next review of the Code will commence in mid-2011, which will be upon us very quickly.

At the end of June 2010, the Parliamentary Secretary to the Minister for Health, the Honourable Mark Butler MP, issued the Australian Government’s Position Paper on the Promotion of Therapeutic Goods. The Government has proposed that the therapeutic goods industry strengthen and standardise self-regulation through developing universal adherence to consistent industry-wide codes based on a common set of high-level principles. It is expected that the high level principles will create a ‘level playing field’ within the sector, which will meet the Government objective of ensuring that health professionals’ management choices for patients are based on clinical evidence and are not driven by incentives or other influences.

Medicines Australia will be an active participant on the Working Group that is developing the high level principles for industry conduct. We are very pleased that the Government has demonstrated leadership by initiating this process and supporting industry self-regulation. The industry is conscious that if we are unable to step up to the challenge of consistent and effective self-regulation, government regulation can be imposed, which would be a backward step from Medicines Australia’s perspective.

Moving on

At the end of the year Heather Jones, who has been the Code of Conduct Secretary for eight and a half years, decided to leave Medicines Australia to move closer to her family in Perth. Heather has been an outstanding advocate for high ethical standards in the industry and an encyclopaedic resource of knowledge about the Code. We wish her every success for the future.
Complaints received by Medicines Australia are considered by the Code Committee and, when required, by the Appeals Committee.

Neither the Medicines Australia Board nor Secretariat staff adjudicate on complaints or appeals.

Membership of Committees

The permanent members of all Committees (Code, Appeals and Monitoring) are independent of Medicines Australia. The members of these Committees bring extensive experience in trade practices law, public health, general practice, specialist medicine, consumer advocacy and medicines evaluation from a variety of research and clinical situations.

Short biographies of all permanent members of the Code, Appeals and Monitoring Committees are available on the Medicines Australia website at http://www.medicinesaustralia.com.au

Conflict of Interest

A person participating on a Code-related Committee must not have a conflict of interest with the therapeutic area/s or company/ies against which a complaint has been lodged or with the Complainant, or in the case of the Monitoring Committee no conflict of interest with either the therapeutic area subject to review or the companies who have submitted materials for review. This also extends to financial or any perceived bias with any of the matters considered at the meeting which they attend.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered in a meeting of any Committee, members must also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Committee may be influenced in reaching a decision by factors other than the merits of the case.
Code of Conduct Committee

Code of Conduct Committee meetings are held on the third Monday of each month. A list of meeting dates is available from the Medicines Australia website at http://www.medicinesaustralia.com.au

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nominee/s</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full Members (Voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td>Panel of Chairs</td>
<td></td>
</tr>
</tbody>
</table>
| One independent Lawyer (Chairman) selected from a panel of six trade practices lawyers | Mr Michael Daniel, PricewaterhouseCoopers Legal  
Mr Michael Gorton, Russell Kennedy  
Mr John Kelly, John G Kelly & Associates  
Mr Alan Limbury, Strategic Resolution  
Mr Bernard O’Shea, Norton Rose  
Mr Ian Tonking SC, Selbourne Chambers |
| Australian General Practice Network (AGPN)                                   | Dr Ruth Ratner                                                            |
| Australian Medical Association (AMA)                                         | Associate Professor John Gullotta AM                                       |
| Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) (One ASCEPT member selected from the panel of four members) | Professor Richard O Day AM  
Professor Paul Seale  
Professor John Miners  
Associate Professor Ken Williams |
| Consumers Health Forum of Australia (CHF) (Edition 16 - two CHF representatives to participate in complaints where the activity is directed at the general public or patients) | Ms Anne McKenzie  
Ms Sharon Caris (Alternate) |
| Royal Australasian College of Physicians (RACP) (One RACP member selected from the panel of three members) | Dr Avi Lemberg  
Dr Catherine Streeton  
Dr Christian Gericke |
| Royal Australasian College of General Practitioners (RACGP)                  | Dr Harry Nespolon                                                         |
| Therapeutic goods Administration (TGA) (Edition 16 - TGA reverted to Observer status at its request) | Dr Craig Davies/Dr Peter Bird 2009  
Dr Susan Coates 2010 |
| Medicines Australia Association Representatives (maximum of 3) (Edition 16 - maximum two Medicines Australia Member Company Senior Executives and maximum one Medicines Australia Member Company Marketing Director) | Various, depending on complaints |
| Medicines Australia Member Company Medical/Scientific Directors (maximum of 2) | Various, depending on complaints |
| **Observers (No voting rights)**                                            |                                                                           |
| Medicines Australia member companies’ employees (max of 2)                   | Various, depending on complaints                                           |
| Observer nominated by Medicines Australia (maximum of 1)                     | Various, depending on complaints                                           |
| **Medicines Australia Advisors (No voting rights)**                          |                                                                           |
| Secretary, Code of Conduct Committee                                         | Ms Heather Jones                                                          |
| Medicines Australia Chief Executive Officer or delegate                      | Mr Ian Chalmers 2009  
Mr Brendan Shaw 2010 |
| Medicines Australia Officer responsible for Scientific and Technical Affairs (Edition 16 - Medicines Australia Officer responsible for Ethical Conduct) | Ms Deborah Monk |
The Code Committee held 12 meetings in 2009-2010. As shown in Figure 1, all permanent members of the Code Committee attended the scheduled meetings.

**Figure 1**

*Code Committee Meeting Attendance 2009/2010*

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nominee/s</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full Members (Voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td>Panel of Chairs</td>
<td></td>
</tr>
<tr>
<td>One independent Lawyer (Chairman)</td>
<td>Mr Michael Daniel, PricewaterhouseCoopers Legal</td>
</tr>
<tr>
<td>selected from a panel of six</td>
<td>Mr Michael Gorton, Russell Kennedy</td>
</tr>
<tr>
<td>trade practices lawyers</td>
<td>Mr John Kelly, John G Kelly &amp; Associates</td>
</tr>
<tr>
<td></td>
<td>Mr Alan Limbury, Strategic Resolution</td>
</tr>
<tr>
<td></td>
<td>Mr Bernard O’Shea, Norton Rose</td>
</tr>
<tr>
<td></td>
<td>Mr Ian Tonking SC, Selbourne Chambers</td>
</tr>
<tr>
<td>One representative from:</td>
<td></td>
</tr>
<tr>
<td>Australian General Practice Network</td>
<td>Dr Marcela Cox</td>
</tr>
<tr>
<td>(AGPN), or</td>
<td>Dr Martine Walker</td>
</tr>
<tr>
<td>Australian Medical Association (AMA),</td>
<td>Dr Brian Morton</td>
</tr>
<tr>
<td>or</td>
<td></td>
</tr>
<tr>
<td>Royal Australian College of</td>
<td></td>
</tr>
<tr>
<td>General Practitioners (RACGP)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Australasian Society of Clinical</td>
<td>Professor Richard O Day</td>
</tr>
<tr>
<td>and Experimental Pharmacologists</td>
<td>Professor Paul Seale</td>
</tr>
<tr>
<td>and Toxicologists (ASCEPT) (Edition</td>
<td>Professor John Miners</td>
</tr>
<tr>
<td>16 - one ASCEPT member selected from</td>
<td>Associate Professor Ken Williams</td>
</tr>
<tr>
<td>the panel of four members)</td>
<td></td>
</tr>
</tbody>
</table>
Table 2 continued
Appeals Committee Members

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nominee/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers Health Forum (CHF)</td>
<td>Ms Judith Maher [Alternate] Ms Patti Warn</td>
</tr>
<tr>
<td>(Edition 16 - two CHF representatives to participate in complaints where the</td>
<td>activity is directed at the general public or patients)</td>
</tr>
<tr>
<td>The College and/or Society associated with the therapeutic class of the</td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td>product subject to appeal</td>
<td></td>
</tr>
<tr>
<td>Medicines Australia Association Representatives (maximum of 2)</td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td>(Edition 16 maximum 1 Medicines Australia Member Company Senior Executive and</td>
<td></td>
</tr>
<tr>
<td>maximum 1 Medicines Australia Member Company Marketing Director)</td>
<td></td>
</tr>
<tr>
<td>Medicines Australia Member Company Medical/Scientific Directors</td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td>(maximum of 1)</td>
<td></td>
</tr>
<tr>
<td>Medicines Australia Advisors (No voting rights)</td>
<td>Ms Heather Jones</td>
</tr>
<tr>
<td>Secretary, Code of Conduct Committee</td>
<td></td>
</tr>
<tr>
<td>Medicines Australia Chief Executive or delegate</td>
<td>Mr Ian Chalmers 2009 [Dr Brendan Shaw 2010]</td>
</tr>
<tr>
<td>Edition 16 Medicines Australia Officer responsible for Ethical Conduct</td>
<td>Ms Deborah Monk</td>
</tr>
</tbody>
</table>

The Committee held 4 meetings in 2009-2010 to consider 5 appeals. As shown in Figure 2 all permanent members of the Appeals Committee attended the scheduled meetings.

Figure 2
Appeals Committee Meeting Attendance 2009/2010
Monitoring Committee

Monitoring Committee meetings are held on the third Monday of each month. A list of meeting dates is available from the Medicines Australia website at http://www.medicinesaustralia.com.au/pages114.asp

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nominee/s</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full Members (Voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td>Panel of Chairs</td>
<td>Mr Russell Edwards Dr Mike Wyer</td>
</tr>
<tr>
<td>Australian Medical Association (AMA)</td>
<td>Dr Robyn Napier</td>
</tr>
<tr>
<td>Royal Australian College of General Practitioners (RACGP)</td>
<td>Dr Sue Whicker</td>
</tr>
<tr>
<td>Consumers Health Forum (Edition 16 - two CHF representatives to participate in reviews where activities are directed at the general public or patients)</td>
<td>Ms Sheila Rimmer AM Mr Henry Ko (Alternate) Ms Patricia Greenway (Alternate) Mr Brian Stafford (Alternate)</td>
</tr>
<tr>
<td>The College and/or Society associated with the therapeutic class of the product(s) subject to review</td>
<td>Various, depending on the materials or conduct being reviewed</td>
</tr>
<tr>
<td>Medicines Australia Member Company Medical/Scientific Director</td>
<td>Various, depending on the materials or conduct being reviewed</td>
</tr>
<tr>
<td>Medicines Australia Member Company Marketing Director</td>
<td>Various, depending on the materials or conduct being reviewed</td>
</tr>
<tr>
<td><strong>Medicines Australia Advisors (No voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td>Secretary, Code of Conduct Committee</td>
<td>Ms Heather Jones</td>
</tr>
<tr>
<td>Medicines Australia Officer responsible for Scientific and Technical Affairs (Edition 16 Medicines Australia Officer responsible for Ethical Conduct)</td>
<td>Ms Deborah Monk</td>
</tr>
</tbody>
</table>

The Committee held 14 meetings in 2009-2010. Additional meetings to the scheduled monthly were scheduled to enable the Committee to review educational event reports. As shown in Figure 3, all permanent members of the Monitoring Committee attended the scheduled meetings. Two consumer representatives participated in the review of education event reports and under the new provisions in Edition 16 of the Code two consumer representatives also participated in the review of activities directed at the general public.
Code Secretariat

Medicines Australia, through the Code Secretariat, is responsible for:

- ensuring the Code is reviewed regularly to reflect professional and societal expectations of ethical conduct by pharmaceutical companies;
- administration of the Code complaints and appeals process;
- administering the business of the Monitoring Committee in its reviews of company activities as required by the Code;
- organising educational activities relating to the Code for members, non-member companies and other stakeholders to encourage awareness, understanding and compliance;
- applying for authorisation of the Code by the ACCC when required.

Code Secretariat Staff

- Ms Deborah Monk, Director Innovation and Industry Policy
- Ms Heather Jones, Manager Code of Conduct
- Ms Romina Bommes, Code Administration Officer (July 2009 – May 2010)
- Ms Romina Bognolo, Code Administration Officer (from June 2010)
Communications

Medicines Australia regularly engages with pharmaceutical companies, healthcare professional organisations, consumers, health consumer organisations and agencies and businesses working with the industry (such as advertising and public relations agencies, suppliers, event organisers) to raise awareness, promote understanding of and encourage compliance with the Code. In our communications with stakeholders external to the industry, we explain the standards by which the industry operates and the conduct that stakeholders should expect when engaging with individual companies.

The Medicines Australia Code is consistent with the principles set out in the International Federation of Pharmaceutical Manufacturers and Associations’ (IFPMA) Code of Pharmaceutical Marketing Practices. In February 2010, the IFPMA convened the eighth International Code Compliance Network (CCN) Conference in Geneva to discuss and debate the challenges and potential of self-regulation of ethical promotion of pharmaceutical medicines. The two-day conference was attended by 30 compliance officers involved in the management of self-regulatory Codes in 15 countries. Medicines Australia was represented by Ms Deborah Monk. Within the Australian environment, Ms Monk and Ms Jones also responded to many requests for guidance and advice on code provisions and interpretations.

In 2009-2010 Code Secretariat staff conducted or participated in 50 events pertaining to communication about the Code, with a combined audience of 640. See Table 4 for details on these events.

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>No. of Events</th>
<th>No. of Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conferences - sessions on the code</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Presentations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
<td>9</td>
<td>195</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td>14</td>
<td>149</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Workshops – sessions on the Code</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td>3</td>
<td>85</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Others (ACCC)</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td><strong>Meetings to discuss Code changes and/or amendments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td>7</td>
<td>18</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Other (TGA, DoHA, Gov’t)</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>50</td>
<td>640</td>
</tr>
</tbody>
</table>
In addition to the education sessions listed above, Medicines Australia Code Secretariat staff attended the General Practice Conference & Exhibition (GPCE) and Practice Nurse Conference, which was attended by over 1,200 general practitioners (GPs) and practice nurses. The aim of the trade display was to raise awareness of the Medicines Australia Code of Conduct and that there is value to healthcare professionals from pharmaceutical companies engaging with them to provide information. We were also keen to promote the ethical conduct and professionalism of pharmaceutical company representatives.

In addition to brochures highlighting the Code for GPs, brochures for consumers were also made available for GPs to place in their practice. The purpose of these brochures is to inform consumers that there is a Code of Conduct that ensures that the relationship between pharmaceutical companies and their doctor is ethical and is based on promoting the best interests of consumers.

Copies of the GP and consumer brochures are available by contacting Medicines Australia on 02 6122 8500 or email at secretarycodecommittee@medicinesaustralia.com.au
Medicines Australia’s Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard.

CEP is primarily directed at medical representatives working within the prescription medicines industry, but is also recommended to people who may not be currently employed within the industry but would like to pursue a career as a medical representative. It is also available to personnel working for organisations interacting with the pharmaceutical industry.

The Code requires that the entire CEP is completed by medical representatives within two years of commencing employment within the pharmaceutical industry (refer to Section 4.13 of Edition 15 and Section 6.4 of Edition 16 of the Code).

In addition to medical representatives the Medicines Australia Code of Conduct (Section 4.14 of Edition 15 and Section 6.5 of Edition 16) states that the Medicines Australia Code of Conduct (Program 1) must be completed by “Any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public (this includes Product Managers, medical marketing or sales staff); or has direct interaction with healthcare professionals for the purpose of promoting a prescription medicine, whether part-time or full-time,...within the first twelve months of commencement of employment.”

The CEP is offered in distance learning and online modalities through UQ Health Insitu, which is backed by the resources of the University of Queensland. The course is tailored for adult learning and designed to provide flexibility for participants in full-time employment.

**CEP Programs available through UQ Health Insitu**

**Program 1: The Medicines Australia Code of Conduct**
Ethical practices within the pharmaceutical industry, including the obligations and practices of companies in their relationship with the health care industry and the public

**Program 2: The Pharmaceutical Industry**
The historic development of the industry, government regulatory processes and the industry’s role in the Australian health care system

**Program 3: An Introduction to Pharmacology**
Pharmacokinetics and pharmacodynamics, how drugs are administered, transported through the body and absorbed

**Program 4: Understanding Product Information**
An overview of the scientific, medical and therapeutic information contained in Product Information, including how the information is structured to comply with Therapeutic Goods Administration (TGA) requirements

**Program 5: Understanding Clinical Trials and Scientific Literature**
A systematic approach to the analysis of published clinical papers, including how clinical trials are designed and conducted, and the four phases of clinical trials
**Introduction to the Human Body**  
This program introduces a student without prior knowledge of human biology to the foundation biological principles of the human body and an introduction to medical terminology. This course is a prerequisite for Program 3, Introduction to Pharmacology. Company representatives who have a similar university level qualification or health science background may be eligible for recognition of prior learning (RPL).

**Code Refresher**  
This 2-hour self-directed program informs about the differences between the current and new edition of the Medicines Australia Code of Conduct. This program is for individuals who completed Program 1 under an earlier edition of the Code.

For more information please visit the CEP website at [http://ma.healthinsitu.uq.edu.au](http://ma.healthinsitu.uq.edu.au)

**CEP Enrolments in 2009-2010**

Table 5 shows the number of enrolments in Semester 2, 2009 and Semester 1, 2010. Please note some candidates may be enrolled in more than one program in the semester, for example Programs 1 and 2.

<table>
<thead>
<tr>
<th></th>
<th>Semester 2, 2009</th>
<th>Semester 1, 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program 1</td>
<td>387</td>
<td>388</td>
</tr>
<tr>
<td>Program 2</td>
<td>265</td>
<td>192</td>
</tr>
<tr>
<td>Program 3</td>
<td>167</td>
<td>172</td>
</tr>
<tr>
<td>Program 4</td>
<td>204</td>
<td>200</td>
</tr>
<tr>
<td>Program 5</td>
<td>211</td>
<td>162</td>
</tr>
<tr>
<td>Introduction to the Human Body</td>
<td>150 (RPL)</td>
<td>142 (RPL)</td>
</tr>
<tr>
<td>86 (RPL)</td>
<td>59 (RPL)</td>
<td></td>
</tr>
<tr>
<td>Code Refresher</td>
<td>18</td>
<td>1078</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1488</td>
<td>2393</td>
</tr>
</tbody>
</table>

**CEP Evaluation**

As part of the program completion process for all CEP Programs, students are required to submit an online evaluation form. Completion of the evaluation form is mandatory. In all evaluations, students are asked to rate the extent that their expectations were met on six areas, and are invited to add a text comment for each if desired. The six evaluation areas are:

1. The student kit (Student Handbook and Program Notes)  
2. The facilitator  
3. The online learning modules and activities  
4. The student support services  
5. The assessment process  
6. Overall program experience

Evaluation data for Semester 2, 2009 and Semester 1, 2010 are presented in Table 6.
Medicines Australia is pleased with the overall satisfaction ratings (exceeded/met expectations) of 98.9%.

In 2010 Medicines Australia formed a CEP Working Group to review the relevance and value of the current programs. The Working Group will be conducting a survey and/or focus groups with Member Companies in September 2010. The outcomes of this review will help formulate any changes to the CEP.
CEP Awards

The CEP Awards for 2009 (students enrolled between January and December 2009) were presented at an Awards Dinner in April 2010. The Medicines Australia Chairman, Mr Will Delaat highlighted the importance of a highly trained and ethical workforce interacting with healthcare professionals. Medical representatives are the ambassadors for the industry and provide reliable and accurate information on medicines to these healthcare professionals.

In her address in presenting the UQ Active Learning Prizes Associate Professor Michele Groves from the University of Queensland referred to the role of continuing education for in the healthcare sector and the engagement of pharmaceutical staff when participating in the CEP on-line tutorials.

Awards

UQ Health Insitu Active Learning Prize
- Facilitators nominate one finalist from their program each semester, based on the level and quality of participation in group discussions and personal reflections in the online tutorials.
- Winner selected by a panel from The University of Queensland.

UQ Health Insitu Awards were presented to:

Mr David (Yew Choong) Kam
Merck Sharp & Dohme
(Australia)
Semester 1, 2009

Ms Allanah Campton
Novo Nordisk
Semester 2, 2009
**Code of Conduct Award**
- Finalists include all students who achieve a final mark of 100% for Program 1.
- Excludes anyone who has achieved 100% final mark via resubmission or supplementary assessment.
- Among finalists, winner determined through review of learning log book and online participation by UQ panel; MA to make final decision if difficult to identify a clear winner.

The Code of Conduct Award was presented to:

![Image of award presentation](image1)

Mr Colin Clarke  
Merck Sharp & Dohme  
(Australia)

---

**CEP Achievement Award**
- Winners are the students who achieve the 10 highest aggregate marks for the five core programs (out of a possible total aggregate of 500).
- MA4200 (Introduction to the human body) is not included in the aggregate calculation as not all students are required to undertake this program.
- Excludes anyone who has achieved their marks via resubmission or supplementary assessment.

CEP Achievement Awards were presented to:

![Image of award presentation](image2)

Ms Katie Card  
Bayer Healthcare

![Image of award presentation](image3)

Mr Robert Crumpler  
Pfizer Australia
Ms Alison Evans
Mundipharma

Mr Kresimir Valinger
Novartis

Mr Kieran Kellet
AstraZeneca
CEP Achievement Award recipients not present at the dinner*:

- Ms Trudie Renowden – AstraZeneca
- Ms Claudia Tassone – Boehringer Ingelheim
- Mr Travis Mai – Eli Lilly
- Mr Soenke Tremper – Gilead Sciences
- Mr Russell Mathisen – Servier Laboratories

* Award recipients companies were current at the time of completion of CEP. Some award recipients may have moved to other companies or roles outside industry.
ACCC Authorisation

**Edition 16 Implementation Timeline**
- 15 June 2009 – adoption by Medicines Australia member companies
- 30 June 2009 – application for authorisation submitted to the ACCC
- 16 October 2009 – draft determination by ACCC
- 17 November 2009 – pre-decision conference with ACCC and interested stakeholders
- 3 December 2009 – final determination by ACCC
- 1 January 2010 – Edition 16 effective

“It is not controversial that very significant public benefit flows from the Code.” This was a finding of the Australian Competition Tribunal (Tribunal) in respect of Edition 15 of the Code. This view was also expressed by some participants at the pre-decision conference for Edition 16.

In creating a voluntary industry code there is always a tension between accommodating the different interests of all parties. Edition 16 of the Code incorporates industry and consumer input gathered during an extensive review process. As part of that process Medicines Australia wrote to 161 organisations and received 46 submissions over an eight month period from September 2008 to April 2009.

The Code has evolved over 16 editions. It is now detailed, extensive and the most rigorous it has ever been. These improvements have not involved merely incremental steps. The reporting requirements imposed by the Tribunal upon authorisation of Edition 15, involved a very significant step-up for Members.

It is widely acknowledged that Medicines Australia Members have complied with the letter and spirit of the reporting requirements in Edition 15 of the Code. This has involved Members expending significant effort, time and expense to gather the information required and generate the reports. Medicines Australia has worked hard to retain Members but some have expressed disquiet about these obligations in circumstances where some of their competitors are not subject to comparable burdens or requirements for transparency.

Medicines Australia acknowledges the concerns that have been raised by some healthcare professionals, consumers and academics. However, Medicines Australia considers there is a real risk that if the Code is seen to move any more quickly than is occurring now, the gap between Members and non-members will widen and support for the Code through membership of Medicines Australia will be threatened. Medicines Australia considers that Edition 16 of the Code strikes the right balance between transparency through reporting and the risks associated with imposing further requirements on Members. The Code has never been more rigorous. It can only continue to be effective if Medicines Australia retains a broad based membership.

The Code requires each Member Company to make publicly available on its website a list of Health Consumer Organisations to which it provides financial support and/or significant direct/indirect non-financial support. This is covered under Section 35.4 in Edition 16 of the Code. The list must include a description of the nature of the support and be updated on an annual basis. These arrangements are consistent with equivalent requirements in the EU.

Edition 16 substantially increases fines for moderate, severe and repeat contraventions by 50%, 100% and 100% respectively. In addition, the Code of Conduct Committee has the power to, and
does regularly, impose a range of additional sanctions, including publication of corrective notices and withdrawal of offending materials.

In their final determination the ACCC also highlighted the amendment to the Code (Section 5.2 Explanatory Note) which recommends that compliance with the Code form part of the overall performance assessment of company representatives. Member companies have taken seriously internal training and the provision of current, accurate and balanced information being provided to healthcare professionals in a timely and professional manner.

Guidelines Working Group

The key objectives of the Guidelines Working Group were to:

- Develop information for inclusion in the Guidelines to enhance understanding of the new provisions of the Code (Edition 16); and
- Identify sections of the Code that require further clarification; for example, brand name reminders.

Guidelines Working Group Members

- Ms Marlene Arens – Amgen
- Mr Alistair Barkhouse – Gilead
- Mr Antony Beard – Eli Lilly
- Dr Steevie Chan – Janssen-Cilag
- Mr Wes Cook – Boehringer Ingelheim
- Mr Glenn Denniston – Abbott Australasia
- Ms Petra Klaunzer – AstraZeneca
- Dr Mathieu Miehe – Novartis
- Dr Shaun O’Mara – Novo Nordisk
- Mr Grant Simic – Princeton
- Ms Lorraine Sutherland – Merck Sharp & Dohme
- Ms Maida Talhami – Pfizer
- Ms Heather Jones – Medicines Australia
- Ms Deborah Monk – Medicines Australia

Sections requiring most clarification were brand name reminders and the position of qualifying statements. The Working Group developed a series of advertisements for a prescription medicine to demonstrate the requirements with respect to size and positioning of mandatory text, claims and qualifying statements. These examples and the Guidelines were well received by companies and businesses working with industry.

The Working Group debated at length how to best explain the new provisions pertaining to brand name reminders. As it is not feasible to develop a list of acceptable and unacceptable items, the Working Group designed a decision tree to aid companies in determining what items would comply with the Code.

Medicines Australia would like to thank the members of the Guidelines Working Group for their work over many months and their significant contribution to the development of the Guidelines to accompany Edition 16 of the Code.

The Guidelines to accompany Edition 16 can be found on the Medicines Australia website at www.medicinesaustralia.com.au
Edition 16 Implementation

Since April 2009 the Code Secretariat has worked with companies and businesses working with industry to understand the changes to the Code and how these should be implemented. As set out on page 17 members of the Code Secretariat conducted 50 training sessions and meetings on the Code. Companies have provided intensive internal training on the introduction of Edition 16 and compliance with the new provisions has been exemplary.
Consistent with the provisions of Edition 15 of the Code member companies must report all educational meetings and symposia held or sponsored by the company in a six-month period. During the review of Edition 15 of the Code member companies raised some concerns with these timeframes as the reporting date coincided with the New Year period and the end of the financial year. Prior to submitting the application for authorisation of Edition 16 Medicines Australia approached the ACCC with respect to changing the reporting periods. The ACCC advised that they were prepared to consider such an amendment during the authorisation process. In their final determination the ACCC agreed to the change “to assist companies to comply with their obligations without the competing demands of yearly and half yearly reporting.”

As set out in Table 7 member companies now have 30 days in which to submit their reports, although the publication time is unchanged, and the reporting timeframes have been amended.

<table>
<thead>
<tr>
<th>Reporting Period</th>
<th>Reports to Medicines Australia (from end of reporting period)</th>
<th>Publication on the Medicines Australia website (from end of reporting period)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Edition 15</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>July - December</td>
<td>14 days</td>
<td>3 months</td>
</tr>
<tr>
<td>January - June</td>
<td>14 days</td>
<td>3 months</td>
</tr>
<tr>
<td><strong>Edition 16</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>October - March</td>
<td>30 days</td>
<td>3 months</td>
</tr>
<tr>
<td>April - September</td>
<td>30 days</td>
<td>3 months</td>
</tr>
</tbody>
</table>

Medicines Australia is pleased to report a high level of compliance with the Code with respect to education meetings held by member companies. At the end of each financial year the Monitoring Committee selects and reviews three random months of events, for example August, November and March for review. During the review, as set out in the Code (Section 14.1.1 of Edition 15 and 28.2.2 in Edition 16) the Monitoring Committee is “empowered in any case to request, and Member Companies must provide, any further information concerning a particular educational meeting such as a copy of the invitation to the meeting, agenda, program, a copy of any materials provided to attendees and invoices and receipts.”

Having reviewed the additional information it has requested the Monitoring Committee must consider whether a potential breach of the Code may have occurred. If so the Committee will refer the educational event to the Code of Conduct Committee for a determination. Table 8 provides a summary of the number of educational meetings reported in each of the six reporting periods to date and the number of events found to be in breach of the Code by the Code of Conduct Committee following the referral from the Monitoring Committee.
<table>
<thead>
<tr>
<th>Reporting Period</th>
<th>Number of events reported</th>
<th>Number of events found in breach of the Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Review of July 2007 – June 2008 data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 random months 2007/2008 data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>33</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 random months 2007/2008 data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Jul – Dec 2008 (Report 3)</td>
<td>18,060</td>
<td>Review of 3 random months data</td>
</tr>
<tr>
<td>Jan- Jun 2009 (Report 4)</td>
<td>16,020</td>
<td></td>
</tr>
<tr>
<td>Jul – Dec 2009 (Report 5)</td>
<td>16,790</td>
<td>Review of 3 random months data</td>
</tr>
<tr>
<td>TOTAL</td>
<td>87,196</td>
<td>35</td>
</tr>
</tbody>
</table>

Member Company reports can be found on the Medicines Australia website at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)
Rights

The rights of pharmaceutical companies, healthcare professionals and members of the general public are recognised, including the right to lodge a complaint and the right to an impartial decision. Anonymous complaints will not be accepted by Medicines Australia. This is to protect the integrity of the process. However, where anonymity is requested by a non-industry complainant this will be respected.

The complaints process is free of charge. A Complaints Submission Form for Non-Industry Complainants can be found on the Medicines Australia website at www.medicinesaustralia.com.au

Complainants and Subject Companies have the right to appeal a decision of the Code of Conduct Committee. The appeals process is free of charge for non-industry appellants, however a pharmaceutical company must lodge an appeal bond of $20,000 when lodging an appeal.

Complaints and appeals are considered in a transparent, equitable, objective and unbiased manner by the Code and Appeals Committees. The permanent members of the Code and Appeals Committees are nominated by third parties such as the Consumers Health Forum, AGPN, AMA, RACGP, RACP and TGA and are independent of Medicines Australia. Together with the Chairman the permanent members form a majority of the Committee.

The complaints handling process will reflect the principles of natural justice and procedural fairness.

Accessibility

The complaints process is readily accessible to pharmaceutical companies, healthcare professionals and members of the general public. An independent facilitator is available to assist non-industry complainants.

Where a complaint falls outside the jurisdiction of Medicines Australia the matter will be referred to the most appropriate alternate organisation. For example if a complaint about a device is lodged with Medicines Australia it will be forwarded to the Medical Technology Association of Australia (MTAA) which is the peak body for the devices sector.

Timeframe

The complaints handling process will be prompt and responsive and target times for handling complaints have been set down in the provisions of the Code. The Complainant and Subject Company will be informed of all decisions and provided with the reasons for the decision pertaining to their particular complaint.

Reports

The outcomes of all finalised complaints are published on the Medicines Australia website in quarterly and annual reports. Complaints where the activity is directed towards the general public will be published on the Medicines Australia website within one month of the finalisation of the complaint (the outcomes are also published in the next quarterly and annual report).
Where to find assistance

If you need any assistance in understanding the Code or complaints process you can contact Medicines Australia on 02 6122 8500 or via email at secretarycodecommittee@medicinesaustralia.com.au

The following documents are available on the Medicines Australia website:

- Code of Conduct Edition 16
- Code of Conduct Guidelines (to be read in conjunction with Edition 16)
- Lodging a complaint (non-industry complainant)
- Complaints Submission Form for Non-Industry Complainants
- Responding to and lodging a complaint (pharmaceutical company)
Analysis of Complaints

This section of the Code Annual Report provides information on the source of complaints, outcomes from the determination of complaints, sanctions imposed by the Code and Appeals Committees, sections of the Code pertaining to complaints and time to resolve complaints.

Source of Complaints

In 2009-2010 39 new complaints were received by Medicines Australia. As shown in Table 8 the majority of complaints were submitted by the Monitoring Committee (14 complaints = 36%) and 26% (10 complaints) submitted by pharmaceutical companies. Table 9 provides details on the source of all new complaints received in 2009-2010.

<table>
<thead>
<tr>
<th>Source of complaints</th>
<th>Number of complaints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare professionals</td>
<td></td>
</tr>
<tr>
<td>General practitioners</td>
<td>8</td>
</tr>
<tr>
<td>Hospital physicians/pharmacists</td>
<td></td>
</tr>
<tr>
<td>Specialists</td>
<td></td>
</tr>
<tr>
<td>Organisations</td>
<td>1</td>
</tr>
<tr>
<td>Health Consumer Organisation</td>
<td></td>
</tr>
<tr>
<td>Therapeutic Goods Administration</td>
<td></td>
</tr>
<tr>
<td>Colleges/Society</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
<tr>
<td>Member of the general public</td>
<td></td>
</tr>
<tr>
<td>Academic</td>
<td></td>
</tr>
<tr>
<td>Monitoring Committee</td>
<td>14</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td></td>
</tr>
<tr>
<td>Member Company</td>
<td>10</td>
</tr>
<tr>
<td>Non-Member Company</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>39</td>
</tr>
</tbody>
</table>

Complaint Determinations

Each complaint is usually made up of several different aspects, where the complainant alleges that certain statements or claims in the materials or aspects of a company’s conduct are in breach of one or more sections of the Code. Each element of the complaint is considered and a decision made. Thus, in many complaints there may be decisions where some aspects are found in breach and other aspects not in breach.

Complaints held over from 2009-2009

Four complaints were held over from 2008-2009. One complaint was withdrawn by the complainant and three complaints were considered by the Code and/or Appeals Committees. The decisions with respect to two complaints found some aspects of the allegations to be in breach of the Code and in one complaint all aspects of the allegations were found to be in breach of the Code. Figure 4 provides details of the final decisions of the Code and Appeals Committees with respect to the three
complaints held over from 2008-2009. Links to the reasons for the decisions for the complaints held over from 2008/2009 can be found on pages 44-46.

![Figure 4](image)

**Figure 4**

Outcome of complaints received in 2008-2009 and finalised in 2009-2010

- Where no aspects of a complaint were found to be in breach N = 0
- Where all aspects of a complaint were found to be in breach N = 1
- Where some aspects of a complaint were found to be in breach N = 2

**Complaints received in 2009-2010**

Of the 39 new complaints received in 2009-2010, 22 complaints were considered and finalised by the end of the financial year. Details with respect to the 17 complaints received and not finalised or considered by the Code and/or Appeals Committees in 2009-2010 are listed below:

- 1 complaint withdrawn by the complainant
- 3 complaints forwarded to the TGA
- 1 complaint considered by the Code Committee but subject to appeal in July 2010
- 2 complaints considered by the Code Committee in June 2010 but not deemed finalised as the complainant and subject companies had not had sufficient time to advise of any appeal
- 10 complaints received after the cut off date for complaints for the June 2010 meeting and will be considered in July 2010

As shown in Figure 5, 10 of the 22 complaints were found not in breach of the Code and 12 complaints were found to be in breach of some or all aspects of the allegations. The link to the reasons for the decision with respect to these complaints can be found on pages 44-46.
Appeals
In 2009-2010, 22% of complaints considered by the Code Committee were appealed. Figure 6 shows the outcomes of the five appeals held in 2009-2010. Two appeals pertained to the same matter and were considered together at one meeting.

Figure 5
Outcomes of complaints received and finalised in 2009-2010

- Where no aspects of a complaint were found to be in breach N = 10
- Where all aspects of a complaint were found to be in breach N = 4
- Where some aspects of a complaint were found to be in breach N = 8

Figure 6
Outcomes of 2009-2010 Appeals

- Appeal upheld and sanction removed
- Some aspects of appeal upheld and sanction amended
- Appeal not upheld and sanctions amended
- Appeal not upheld and sanctions not amended
Sanctions
Sanctions may be imposed on a company where breaches of the Code have been established. Under the provisions of Editions 15 (Section 12) and 16 (Section 24), sanctions may consist of one or more of the following:

- cessation of conduct and/or withdrawal of materials
- corrective action (letter and/or advertisement)
- monetary fine

The requirement to withdraw and cease using materials found in breach can only apply to materials that might otherwise be used again. It cannot be required for an activity that has already taken place and is not continuing, such as a competition or educational event.

Figure 7 summarises the sanctions imposed by the Code and Appeals Committees on companies found in breach of the Code in 2009-2010.
**Monetary fines**

Figure 8 shows the financial penalties imposed on companies found in breach of the Code. 75% of fines were under $75,000, with one fine in the $75,000 - $99,999 bracket and two fines in the $100,000 - $149,999 bracket.

![Figure 8](image)

**Figure 8**

Fines imposed by the Code & Appeals Committee on companies found in breach of the Code

- Complaints received in 2008-2009 & finalised in 2009-2010
- Complaints received & finalised in 2009-2010

<table>
<thead>
<tr>
<th>Bracket</th>
<th>2008-2009</th>
<th>2009-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0 - $24,999</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>$25,000 - $49,999</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>$50,000 - $74,999</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>$75,000 - $99,999</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>$100,000 - $149,999</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>$150,000 - $200,000</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Complaints resolution timeframe

Complaint resolution time is measured from the date a complaint is received at Medicines Australia to the date of the Code or Appeals Committee meeting (working days). Medicines Australia publishes on the website a list of meeting dates and cut off dates for complaints for each meeting. Complaints are received at any time in the month with some complaints being received just after the cut off date for the monthly meeting and this extends the timeframe for resolution as it will be referred to the following meeting.

As shown in Figure 9, the average time to resolve a complaint received and finalised in 2009-2010 was 41 working days. This time was reduced where the complaint was not subject to appeal to 32 working days. The shortest time to resolve a complaint was 16 working days.

The average time to resolve a complaint in 2009-2010 was slightly less than 2008-2009 where the average time was 43 working days.

![Figure 9](image_url)

**Length of time to resolve all finalised complaints**

- Complaints received in 2008-2009 & finalised in 2009-2010
- Complaints received & finalised in 2009-2010
**Code provisions subject to complaint**

Complaints in 2009-2010 were considered under Editions 15 and 16. Figure 10 provides a snapshot of the alleged and actual breaches by section of the Code for complaints held over from 2008-2009 and finalised in 2009-2010. These complaints were considered under Edition 15 of the Code.

![Figure 10](Image)

**Figure 10**

Number of alleged and actual breaches of the Code (Edition 15) for complaints received in 2008-2009 and finalised in 2009-2010 (N = 3)

<table>
<thead>
<tr>
<th>Section</th>
<th>Breach</th>
<th>No breach</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 11 provides a snapshot of the alleged and actual breaches by section of the Code for complaints received and finalised in 2009-2010 that were considered under Edition 15 of the Code.

![Figure 11](Image)

**Figure 11**

Number of alleged and actual breaches of the Code (Edition 15) for complaints received and finalised in 2009-2010 (N = 22)

<table>
<thead>
<tr>
<th>Section</th>
<th>Breach</th>
<th>No breach</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>45</td>
<td>29</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>10</td>
<td>15</td>
<td>6</td>
</tr>
</tbody>
</table>
Figure 12 provides a snapshot of the alleged and actual breaches by section of the Code for complaints received and finalised in 2009-2010 and considered under Edition 16 of the Code.

![Bar chart](image)

**Figure 12**

Number of alleged and actual breaches of the Code (Edition 16) for complaints received and finalised in 2009-2010 (N = 2)

- Section 1: 1 breach, 1 no breach
- Section 2: 1 breach, 1 no breach
- Section 12: 1 breach, 1 no breach
- Section 13: 3 breaches, 2 no breaches
- Section 18: 1 breach, 1 no breach
Definitions

The definitions in this list apply only to terms used in this Annual Report. A more extensive glossary of terms is included in Editions 15 and 16 of the Code of Conduct.

**Accommodation** means a company may provide a reasonable level of expenses to enable a healthcare professional to attend the meeting.

**Advertisement** means any communication which promotes or discourages the use, sale or supply of products (whether or not the communication identifies particular products or services).

**Australian approved name** means the active ingredients or chemical components of a medicine.

**Brand name** has the same meaning as ‘proprietary name’ which is the registered trade mark of the therapeutic product of the unique name assigned to the product.

**Brand name reminder (BNR)** means such items of low monetary value which are intended to remind healthcare professionals of the existence of a product.

**Complainant** means an individual, organisation or company who lodges a complaint under the Code of Conduct.

**Company event** is an educational event organised by a pharmaceutical company for healthcare professionals.

**Congress** is an extended educational meeting usually organised by a medical society or college, university or other non pharmaceutical company entity.

**Consumers** and the **general public** are persons other than healthcare professionals.

**Consumer Medicine Information (CMI)** is information about a medicine written by the pharmaceutical company that makes the medicine. It is easy to understand and written for consumers.

**Continuing Education Program (CEP)** is an education program designed to educate medical representatives to a recognised industry standard.

**Entertainment** means the provision of any diversion or amusement.

**Guidelines** mean the current Code of Conduct Guidelines.

**Healthcare professional (HCP)** includes members of the medical, dental, pharmacy or nursing professions and any other persons who, in the course of their professional activities, may prescribe, supply or administer a medicine.

**Hospitality** means the provision of food and/or beverages.

**Indications** mean the registered therapeutic use of a medicine as approved by the Therapeutic Goods Administration (TGA).
**International congress** means a congress held in Australia where a Society or College in an overseas country is actively organising and has joint control over the conference with an Australian Society or College.

**IFPMA** means International Federation of Pharmaceutical Manufacturers and Associations.

**Medical representative** means a person expressly employed by a company whose main purpose is the promotion of the company’s products to healthcare professionals.

**Member** means a company holding membership of Medicines Australia.

**Minor breach** is a breach of the code that has no safety implications to the patient’s well being and will have no major effect on how the medical professional will prescribe the product.

**Moderate breach** is a breach of the Code that has no safety implications for a patient’s well-being but may have an impact on how the medical profession prescribes the product.

**Non-member** means a company who does not hold membership of Medicines Australia.

**PBS** means the Pharmaceutical Benefits Scheme of the Commonwealth Department of Health and Ageing.

**Patient Support Program (PSP)** means a program run by a company, with or without involvement from a health consumer organisation, with the aim of increasing patient compliance and positive health outcomes.

**Pharmaceutical industry** means companies supplying prescription medicines in Australia.

**Product Familiarisation Program (PFP)** means a program run by the company with the aim of allowing the medical profession to evaluate and become familiar with the product.

**Product Information (PI)** means a document submitted to the TGA which includes the following information; description, pharmacology, clinical trials, indications, contraindications, precautions, adverse reactions, dosage and administration.

**Promotional material** means any representation concerning the attributes of a product conveyed by any means whatever, for the purpose of encouraging the usage of a product.

**Repeat of a previous breach** is where the same or a similar breach is repeated in the promotion of a particular product of a company which has been found in breach.

**Starter pack** means a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists. Starter packs are also referred to as ‘samples’ by healthcare professionals.

**Satellite meeting** is a meeting held in conjunction with international or Australasian Congresses.

**Severe breach** is a breach of the Code that will have safety implications to a patient’s well-being, and/or will have a major impact on how the medical profession will prescribe the product and/or will have a significant commercial impact on the relevant market. A severe breach of the Code will also be found for activities that bring discredit upon or reduce confidence in the pharmaceutical industry.
Subject Company means a pharmaceutical company against whom a complaint under the Code of Conduct has been lodged.

Symposium is a meeting between a number of experts in a particular field at which papers are presented by specialist on particular subjects and discussed with participants. Symposia may be organised by a pharmaceutical company as a separate educational event or as satellites to another congress or conference.

Therapeutic Goods Administration (TGA) is the Division of the Commonwealth Department of Health and Ageing that is responsible for the regulation of therapeutic goods in Australia.

Trade pack means a package of a product which is sold by the company.
Complaints finalised in 2009/2010 were considered under Editions 15 (N = 23) or 16 (N = 2) of the Code. Table 8 provides a summary of each complaint finalised in 2009/2010. To view the detailed reasons for the decision please click on the complaint number in column 1.

The decisions pertain to sections found to be in breach and not in breach of the Code. Complaints that were withdrawn or forwarded to the TGA are not included in Table 10 as they were not considered by the Code Committee.

<table>
<thead>
<tr>
<th>No.</th>
<th>Subject Company</th>
<th>Material or information subject to complaint</th>
<th>Product</th>
<th>Complainant</th>
<th>Outcomes</th>
<th>Sanction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1016</td>
<td>CSL</td>
<td>Information to the general public</td>
<td>HPV Vaccine</td>
<td>Member of the general public</td>
<td>No breach 9.4, 9.5.7, 10.8 Breach 9.5.4</td>
<td>• Ensure address is on future materials • Fine - $1,000</td>
</tr>
<tr>
<td>1017</td>
<td>Genzyme</td>
<td>Promotional material for HCPs</td>
<td>Renagel</td>
<td>Shire</td>
<td>Breach 9.4, 9.5 No breach 1.2.1</td>
<td>• Withdraw • Fine - $25,000 • Corrective letter</td>
</tr>
<tr>
<td>1018</td>
<td>CSL</td>
<td>Starter Packs</td>
<td>Various</td>
<td>John Hunter Hospital</td>
<td>Breach 4.5, 5.1.2</td>
<td>• Fine - $1,000</td>
</tr>
<tr>
<td>1022</td>
<td>Pfizer</td>
<td>Promotional material for HCPs</td>
<td>Lipitor</td>
<td>Healthcare Professional</td>
<td>No breach 1.1, 1.2.2, 1.3, 1.7</td>
<td>N/A</td>
</tr>
<tr>
<td>1023</td>
<td>Allergan</td>
<td>Promotional material for HCPs</td>
<td>Botox</td>
<td>Monitoring Committee</td>
<td>Breach 1.2.2, 1.3</td>
<td>• Withdraw • Corrective letter • Fine - $100,000</td>
</tr>
<tr>
<td>1024</td>
<td>Pfizer</td>
<td>Information to the general public</td>
<td>N/A</td>
<td>Member of the general public</td>
<td>No breach 9.4, 9.5, 9.10</td>
<td>N/A</td>
</tr>
<tr>
<td>1025</td>
<td>Sanofi-aventis</td>
<td>Promotional material for HCPs</td>
<td>Copaxone</td>
<td>Merck Serono</td>
<td>Breach 1.1, 1.3, 1.7</td>
<td>• Withdraw • Corrective letter • Fine - $25,000</td>
</tr>
<tr>
<td>1027</td>
<td>Janssen-Cilag</td>
<td>Educational Event</td>
<td>N/A</td>
<td>Monitoring Committee</td>
<td>No breach 6.2, 10.2, 10.8</td>
<td>N/A</td>
</tr>
<tr>
<td>No.</td>
<td>Subject Company</td>
<td>Material or information subject to complaint</td>
<td>Product</td>
<td>Complainant</td>
<td>Outcomes</td>
<td>Sanction</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------</td>
<td>---------------------------------------------</td>
<td>---------------</td>
<td>------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>1028</td>
<td>Merck Sharp &amp; Dohme</td>
<td>Educational Event</td>
<td>N/A</td>
<td>Monitoring Committee</td>
<td>Breach 6.2, 10.2, No breach 10.8</td>
<td>• Fine - $20,000</td>
</tr>
<tr>
<td>1029</td>
<td>Nycomed</td>
<td>Promotional material for HCPs</td>
<td>Somac</td>
<td>AstraZeneca</td>
<td>No breach 1.1, 1.2.2, 1.3, 1.5, 1.7, 4.1, 4.4, 10.5.1, 10.5.2, 10.8</td>
<td>N/A</td>
</tr>
<tr>
<td>1030</td>
<td>Servier</td>
<td>Promotional material for HCPs</td>
<td>Coversyl</td>
<td>Boehringer Ingelheim</td>
<td>Breach 1.1, 1.3, 1.7, 1.10, No breach 4.1</td>
<td>• Withdraw</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Fine - $100,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Corrective letter</td>
</tr>
<tr>
<td>1031</td>
<td>Schering Plough</td>
<td>Promotional material for HCPs</td>
<td>Olmetec</td>
<td>Healthcare Professional</td>
<td>Breach 1.1, 1.10, 3.1.4, No breach 1.9, 10.8</td>
<td>• Withdraw</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Fine - $35,000</td>
</tr>
<tr>
<td>1032</td>
<td>Merck Sharp &amp; Dohme</td>
<td>Educational Event</td>
<td>N/A</td>
<td>Monitoring Committee</td>
<td>Breach 6.2, 10.2, No breach 10.8</td>
<td>• Fine - $40,000</td>
</tr>
<tr>
<td>1033</td>
<td>Merck Sharp &amp; Dohme</td>
<td>Educational Event</td>
<td>N/A</td>
<td>Monitoring Committee</td>
<td>Breach 6.2, 10.2, 10.8</td>
<td>• Fine - $10,000</td>
</tr>
<tr>
<td>1034</td>
<td>Innovex (Pharmalink)</td>
<td>Educational Event</td>
<td>N/A</td>
<td>Monitoring Committee</td>
<td>Breach 6.2, 6.8, 10.2, 10.3, 10.8</td>
<td>• Fine - $50,000</td>
</tr>
<tr>
<td>1035</td>
<td>Allergan</td>
<td>Promotional material for HCPs</td>
<td>Ganfort</td>
<td>Alcon</td>
<td>No breach 1.1, 1.2.2, 1.3, 1.7</td>
<td>N/A</td>
</tr>
<tr>
<td>1036</td>
<td>Ferring</td>
<td>Advertisement in HCP publication</td>
<td>Pentasa</td>
<td>Healthcare Professional</td>
<td>No breach 1.1, 1.3, 1.3.1</td>
<td>N/A</td>
</tr>
<tr>
<td>1037</td>
<td>Pfizer</td>
<td>Advertisement to the general public</td>
<td>N/A</td>
<td>Member of the general public</td>
<td>No breach 9.4, 9.5, 9.10</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Table 10
Complaints finalised in 2009/2010

<table>
<thead>
<tr>
<th>No.</th>
<th>Subject</th>
<th>Company</th>
<th>Material or information subject to complaint</th>
<th>Product</th>
<th>Complainant</th>
<th>Outcomes</th>
<th>Sanction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1038</td>
<td>Pfizer</td>
<td>Advertisement to the general public</td>
<td>N/A</td>
<td>Member of the general public</td>
<td>No breach 9.4, 9.5, 9.10</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>
| 1039 | GSK     | Advertisement to the general public | Valtrex                                      | Member of the general public | Breach 9.4, 9.5         | No breach 9.10             | - Pay a fine of $20,000  
- Revise company policies to monitor agencies acting on behalf of GSK      |
| 1041 | Biogen Idec | Advertisement in HCP publication and promotional material | Tysabri | Bayer Healthcare | 3 claims Breach 1.2 x 1, 1.3 x 3  
No breach 1.2 x 2, 10.8 |                                                                 | - Withdraw materials found in breach  
- Publish a corrective advertisement  
- Pay a fine of $75,000 |
| 1042 | GSK     | Company supported medical practice activity | Seretide MDI | Healthcare Professional | No breach 7.1.1, 7.1.2, 7.1.5, 10 preamble, 10.8 | N/A                       |                                                                            |
| 1043 | sanofi-aventis | Promotional material for HCPs | Clexane                                      | Healthcare professional | Breach 1.3  
No breach 1.1, 1.2 |                                                                 | - A corrective letter had been sent. No further sanction imposed |
| 1044 | Boehringer Ingelheim | Advertisement and an Advertorial for HCPs | Mobic                                        | Arthritis Australia | Breach 2.1.1.4, 13 preamble, 13.2  
No breach 13.3, 18 |                                                                 | - Publish a corrective advertisement  
- Pay a fine of $50,000 |
| 1046 | Pfizer Australia | Website for the general public | Champix                                      | Healthcare professionals | No breach 1.3, 12.3 | N/A                       |                                                                            |
**HPV Vaccine 1016**

**Subject Company:** CSL

**Complainant:** Member of the general public

**Product:** HPV Vaccine

**Complaint**
The complainant was of the view that the advertising campaign, directed at women aged 12 – 26 years, encouraging them to be vaccinated with the cervical cancer vaccine before the Government-funded catch-up program ended on 30 June 2009 contravened State and Commonwealth laws and breached the Code of Conduct. While no brand name was used in the commercial, the name ‘cervical cancer vaccine’ had been used. Given that at the time only one brand of HPV vaccine was available on the National Immunisation Program catch-up program, this was equivalent to encouraging members of the general public to seek a prescription for a specific prescription only medicine.

**Sections of the Code**
Conduct alleged to be in breach of the following Sections of the Code:
- 9.4 Promotion to the General Public
- 9.5.4 Patient Education
- 9.5.7 Patient Education
- 9.10 Discredit to and reduction of confidence in the Industry

**Response**
CSL responded that the key objective of the Government funded immunisation program is long term control of disease. High levels of vaccine coverage are critical to the success of immunisation programs. CSL implemented a multi-faceted disease education and program awareness campaign, of which radio and television announcements were one component. A secondary message throughout the campaign is the importance of completing all three vaccine doses and of continuing with regular pap smears.

CSL disagreed that the radio and television advertisements will encourage a consumer to seek a specific product. The brand of vaccine used in immunisation programs is determined by State Health Departments through a tender process. Therefore the option of selecting a specific brand of vaccine is not given to the consumer or the healthcare professional.

Vaccine programs rely on consumer participation for successful implementation. Vaccine experts have commented in local and international conferences that activities conducted by CSL to inform and educate participants have been a contributing factor to the success of the program.

**Code Committee decision**
- In a majority decisions the Committee did not find a breach of Section 9.4 of the Code.
- In a majority decision the Committee found a technical breach of Section 9.5.4 of the Code.
- In a majority decision the Committee did not find a breach of Section 9.5.7 of the Code.
- In a unanimous decision the Committee did not find a breach of Section 10.8 of the Code.

**Sanction**
- Pay a fine of $1,000.
- Ensure that any future educational messages broadcast on radio or television includes the address or locality of the registered office of the company.

**Consideration of the complaint**
The Committee noted that the complainant had been unable to be specific about the dates, times and broadcaster of the television and radio advertisements subject to complaint except for one radio announcement on 1 June 2009 on an Adelaide FM radio station. The complainant had been
provided with three publicly sourced examples, however CSL was not provided with these examples prior to its response to the complaint being lodged. CSL had supplied a radio announcement transcript from 1 June 2009 on Adelaide FM radio and text of the television announcement that had screened in May to June 2009 which CSL confirmed were components of a campaign it had implemented. The Committee relied on these advertisements supplied by CSL in its consideration of the complaint.

The majority of members were of the view that as the HPV Vaccination Program is listed on the National Immunisation Program (NIP) Schedule and funded under the Immunise Australia Program it was in the public interest for women to be aware of the existence of the vaccine and that three vaccinations are required to complete the course. It was also noted that there was support from Government and other key stakeholders for the immunisation program. Members also noted that the decision on which HPV vaccine is administered as part of the NIP is determined through a State tender process and is not selected by the individual general practitioner.

The complainant’s submission that CSL used the term ‘HPV Vaccine’ in the communications to the general public. The complainant had asserted that whilst the brand name was not used, a prescription-only medicine had been identified. Members of the Committee commented that there had been no reference to the brand name (Gardasil) or the Australian Approved Name (Quadrivalent Human Papillomavirus Vaccine); only that girls and women within the specified age group can access cervical cancer vaccination through the free NIP. A majority of the Committee considered that the campaign was encouraging women to see their doctor to be immunised against cervical cancer and to receive the complete course but was not encouraging members of the general public to seek a prescription for a specific prescription only medicine. The Committee considered that the argument concerning whether a doctor actually writes a prescription for the vaccination was not relevant to its consideration of the complaint.

A minority of members took an alternative view, that the campaign was creating a demand for a specific prescription-only medicine. These members considered that whilst the advertisements do not identify a specific prescription medicine by generic name or brand name, there was only one brand of HPV vaccine that was available free of charge through the NIP for the ‘catch-up’ program. These members considered that the communication campaign was equivalent to encouraging women to seek a particular prescription-only medicine.

In a majority decision the Committee did not find a breach of Sections 9.4 or 9.5.7 of the Code.

In a unanimous decision the Committee did not find a breach of Section 9.10 of the Code.

In a unanimous decision the Committee found a technical breach of Section 9.5.4 of the Code because the locality of the sponsor was not included in the radio announcement.

During its discussion of the complaint the Committee particularly noted that whilst it was aware of the public health benefits of vaccination, this or any other disease communication campaign must be judged against the requirements of the Code and not on its public health benefit or the public interest.
Sanctions
Having found a technical breach of Section 9.5.7 of the Code, the Committee determined that CSL should:
• Pay a fine of $1,000.
• Ensure that any future educational messages broadcast on radio include the address or locality of the registered office of the company.
**Renagel 1017**

**Subject Company:** Genzyme Australasia (Genzyme)

**Complainant:** Shire Australia (Shire)

**Product:** Renagel

**Complaint**

Shire alleged that two items produced by Genzyme – a leave behind for healthcare professionals and a non-branded phosphate binder patient education leaflet – were in breach of the Code.

Shire asserted that the leave behind was an irresponsible representation of the available data, was misleading, failed to substantiate the claim with appropriate evidence and made an unbalanced comparison of the various phosphate binders used in hyperphosphataemia in chronic renal failure. It was further asserted that the patient education piece was promotional and made disparaging comparative statements towards metal phosphate binders and was direct-to-consumer advertising.

**Sections of the Code**

Shire alleged that the leave behind for healthcare professionals was in breach of the following Sections of the Code:
- 1.1 Responsibility
- 1.2.1 Provision of substantiating data
- 1.3 False or misleading claims

Shire alleged that the patient education leaflet was in breach of the following Sections of the Code:
- 9.4 Promotion to the General Public
- 9.5 Patient Education
- 1.2.1 Provision of substantiating data

**Response**

Genzyme denied that either the leave behind or the patient education leaflet were in breach of the Code. It asserted that the claim “bind without buildup” was a factual statement consistent with the approved Product Information and was not misleading or comparative.

Genzyme also rejected the allegation that the patient education leaflet was promotional to patients and denied any breach of the Code of Conduct or the principles underlying it.

**Code Committee decision**

**Leave Behind**

In a majority decision no breach of Sections 1.1, 1.2.1, 1.3 of the Code.

**Patient Education leaflet**

In a unanimous decision a breach of Sections 9.4 and 9.5 (specifically 9.5.1, 9.5.4, 9.5.6 and 9.5.7) of the Code. No breach of Section 1.2.1.

**Sanction**

- Withdraw the patient education leaflet found in breach (The Code Committee acknowledged that Genzyme had agreed to withdraw the materials in the intercompany dialogue)
- Pay a fine of $25,000
- Send a corrective letter to all renal physicians and clinical nurse consultants in charge of renal and dialysis units informing them of the Code of Conduct Committee decision and requesting that they destroy the patient education material found in breach or return it to Genzyme. This letter should be sent to all renal physicians and units who had been provided the patient education material found in breach.

**Consideration of the complaint**

The Committee was informed that Genzyme had requested advice from the Code Secretariat about the inclusion of Appendix J (a separate item of patient education) in the complaint documentation when this item was not subject to complaint or discussed in the intercompany dialogue. The Secretariat
had obtained clarification from Shire. Shire had advised that this item was an example of good patient education provided by Genzyme. Shire commented that this had been raised with Genzyme during intercompany dialogue. The Committee determined that Appendix J was irrelevant to its consideration of the complaint and would not form part of its consideration of this complaint.

Leave Behind
The Committee reviewed the pharmacodynamics section of the Renagel Product Information (PI) which states that Renagel contains sevelamer a non-absorbed phosphate binding poly (allylamine hydrochloride) polymer, free of metal and calcium.

While noting that the recipients of this leave behind are a small, highly specialised group of physicians, some members were of the view that the audience is irrelevant. The Code does not differentiate between audiences when considering if a claim is misleading.

Members commented that the leave behind did not identify the salts that are actually used in phosphate binding (for example, calcium carbonate or lanthanum carbonate); it only stated the name and symbols for the ions calcium, magnesium, aluminium and lanthanum, which therefore makes the information incomplete. Some members were of the view that by grouping these phosphate binders together this was an implied comparison with Renagel, suggesting that lanthanum has the same ‘build up’ as magnesium, calcium and aluminium phosphate binders. Members also considered that the reference by Chertow et al to support the ‘bind without build up’ claim was irrelevant to the claim because it only compared sevelamer with calcium carbonate, not other phosphate binders.

From the information supplied members noted that issues with specific metal-based phosphate binders, including:

- Aluminium based phosphate binders – central nervous system effects and unmasking of Alzheimer’s disease
- Calcium based phosphate binders – calcium has been shown to build up in the vasculature of renal patients causing calcification in coronary arteries

The Committee noted that Shire had stated that none of these effects had been found with lanthanum carbonate.

A minority of the Committee considered that by grouping magnesium, aluminium and calcium together with lanthanum the leave behind could be interpreted to imply that lanthanum may cause similar clinical consequences to those experienced with magnesium-, calcium- and aluminium-based phosphate binders, which could not be substantiated.

However, a majority of members were of the view that whilst the material demonstrated a lack of attention to detail, was incomplete and far from best practice, it was not in breach of the Code because the claims ‘bind without build up’ and ‘Renagel… a non-absorbed phosphate binding polymer, free of metal’ were factual and consistent with the PI and were not misleading. The Committee concluded that the leave behind only compared sevelamer with the other phosphate binders with respect to whether they are metals and whether they resulted in a ‘build up’ in the body, which could be substantiated from the Product Information documents for Renagel and Fosrenol (lanthanum carbonate). The leave behind did not claim that this build up caused any clinical effects.

Members noted that Genzyme had stated that this was a one-off mailer and would not be printed again and no more copies
would be distributed. Genzyme had also given an undertaking that any future materials which linked lanthanum with calcium, magnesium and aluminium would make it clear that there is a difference between lanthanum and other metal phosphate binders and include a qualifying statement for lanthanum regarding the clinical significance of its accumulation based on the Fosrenol PI.

By a majority decision the Code Committee determined that the leave behind for Renagel did not breach sections 1.1, 1.2.1 or 1.3 of the Code.

**Patient Education leaflet**

Members were very concerned by the alarmist nature of the images and text in the patient education leaflet. The images and text implied that the patient should be very concerned about taking certain phosphate binding medicines containing calcium or metal. The images initially suggest lack of control and chaos. On pages 6 and 7, where phosphate binders are discussed, the images and text suggest that accumulation from taking a phosphate binder results in another uncontrollable problem. When the reader reaches the last page the image is of a tidy room, with everything in order, together with the statement “Genzyme Australia strongly recommends speaking to your healthcare professional for further information about your treatment”, which suggests that the Genzyme product can solve the problem.

While noting the response from Genzyme that the patient education item was intended to be used by the physician with the patient, the text did not give this impression. It directly encouraged the patient to talk to their health professional, which would not be necessary if the item was intended to be used by a health professional in a consultation. The Committee also noted the assertion from Shire that this item could be found in renal physician waiting rooms and treatment rooms of dialysis units.

The Committee was particularly concerned by the statements on page 6 of the patient education leaflet “Some phosphate binders can accumulate in your body over time. So while they clean up phosphorus, they may create other complications with your heart, bones, brain or other tissue.” and on page 7 “Some phosphate binders contain calcium or metal that may be left behind. This calcium and metal can accumulate and may create complications.” These references to differences between the side effects of phosphate binders were comparative; such comparisons are not appropriate in materials for the general public or patients. These statements would encourage a patient to be concerned about their treatment and to seek an alternative treatment. The leaflet promotes fear, confusion and alarm for patients.

The Committee was concerned that the leaflet would confuse the patient. It first explains the concept of accumulation as meaning accumulation of phosphorus and then discusses accumulation of calcium and metal as a result of taking a medicine to bind phosphate.

Members were also concerned by the use of the Genzyme company name on every page of the item. It noted that the name appeared four times on the last page and the Genzyme website was given on the last page, which may add to the encouragement to a patient to seek the Genzyme product. The Committee commented that the comparative statements on pages 6 and 7 and the statement on page 8 “Genzyme Australia strongly recommends speaking to your healthcare professional for further information about your treatment” suggests to a patient that there may be a problem with their treatment and they should ask about the Genzyme treatment.
The Committee considered that the leaflet was promotional and was in breach of Section 9.4 of the Code. The use of ‘strongly recommends’ particularly implies that there is a problem that needs to be addressed and suggests to a patient that they need to see their doctor urgently.

In a unanimous decision the Committee found the patient education leaflet to be in breach of Sections 9.4 and 9.5 of the Code. Members were of the view that the item was not balanced (9.5.1), the name of the supplier was prominent as it appeared on every page of the document (9.5.4), the tone of the message (text and images) may cause alarm or misunderstanding (9.5.6) and the leaflet was not written in a manner which was balanced and could raise unfounded hopes of successful treatment (9.5.7). Members considered that the patient leaflet was not educational but may encourage a patient to seek a prescription for a specific prescription-only medicine and were therefore in breach of Section 9.4.

The Committee considered the allegation that the leaflet may also breach Section 1.2.1 of the Code. The Committee noted that this section relates to the provision of substantiating data. There had been no evidence presented that Genzyme had failed to respond to a request for substantiating data. No breach of Section 1.2.1 was found.

**Sanctions**

Having found a breach of Sections 9.4 and 9.5 of the Code, the Committee determined that Genzyme should:

- Withdraw the patient education leaflet found in breach. (The Committee noted that Genzyme had agreed to withdraw the item in the intercompany dialogue.)
- Send a corrective letter to all renal physicians and clinical nurse consultants in charge of renal and dialysis units informing them of the Code of Conduct Committee decision and requesting that they destroy the patient education leaflet found in breach or return it to Genzyme. This letter should be sent to all renal physicians and units who had been provided with the patient education material found in breach.
- Pay a fine of $25,000, by a majority decision. Members noted that this fine was lower than might otherwise have been applied because Genzyme had already agreed to withdraw the item and not use it again.
**CSL Starter Packs 1018**

**Subject Company:** CSL

**Complainant:** John Hunter Hospital (JHH)

**Product:** Various

**Complaint**
The Director of Pharmacy at John Hunter Hospital alleged that a CSL representative had provided product samples to the Dermatology Clinic at John Hunter Hospital. The Director stated that this was in breach of the John Hunter Hospital Protocol for Liaison with Pharmaceutical Company Representatives which requires all medicine samples to be left with the Pharmacy Department and not left in clinical areas or with Medical Officers. The Director of Pharmacy asserted that CSL’s explanation that the representative was new to the role and was not aware of the hospital policy was not an adequate reason for non-compliance. All company representatives visiting the Hospital should read and comply with the Hospital’s policies and procedures.

**Sections of the Code**
Conduct alleged to be in breach of the following Sections of the Code:
- 4.5 Company Representatives
- 5.1.2 Product Starter Packs

**Response**
CSL responded that the complaint had arisen due to a miscommunication and misunderstanding between CSL and John Hunter Hospital. CSL asserted that during a meeting at John Hunter Hospital to discuss clinical papers, which was attended by a CSL company representative, dermatology registrars and three nurses, the representative announced that starter packs were available for three CSL dermatological products. One of the nurses present had explained that the starter packs would have to be taken to the Pharmacy Department. The representative said she would take the starter packs to Pharmacy, but the nurse insisted on doing so herself. CSL has confirmed that the starter packs arrived at Pharmacy at John Hunter Hospital the very same day.

CSL stated that significant effort had been made to contact the Director of Pharmacy, but apart from one phone call, CSL was unable to speak with him directly. CSL considered the complaint had arisen due to a miscommunication between CSL and John Hunter Hospital, and a misunderstanding of the circumstances relating to the delivery of the starter packs to the Pharmacy. CSL asserted there had been no breach of the hospital policy or Sections 4.5 and 5.1.2 of the Code.

**Code Committee decision**
- In a majority decision the Committee found a minor breach of Sections 4.5 and 5.1.2 of the Code.

**Sanction**
- Pay a fine of $1,000
- Provide education to all company representatives of the importance of adherence to hospital policies.

**Consideration of the complaint**
The Committee noted the chronological sequence of events relating to this complaint. Members were of the view that there had been miscommunication and misunderstanding between CSL and the JHH.

Members accepted that the representative was apparently aware of the hospital policy which required starter packs to be delivered directly to the hospital pharmacy, and it was the intention to deliver the starter packs to pharmacy. However, on CSL’s admission, the representative had provided them to a nurse on the undertaking that she would deliver them to the hospital pharmacy. The CSL representative had no surety that the starter packs would be delivered to the pharmacy and there was
no evidence provided that the nurse had signed for receipt of the starter packs. It was noted that the starter packs evidently were provided to the Pharmacy on the same day by the nurse, which had prompted the Director of Pharmacy to contact CSL that day.

The Committee by a majority decision found a minor breach of Sections 4.5 and 5.1.2 of the Code because the representative had not complied with hospital policy. However members acknowledged that the representative had intended to adhere to hospital policy but a staff member of the hospital had contributed to the failure of the representative to fully adhere to the policy.

Members recommended that the hospital provide information to its staff in relation to the hospital’s policy for the delivery of starter packs and that CSL reinforce to its representatives adherence to hospital policies and the Code and that these responsibilities may not be carried out by another person on a representative’s behalf.

Sanctions
Having found a minor breach of Sections 4.5 and 5.1.2 of the Code, the Committee determined that CSL should:

- Pay a fine of $1,000
- Provide education to all company representatives of the importance of adherence to hospital policies.
Lipitor 1022

Subject Company: Pfizer Australia (Pfizer)

Complainant: Healthcare professional

Product: Lipitor

Complaint
The complainant had stated that the vast majority of research on statins has shown that they are of little or no benefit to women. Although a small cardiovascular benefit is seen in women with pre-existing cardiovascular (CV) disease, there is no overall mortality benefit with treatment, and for those without CV disease, statins have not proven to reduce CV disease. Even though some trials have suggested CV benefits, the majority of research has not.

The healthcare professional suggested that Lipitor is unlikely to protect older women but may cost them money and put them at risk of the well documented side effects.

The complainant alleged that the Pfizer advertisement is misleading, and not based on conclusive evidence, and should be removed from the media.

Sections of the Code
Pfizer was asked to respond to the complaint under the following sections of the Code:
• 1.1 Responsibility
• 1.2.2 Level of substantiating data
• 1.3 False and misleading claim
• 1.7 Comparative statements

Response
Pfizer responded that it did not accept that the advertisement is misleading, out of step with existing policies and guidelines and was not in breach of the Code of Conduct.

Pfizer also asserted that the advertisement was fully supported by the Product Information, consistent with the TGA approved indications for Lipitor, within the PBS listing for lipid-lowering drugs, aligned with independent guidance on lipid management in men and women and supported by clinical trial data.

Code Committee decision
• In a majority decision the Committee found no breach of Section 1.3 of the Code.
• In a unanimous decision the Committee found no breach of Sections 1.1, 1.2.2 and 1.7 of the Code.

Consideration of the complaint
The Committee noted that the three advertisements subject to complaint were included in one issue of an on-line newsletter for healthcare professionals. The Committee reviewed the three advertisements and noted that they included different levels of information:
• first advertisement does not include any reference to the indications, but does include a direct link to the Product Information and PBS listing;
• second advertisement includes the PBS listing and a statement to review the Approved Product Information in the Primary Advertisement in this publication; and
• third advertisement is the Primary advertisement which includes a statement of the approved indications, the Minimum Product Information and PBS listing.

The Code permits a company to refer from a short advertisement to a Primary advertisement and provide a direct link to the Product Information when the advertising is in an electronic format.

In considering the complainant’s allegation that there was no evidence to support the benefit to women of statins in CV disease, members reviewed the Lipitor Product Information and noted that there was no distinction between male and
female patients in the approved indications. In the clinical studies provided by Pfizer, which included thousands of subjects, women had been included in the study population, although at lower numbers than men (in one study women were 19% of the study population). All patients in the trials were hypertensive or hypercholesterolemic or had a CV event – that is they had CV risk factors. Members noted the American Heart Association “Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women” which include data on women in high, intermediate and low risk groups. The Committee concluded that there is evidence that statins are of benefit to both men and women in the prevention of CV disease where a person has CV risk factors.

The Committee discussed whether the advertisements could be interpreted to infer that all older women need cardioprotection with Lipitor, regardless of whether they had risk factors. Members commented that a healthcare professional will assess whether a patient, male or female, meets the approved indications and PBS criteria for treatment with a statin. The advertisements are directed at healthcare professionals who are familiar with prescribing statins.

One member was of the view that because the advertisements do not make it clear that the ‘grandma’ depicted has CV risk factors or meets the criteria for treatment with a lipid-lowering drug, they are potentially misleading.

The majority of members considered that the advertisements were not inferring that all older women need Lipitor regardless of risk factors.

Some members were of the view that the first and second advertisements in particular could be clearer and avoid any risk of misinterpretation of the cardioprotection claim if it was clearly stated in the advertisement that ‘grandma’ must have CV risk factors to be prescribed Lipitor.

In a majority decision the Committee found no breach of Section 1.3 of the Code as the advertisements provided sufficient reference to the Product Information and PBS listing information, which identify the criteria for prescribing Lipitor, or had included this information within the advertisement.

The Committee accepted that there is no distinction between male and female patients in the approved indications for Lipitor or in the PBS listing criteria for lipid-lowering drugs. Other independently published guidelines do not differentiate between men and women in the treatment criteria for statins. In a unanimous decision the Committee found no breach of Sections 1.1, 1.2.2 and 1.7 of the Code.
**Botox 1023**

**Subject Company:** Allergan Australia  
**Complainant:** Medicines Australia Monitoring Committee  
**Product:** Botox

**Complaint**  
*Item 1: Rejuvenation begins with Botox:* The Monitoring Committee was of the view that the claim that there is a ‘low frequency’ of adverse events with Botox, based on the presented data from a pharmacoeconomic study, is not consistent with the commonly accepted rates of adverse events in the Australian and international regulatory environment whereby events occurring at a frequency of greater than or equal to 10% is considered to be ‘common’ or ‘very common’. The frequency of individual adverse events with Botox treatment reported in the graph ranged from 7% to 23% with an overall rate of 15%. Monitoring Committee members were of the view that the claim ‘low frequency of adverse events’ was therefore misleading and in breach of Section 1.3 of the Code.

*Item 4 Be proactive:* The Monitoring Committee was concerned that the variation in lighting effects and photographs of the ‘Regular Botox’ and ‘Minimal Botox’ users gave a misleading impression of the likely outcomes of Botox treatment. Monitoring Committee members agreed that this aspect of Item 4 was in breach of Section 1.3 of the Code because the photographs were of sufficiently different quality to be misleading. Additionally, the Monitoring Committee considered that there was insufficient evidence to support the claimed relationship between the use of Botox and behaviour modification (‘Not only inhibiting ability to contract the target muscles but also perhaps through behaviour modification’) and therefore was in breach of Section 1.2.2 of the Code.

**Sections of the Code**

Materials alleged to be in breach of the following Sections of the Code:  
- 1.2.2 Level of Substantiating Data  
- 1.3 False or Misleading Claims

**Response**

Allergan disagreed that the promotional materials subject to complaint were in breach of Sections 1.2.2 or 1.3 of the Code of Conduct. The company provided data to support its assertion that it is not misleading to state that the frequency of adverse events is low with Botox when compared with the alternative botulinum toxin product. Allergan further stated that the photographs included in the promotional piece are sufficiently technically differentiated so as to clearly define the difference in wrinkle severity between the ‘regular’ and ‘minimal’ Botox users and are not misleading and are not in breach of Section 1.3 of the Code. Allergan commented that the supplied references support the behaviour modification claim which is therefore not in breach of Section 1.2.2 of the Code.

**Code Committee determination**

*Item 1*  
‘Low frequency of adverse events with Botox’ and ‘pre-clinical data suggest minimised migration with Botox allows greater physician control and decreased adverse events’ – in a unanimous decision a breach of Section 1.3 of the Code was found

*Item 4*  
- Variation in lighting – in a majority decision a breach of Section 1.3 of the Code was found  
- Behaviour modification – in a unanimous decision a breach of Section 1.2.2 of the Code was found
Sanction

- Withdraw items found in breach and not use them again or in a manner that conveys the same or similar meaning
- Send a corrective letter to all healthcare professionals who received or were detailed with the items found in breach of the Code
- Pay a fine of $100,000

Consideration of the complaint

Item 1
The Committee was particularly concerned with the use of the claim ‘low adverse events’ in the promotional item. The term ‘low’ is not the same as the ‘lower’ when comparing two products. While the adverse events may be lower for Botox than Dysport, it is not correct to state that they are ‘low’ overall for Botox. There are internationally accepted terms for describing the frequency of adverse events to medicines. Members noted the Allergan response that adverse events for Botox had not been described in terms of Council for International Organisations of Medical Sciences (CIOMS) definitions and that the claim uses ‘low’ rather than ‘uncommon’. The overall frequency of adverse events for Botox in the referenced study was 15%, and for individual types of adverse events up to 23%, which is not consistent with the description of ‘low’ frequency.

The Committee accepted that Botox and Dysport (also a botulinum toxin) are not identical and have a different molecular weight. The Committee particularly reviewed Allergan’s explanation of how toxin spread in the mouse model related to adverse effects in humans, but did not accept that this explanation was valid. The Committee considered that the claim that ‘pre-clinical data suggest that minimised migration with Botox allows greater physician control and decreased adverse events’ was misleading because it sought to link a clinical claim to animal data which could not be substantiated and was therefore misleading.

In unanimous decisions the Committee found that the claims of ‘low adverse events’ and ‘pre-clinical data suggest that minimised migration with Botox allows greater physician control and decreased adverse events’ were in breach of Section 1.3 of the Code.

Item 4
Variation in lighting in photos
Members were of the view that it was not acceptable to make treatment comparisons using photos with different lighting (intensity and brightness) for each of the twins in the case study to compare ‘regular Botox’ and ‘minimal Botox’ use. If a comparison is to be made, the positioning of the faces and the same quality lighting must be used.

Members also commented that it is not appropriate to use a single case study comparing results in one pair of twins to support a general claim about outcomes of Botox treatment.

In a majority decision the Committee found the photos were misleading and in breach of Section 1.3 of the Code.

Behaviour modification
The Committee was unanimous in their view that there was insufficient evidence to support the claim: ‘Not only inhibiting ability to contract the target muscles but also perhaps through behaviour modification’. The referenced paper included in its discussion section uses terms such as ‘perhaps’ and ‘appears’. This was expressing the views of two individuals but there was no evidence contained in the study to support this conjecture. Members also commented that it is not the responsibility of the Monitoring Committee to demonstrate that the study referenced by Allergan does not constitute the body of evidence with regard to current thinking on
behaviour modification, as was asserted by Allergan. A company must demonstrate to the satisfaction of the Monitoring or Code Committees that there is sufficient evidence to support a claim.

The Committee unanimously found the behaviour modification claim was in breach of Section 1.2.2 of the Code.

The Committee expressed a consensus view that there had been insufficient attention to the details of ensuring there was appropriate supporting evidence for claims in the two promotional items and recommended that Allergan’s compliance and internal approval processes should be reviewed and that the concerns of the Committee should be taken seriously.

Sanctions
Having found several breaches of the Code the Committee considered appropriate sanctions. The Committee determined that there were no safety implications for patients as a result of the promotional materials, but the Committee considered that the claims were seriously misleading. The Committee therefore determined that Allergan should:

• Withdraw items found in breach and not use them again or in a manner that conveys the same or similar meaning
• Send a corrective letter to all healthcare professionals who received or were detailed with the items found in breach of the Code. The corrective letter must refer to all claims and graphics found in breach of the Code. It must 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 Committee’s decision.
• Pay a fine of $100,000
Television advertisement for erectile dysfunction 1024

Subject Company: Pfizer Australia

Complainant: Member of the general public

Product: N/A

Complaint
The complainant had stated that because Pfizer was advertising its logo and name to the public at the end of an advertisement it paid for about erectile dysfunction, this was in fact advertising its product for erectile dysfunction to the general public and was therefore in breach of the Code.

Sections of the Code
Pfizer had been requested by the Secretariat to respond to the complaint with regard 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 had responded that the company takes this matter very seriously. All public broadcasts undergo a stringent internal approval process to ensure alignment with the Code, relevant legislation and Pfizer policies.

The educational broadcast subject to complaint does not mention a prescription product by name, nor does it direct patients to a particular prescription product. There are several registered and available treatments for erectile dysfunction in addition to the two Pfizer products, Viagra and Caverject. Healthcare professionals will make a decision on appropriate treatments if required.

Code Committee determination
In a unanimous decision no breach of Sections 9.4, 9.5 or 9.10 of the Code was found.

Consideration of the complaint
The Committee noted that the television advertisement did not mention a prescription medicine by name, nor did it direct patients to a specific product. Members also noted that there is a range of treatments available in Australia for erectile dysfunction, of which Pfizer supplies two. The Committee determined that the advertisement was not an advertisement for a particular prescription medicine and did not encourage members of the general public to seek a prescription for a particular product. The Committee unanimously determined that the advertisement was not in breach of Section 9.4 of the Code.

One Committee member noted that the advertisement stated “You can find more information on the website or talk to your doctor” (emphasis added). The member considered that it would be preferable to direct people to the website and their doctor, rather than as alternatives.

In reviewing the complaint the Committee noted that the complainant had stated that Viagra is available on the PBS. Viagra is not available on the PBS; however it is available on the Repatriation Pharmaceutical Benefits Scheme (RPBS); for other patients it is available as a private prescription only.

Members referred to the Section 9.5.4 of the Code which states “The educational material must include the name and the city, town or locality of the registered office of the supplier of the material, but their location should not be given prominence.” The Code thus requires that the name of the company is included in any educational communication. The Committee unanimously determined that
no breach of Section 9.5.4 or 9.5 had occurred.

The Committee unanimously determined that there was no breach of Section 9.10 of the Code as the information was educational in nature, did not encourage a patient to seek a prescription for a specific prescription medicine and did not bring the industry into disrepute.
Copaxone 1025

Subject Company: sanofi-aventis

Complainant: Merck Serono

Product: Copaxone

Complaint
Merck Serono stated that the claim “Works as quickly and effectively as high-dose INF-β-1a 44mcg” is a broad and unqualified comparison of Copaxone and Rebif which does not adequately reflect the evidence provided by the REGARD study to which it is referenced and which constitutes the body of evidence.

Sections of the Code
Materials alleged to be in breach of the following Sections of the Code:
- 1.1 Responsibility
- 1.3 False and misleading claims
- 1.7 Comparative statements

Response
Sanofi-aventis denied that the claim was in breach of the Code as it is an accurate representation of the primary outcome of the REGARD Study, which was time to first relapse and which is supported by the wider body of evidence.

Code Committee determination
In a unanimous decision the Committee found a breach of Sections 1.1, 1.3 and 1.7 of the Code.

Sanctions
- Withdraw materials found in breach
- Send a corrective letter to all neurologists
- Pay a fine of $25,000

Consideration of the complaint
The Committee considered the results in the Mikol et al study, which is the supporting reference for the claim “Works as quickly and effectively as high-dose INF-β-1a 44mcg”. It noted that the primary endpoint in the study was time to first relapse for which the two treatments (Betaferon beta-1a and glatiramer acetate) were comparable. A number of secondary and tertiary measures based on MRI scans were included in the study, some of which had reached statistical significance. The authors had concluded

“There was no significant difference between Betaferon beta-1a and glatiramer acetate in the primary outcome. The ability to predict clinical superiority on the basis of the results from previous studies might be limited by a trial population with low disease activity, which is an important consideration for ongoing and future trials in patients with RRMS.”

The Committee noted that the study did not accrue the number of relapse events required to detect a statistical difference in the primary endpoint. The study was statistically underpowered due to an overestimate of the expected rate of relapse events.

The Committee considered the letter from a professor of neurology to sanofi-aventis and noted that the professor’s comments were somewhat qualified through use of terms such as ‘broadly’, ‘limitations’ and ‘roughly equivalent’. The Committee noted the professor’s comments that the role of MRIs in multiple sclerosis is most relevant to diagnosis rather than in determining effectiveness of treatments.

The Committee was of the view that the claim “Works as quickly and effectively as high-dose INF-β-1a 44mcg” did not accurately reflect the conclusions of the Mikol et al study. Whilst the primary endpoint of the study, time to first relapse, was not statistically significantly different for each of the treatments, the claim of equal effectiveness is broader than can be substantiated from the study methodology or outcomes. Further, there was no evidence in the referenced study...
to support the claim ‘works as quickly’. The Committee concluded that the claim was misleading, had made a comparison between Copaxone and Rebif that could not be substantiated and was therefore in breach of Sections 1.1, 1.3 and 1.7 of the Code.

The Committee determined that this was a moderate breach of the Code.

Sanctions
Having found several breaches of the Code, the Committee determined that sanofi-aventis should:

- Withdraw the materials containing the claim found in breach of the Code and not use the claim again or in a manner which conveys the same or a similar meaning
- Send a corrective letter to all neurologists. The corrective letter must 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 Committee’s decision.
- Pay a fine of $25,000
Janssen-Cilag Educational Event 1027

<table>
<thead>
<tr>
<th>Description of function including duration of educational content delivered</th>
<th>Venue</th>
<th>Professional status of attendees</th>
<th>Hospitality provided</th>
<th>Total cost of hospitality</th>
<th>Number of attendees</th>
<th>Total cost of function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department Meeting - 1.5 hours</td>
<td>Hanauman Restaurant, Alice Springs</td>
<td>Psychiatrists, Registrars</td>
<td>2 course meal with alcohol/non-alcoholic beverages</td>
<td>$230</td>
<td>6</td>
<td>$230</td>
</tr>
</tbody>
</table>

Subject Company: Janssen-Cilag

Complainant: Medicines Australia Monitoring Committee

Complaint
The Monitoring Committee noted that whilst there was minimal hospitality, at a cost of $38.33 per person, members were of the view that the sponsorship of a department planning meeting did not meet the requirement for there to be an educational purpose for meetings with healthcare professionals where hospitality is provided. The event was therefore forwarded to the Code of Conduct Committee as a formal complaint.

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

Response
Janssen-Cilag acknowledged that the information provided in the original report and to the Monitoring Committee was unclear and contained an inaccurate description of the function and apologised to the Committee.

The event was an in-service for the departmental staff which followed a departmental planning day. The in-service meeting was held at a location outside the hospital for the convenience of the staff who were also attending the planning day at that location. Janssen-Cilag did not provide any support for the departmental planning day meeting and the staff who did not attend the in-service did not receive any hospitality from Janssen-Cilag.

The in-service agenda was prepared in response to concerns about debilitating side effects that occur among people in indigenous communities with schizophrenia who are treated with antipsychotics. The in-service was of 1.5 hours duration and included a presentation of clinical data, a demonstration of the reconstitution of Risperdal Contra and addressed questions in relation to side effects and long term issues.

The hospitality was modest at $38.33 per head and there was meaningful education. Janssen-Cilag argued that no breach of Sections 6.2, 10.2 and 10.8 of the Code had occurred.

Code Committee determination
In a majority decision the Committee did not find a breach of Sections 6.2, 10.2 or 10.8 of the Code.
Consideration of complaint
The Committee had a robust discussion with respect to what had occurred at this event. The Committee was concerned that companies should fully investigate any matter raised by the Monitoring Committee and provide that Committee with full, detailed and accurate information rather than only providing this information once it has been referred to the Code Committee.

Some members questioned whether there was valid education provided at the event in question, such as the demonstration of the reconstitution of Risperdal Contra, or should the event more properly be characterised as product promotion. These members questioned the necessity of conducting what appeared to be product promotion at a location away from the workplace with hospitality provided. However other members commented that whilst in-services are usually held within the institution, on this occasion healthcare professionals from the Alice Springs area were at off-site at the planning meeting and it was convenient to hold the in-service immediately after their planning day. These members accepted that, on balance, there was an educational purpose for the meeting and the hospitality provided was very modest and proportional to the education.

In relation to the meeting agenda, which included discussion of a 2006 paper, some members commented that this did not appear to be very recent information that required communication in an educational event. Other members accepted that the study in question may be the only study in the indigenous population in the therapeutic area and its discussion in the context of side effects to antipsychotics may be valid.

In a majority decision, Members accepted that the hospitality provided was proportionate to the educational content and found no breach of Sections 6.2, 10.2 or 10.8 of the Code.
Merck Sharp & Dohme (Australia) Educational Event 1028

<table>
<thead>
<tr>
<th>Description of function including duration of educational content delivered</th>
<th>Venue</th>
<th>Professional status of attendees</th>
<th>Hospitality provided</th>
<th>Total cost of hospitality</th>
<th>Number of attendees</th>
<th>Total cost of function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congress - European Society of Cardiology (ESC) delegate dinner</td>
<td>Wirtshaus Grunta, Munich</td>
<td>Specialists</td>
<td>3 course dinner with alcoholic &amp; non-alcoholic beverages</td>
<td>2,719</td>
<td>11</td>
<td>2,719</td>
</tr>
</tbody>
</table>

**Subject Company:** Merck Sharp & Dohme (MSD)

**Complainant:** Medicines Australia Monitoring Committee

**Complaint**
The Monitoring Committee had asked MSD to provide justification for the cost of the dinner held in Munich in association with the European Society of Cardiology Conference (ESC).

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

**Response**
MSD asserted that the hospitality provided was secondary to the educational purpose of the event and was consistent with the professional standing of delegates. The venue is popular with locals, has a casual outdoor seating area where the dinner was held and was at the lower end of the price range of restaurants offered by the organising agency. MSD stated that the price for the standard menu during this conference was almost triple the usual price.

The hospitality in question was provided by the joint venture of MSD and Schering-Plough. MSD reported this event because it was organised through its headquarters, Merck & Co. The invoice for the dinner was sent to Merck & Co, as the restaurant was booked by the agency used by Merck & Co. Schering-Plough was later cross-charged by MSD for its portion of the dinner. Of the 18 attendees, 11 were hosted by the joint venture and 7 were hosted by Schering-Plough.

The exchange rates used in this response were the rates published by the Reserve Bank of Australia on 2 September 2008.

**Code Committee determination**
In a majority decision the Committee found a breach of Sections 6.2 and 10.2 and no breach of Section 10.8 of the Code.
Sanction

• Pay a fine of $20,000

Consideration of the complaint

The Committee accepted that venues often substantially increase their prices when a large conference is held in a city. An Australian company providing the hospitality must ensure that any agency organising the hospitality on its behalf is aware of the company’s policies and requirements and meets the standards expected under the Medicines Australia Code of Conduct, irrespective of price movements during major conferences.

Some members commented that if the exchange rate had been more favourable there may not have been any question about the cost of the dinner. However, a majority of members considered that the cost of the dinner was extravagant and could not be justified.

The Committee noted that MSD had provided the standard menu and costs for the restaurant but had not provided the actual menu for what was served at the dinner subject to the complaint, nor had the actual receipts from the venue been supplied, only the charges applied from the head office. While the standard menu and standard costs supplied by MSD was not extravagant, the majority of members were of the view that a cost of AUD $205 per head was excessive and would not withstand public scrutiny. Some members also questioned the cost for the provision of a hostess on the coach to take 18 delegates from their hotel to the restaurant.

In a majority decision the Committee found that the event was in breach of Sections 6.2 and 10.2 of the Code. The Committee did not find a breach of Section 10.8 of the Code.

Members commented that there is no obligation on a company to provide a dinner for conference delegates. If it is not possible to find a restaurant at a reasonable cost, the company should not take the delegates to dinner.

Sanction

Having found several breaches of the Code the Committee determined that MSD should:

• Pay a fine of $20,000.
Subject Company: Nycomed

Complainant: AstraZeneca

Complaint
AstraZeneca had alleged that, based on evidence from the GP Monitor survey, the claim of there being a unique lack of interaction between pantoprazole (Somac) and clopidogrel was being delivered by Nycomed representatives. The claim is inconsistent with the current body of evidence, the Australian approved Somac Product Information (PI) and with the current regulatory position in this area. The proportion of sales calls where the issue with clopidogrel was recalled was clearly much higher after calls from the Nycomed representatives, which AstraZeneca asserted demonstrates an active, widespread and sustained campaign.

AstraZeneca asserted that by promoting Somac as the safer proton pump inhibitor (PPI) without robust supporting clinical data, Nycomed sales representatives are misleading the medical community.

AstraZeneca asserted that the messages being promoted to doctors by Nycomed is having an impact on patient care.

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

- 1.1 Responsibility
- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims
- 1.5 Unqualified superlatives
- 1.7 Comparative statements
- 1.10 Distinction of promotional material
- 4.1 Company representatives
- 4.4 Company representatives
- 10.5.2 Medical literature/reprints
- 10.8 Discredit to and reduction of confidence in the industry

Response
Nycomed denied that a widespread national campaign has been undertaken as alleged. Nycomed sales representatives have been detailing the promotional message “Somac has a low potential for drug interactions”. The representatives have been using a sales flier to convey this message. AstraZeneca has not expressed concern about the flier or the claims made within it. The flier is accurate and sufficiently substantiated by the literature.

In the latter part of 2008 and early 2009 data began to emerge in the literature purporting an interaction between clopidogrel and PPIs. At the end of January 2009 an early release version of a paper by Juurlink et al appeared. Subsequently news articles appeared in two popular GP weekly tabloids (Australian Doctor Weekly and Medical Observer). Nycomed had provided its sales representatives with a single copy of these articles and published papers to enable them to answer questions from GPs should they arise. The published papers could be provided to GPs on request to enable them to read the full story referred to in the news articles.

Nycomed has already agreed with AstraZeneca that distribution of the materials by a single hospital representative was inappropriate and action has been taken to ensure this does not occur again.

Nycomed denied that its actions or materials were in breach of the Code.

Code Committee determination

The claim of unique lack of interaction between pantoprazole and clopidogrel

- In a unanimous decision no breach of Sections 1.1, 1.2.2, 1.3, 1.5, 1.7 of the Code
In a majority decision no breach of Sections 4.1 or 4.4 of the Code.

The nature of the promotion that is clearly not aligned to current regulatory opinion and its potential to bring the industry into disrepute.

In a unanimous decision no breach of Sections 10.5.2 of 10.8 of the Code.

The distribution of a selective extract from the medical press and the use of a highlighted, photocopied reproduction as a promotional piece.

In a majority decision no breach of Sections 1.5, 1.7, 1.10, 4.1, 4.4, 10.5.1, 10.5.2 or 10.8 of the Code.

**Consideration of the complaint**

The Committee was informed that the IMS GP Monitor is available via subscription to pharmaceutical companies. A representative sample of Australian GPs (200 – 400) is paid to complete a diary of what they recall following a sales representative visit.

Members agreed that GPs receive information from a variety of sources, including sales representatives, professional journals and publications such as *Medical Observer* and *Australian Doctor Weekly*. With respect to the issues raised by AstraZeneca the Committee noted that the reference to potential interactions between PPIs and clopidogrel had been included in published articles, e-Bulletins and provided by the National Prescribing Service (NPS). In April 2009 the NPS launched an RACGP-accredited clinical audit aimed at reviewing PPI prescribing. This audit made reference to interactions with PPIs (including suspected and possible interactions) including the following statement in relation to clopidogrel “available data suggests no special precautions necessary for pantoprazole”.

Members noted that commentary from the EMEA and FDA have identified that the evidence is evolving but neither regulatory authority has confirmed that a particular PPI is superior with respect to the likelihood of drug interactions. From the evidence, all PPIs have an impact on liver enzyme metabolism and the emerging data on the differences between PPIs in interactions with clopidogrel are not yet conclusive.

The NPS publication for GPs has potentially stimulated discussion amongst the profession and, together with articles in widely read GP publications, may have contributed to GPs seeking clarification from Nycomed with respect to its product Somac.

The Committee determined that there was insufficient evidence of the proactive marketing by Nycomed of an advantage of Somac and its potential for drug interactions. The Committee considered that the GP Monitor data was not sufficient evidence of such activities. Such data do not indicate whether the sales representative raised the issue or the GP as a result of the recent medical press articles, published studies or NPS information.

However, members were of the view that Nycomed should have given a clear directive to its sales representatives not to proactively give the journal/press articles to healthcare professionals; rather the information was to keep the representatives up to date in case of questions from a GP.

Members accepted that Nycomed sales representatives could be detailing doctors as alleged, however there was no evidence provided by AstraZeneca of widespread distribution of the *Medical Observer* or *Australian Doctor Weekly* articles. The Committee did raise some concerns about representatives being provided with articles from publications such as *Medical Observer* and *Australian Doctor Weekly*, which would not include
sufficient detail for a healthcare professional to make an assessment of the veracity of the study. However, it was noted that the representatives were also given the Juurlink et al paper. Further, it was noted that there was only evidence in relation to one representative who had left copies of the articles in a hospital.

In relation to the distribution of a selective extract from the medical press and the use of a highlighted, photocopied reproduction as a promotional piece the Committee found no breach of Sections 1.5, 1.7, 1.10, 4.1, 4.4, 10.5.1, 10.5.2 or 10.8 of the Code. Having considered the information provided by AstraZeneca and Nycomed the Committee determined that there was insufficient evidence that Nycomed was promoting a unique lack of interaction between pantoprazole and clopidogrel. In a unanimous decision no breach of Sections 1.1, 1.2.2, 1.3, 1.5, 1.7 of the Code was found. In relation to the occasion where a Nycomed representative did leave the folder of medical press and scientific journal articles in a hospital, the Committee accepted that Nycomed had taken appropriate action to ensure this did not recur. Further, there was no evidence that any promotional materials making a claim of superiority of Somac in drug interactions with clopidogrel had been provided, and the Juurlink et al article had been included in the folder. In a majority decision no breach of Sections 4.1 or 4.4 of the Code was found.

The Committee also determined that there was insufficient evidence to uphold the complaint that Nycomed was engaging in an active, widespread and sustained campaign to promote Somac outside the PI and did not find a breach of Sections 10.5.2 or 10.8 of the Code.
Coversyl 1030

Subject Company: Servier Laboratories Australia (Servier)

Complainant: Boehringer Ingelheim

Product: Coversyl

Complaint

Boehringer Ingelheim alleged that although the promotional materials found in breach of the Code in Complaint 1006 were withdrawn by Servier, Servier has continued to breach the Code through a promotional campaign which misleads doctors in regard to the data available to support the use of angiotensin receptor blockers. Boehringer Ingelheim had identified several items of promotional material that it alleged continued to make misleading claims regarding the use of Angiotensin Converting Enzyme Inhibitors (ACEI) compared with Angiotensin Receptor Blockers (ARB). Boehringer Ingelheim further alleged that the continued use of these claims was a repeat breach of the Code.

Sections of the Code

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

- 1.1 Responsibility
- 1.2 Level of substantiating data
- 1.3 False and misleading claims
- 1.7 Comparative statements
- 1.10 Distinction of promotional material
- 4.1 Company representatives

Response

Servier asserted that Boehringer Ingelheim had sent the complaint to Medicines Australia without following due process as required by the Code. Servier denied any breach of the Code, or any repeat breach of the Code. Servier alleged that the complaint from Boehringer Ingelheim was vexatious and was in breach of Section 12.3 of the Code. Code and Appeals Committee determinations

Part 1: Misleading promotion of “ACE inhibitor (Coversyl) vs ARBs”

- Unanimous decision of a breach of Sections 1.1, 1.3 and 1.7 of the Code. (Decision confirmed by the Appeals Committee)
- By a majority decision, no repeat breach of Sections 1.1, 1.3 or 1.7 was found.

Part 2: Use of indirect comparisons in detailing material to compare ACEI vs ARB trials

- Complaint not sufficiently made out. No breach was found.

Part 3: Use of Medscape article for inappropriate promotion

- In a unanimous decision a breach of Sections 1.1, 1.2 and 1.3 of the Code was found. (Decision confirmed by the Appeals Committee)
- In a majority decision a breach of Section 1.10 of the Code was found. (Decision confirmed by the Appeals Committee)
- In a unanimous decision no breach of Section 4.1 of the Code was found.
- By a majority decision, no repeat breach of Sections 1.1, 1.3 or 1.7 was found.

Sanctions

The Committee determined that this was a severe breach of the Code.

- Withdraw materials found in breach (Sanction confirmed by the Appeals Committee)
- Publish a corrective advertisement (Requirement for corrective advertisement removed by Appeals Committee)
- Send a corrective letter to all general practitioners and cardiologists (Sanction confirmed by the Appeals Committee)
- Pay a fine of $100,000 (Sanction confirmed by the Appeals Committee)
In relation to the allegation by Servier that Boehringer Ingelheim was in breach of Section 12.3 of the Code, having found several breaches of the Code by Servier which were determined to be severe breaches, the Committee did not find any cause to ask Boehringer Ingelheim to respond to this allegation.

**Consideration of the complaint**

The Committee referred to the minutes for complaint Coversyl 1006 and the sanctions imposed. The Committee noted that Boehringer Ingelheim had asserted in the current complaint that Servier had not complied with the sanctions imposed in complaint 1006 and had continued to make promotional claims in relation to the comparative efficacy of ACEIs and ARBs. The current complaint was based in part on evidence provided by the market survey data from GP Monitor and in part on items of promotional material.

The Committee noted the allegation from Servier that Boehringer Ingelheim had lodged the complaint prior to finalisation of the minutes of an intercompany meeting and had not followed due process as set out in the Code. The Committee was satisfied that Servier had had the opportunity to fully respond to the allegations of breach of the Code.

**Part 1: Misleading promotion of “ACE inhibitor (Coversyl) vs ARBs”**

The Committee understood that this part of the complaint related to evidence submitted from the market research service “GP Monitor” regarding promotional claims made by Servier representatives and a Dear Doctor letter issued by Servier on 25 June 2009 (Attachment 3 in the BI complaint) which referenced a meta-analysis by Al Khalaf MM et al 2009. Overall the complaint concerned the manner in which Servier was promoting to healthcare professionals that ARBs were not as effective as ACEIs in reducing the risk of cardiovascular events.

These claims were being made to healthcare professionals in a number of different formats. The Committee was of the view that the ‘Dear Doctor’ letter and Servier item ‘Differential effects of ACE inhibitors and ARBs on cardiovascular events’ (Attachment 7 in the BI complaint) should be considered as part of this complaint.

Members noted the limitations of the evidence submitted from GP Monitor about what Servier representatives have said to doctors. The Committee understood that GP Monitor is a post hoc record by participating GPs of what was said during a particular representative visit. It further noted that none of the GP Monitor reports stated that a Servier representative had made the alleged comments or statements. However, the Committee did not completely disregard the evidence from GP Monitor.

The Committee members were of the view that the ‘Dear Doctor’ letter from Servier of 25 June 2009 and Servier item ‘Differential effects of ACE inhibitors and ARBs on cardiovascular events’ provided evidence that Servier was providing promotional material that was not balanced, did not reflect the body of evidence and had the potential to mislead prescribers. The Committee considered that the Dear Doctor letter did not accurately reflect the full body of evidence. It considered that there was a body of evidence, including the Law et al meta-analysis published in the *British Medical Journal* in 2009, that both ACEIs and ARBs have some protective effects for cardiovascular events. The reference to the El Kalaf MM et al meta-analysis in the Dear Doctor letter was selective and did not reflect the body of evidence. The Committee unanimously determined that Servier was in breach of Sections 1.1, 1.3 and 1.7 of the Code.
By a majority decision, no repeat breach of Sections 1.1, 1.3 or 1.7 was found. The Committee accepted that Servier had not continued to use exactly the same claim as had been found in breach in complaint 1006.

Part 2: Use of indirect comparisons in detailing material to compare ACEI vs ARB trials
The Committee noted that Servier had stated that the material alleged to be in continued use had been withdrawn. The Committee determined that Boehringer Ingelheim had not provided sufficient evidence that that was still being used.

The Committee did not find any breach of Sections 1.1 or 1.3 of the Code with respect to this part of the complaint.

Part 3: Use of Medscape article for inappropriate promotion
The Committee noted that Medscape was a professional news service and the author of the summary article titled “ARBs unable to TRANSCEND placebo in high-risk patients” was a journalist. The Committee considered that the Medscape article did not have equivalent scientific rigour to a peer-reviewed clinical publication and was simply a collation of differing opinions put together by a journalist.

Whilst accepting that Servier had not published the Medscape article, Servier had used the item in a promotional manner, based on the heading relating to ARBs. The Committee considered that this item falls short of the high quality of evidence expected under the Code for materials distributed by a company to healthcare professionals. While noting that the Medscape article was not identified as an item of Servier promotional material, it had been distributed to healthcare professionals by Servier representatives in a promotional manner.

Members were of the view that opinions expressed in the Medscape item were not consistent with the body of evidence for ARBs and was therefore misleading due to the manner in which it was used by Servier.

In a majority decision the Committee found that the item was promotional as defined by the Code, particularly in the manner in which it was used by Servier, and this was in breach of Sections 1.1, 1.2, 1.3 and 1.10 of the Code.

The Committee unanimously found no breach of Section 4.1 of the Code as the representatives had distributed the material which had been approved by the company.

In a majority decision the Committee determined that the distribution of the Medscape article was not technically a repeat breach under the Code and therefore did not find a repeat breach of Sections 1.1, 1.3, or 1.7. However, some members expressed the view that while Servier was using different materials, there was sufficient evidence provided by Boehringer Ingelheim that Servier had continued to distribute misleading promotional material concerning the comparative effects of ARBs and ACEIs.

The Committee found the ongoing, misleading promotion by Servier as reviewed in this complaint to be unacceptable and that this was a severe breach of the Code because it had the potential to have a major impact on prescribing.

Sanctions
Having found several breaches of the Code and determining that this constituted a severe breach of the Code, the Committee determined that Servier should:
• Withdraw the materials found in breach of the Code and not use them again, or in a manner which conveys the same or a similar meaning.
• Publish a corrective advertisement in *Medical Observer* and *Australian Doctor Weekly*.

• Send a corrective letter to all general practitioners and cardiologists. The corrective letter must 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 Committee’s decision.

• Pay a fine of $100,000.

Appeal

Servier appealed the decision of the Code of Conduct Committee on the grounds that the Committee had erred by:

• Failing to dismiss the complaint insofar as it related to the Dear Doctor letter and ‘Rahman’ promotional piece because the complaints made in relation to these materials were not brought to the Committee by following the intercompany dialogue procedure set out in the Code.

• Its determination that the Al-Khalaf meta-analysis did not adequately reflect the current body of evidence concerning the efficacy of Angiotensin Receptor Blockers (ARBs) in reducing cardiovascular events in non-heart failure patients. Of the two randomised controlled trials (RCT) provided by Boehringer Ingelheim, one is in post-myocardial infarction heart failure and therefore irrelevant to the Al Khalaf meta-analysis, which only considered and made conclusions on non-heart failure trials. The other RCT (ONTARGET) is one of three large outcome trials testing telmisartan in high-risk patients but the only one that returned a positive outcome on the primary endpoint. Boehringer Ingelheim chose to include this study only. It therefore does not reflect the body of evidence available regarding telmisartan or the entire ARB class.

• Finding the circulation and distribution of the Dear Doctor letter and ‘Rahman’ promotional piece had breached Sections 1.1, 1.3 and 1.7 of the Code.

• Finding that the Medscape article was a promotional item or distributed in a promotional manner, and that this item was in breach of Sections 1.1, 1.2, 1.3 and 1.10 of the Code.

• Requiring Servier to send a corrective letter to general practitioners and cardiologists who did not receive the Dear Doctor letter and requiring Servier to place corrective advertising, where no advertising of the material subject to complaint had taken place.

Response to appeal

Boehringer Ingelheim responded to the appeal by stating that Servier had provided little or no new evidence from that presented to the Code Committee in support of their position.

With respect to the procedural irregularities alleged by Servier, Boehringer Ingelheim agreed with the Code Committee that Servier had sufficient opportunity to respond to the concerns regarding the misleading promotion of “ACE Inhibitor (Coversyl) versus ARBs” and the use of the MedScape article.

With respect to the Dear Doctor letter and the ‘Rahman’ promotional piece, Boehringer Ingelheim considered that these items were further evidence for the concerns it had raised with Servier regarding the campaign promoting the benefits of ACE Inhibitors versus ARBs. Further the Dear Doctor letter had been raised by Boehringer Ingelheim in
correspondence with Servier and in the intercompany meeting.

Boehringer Ingelheim was of the view that the decisions of the Code Committee should be upheld.

**Consideration of the appeal**

Prior to the appeal being heard by the Committee the Chairman highlighted a number of procedural issues raised in the appeal.

The Appeals Committee noted the Code definition of ‘repeat of previous breach’ which means the same or similar breach is repeated in the promotion of a particular product, whereas the definition ‘breach repetition’ refers to the same breach in the promotion of any of a company’s products. Appendix 1 to the Code, at page 198, uses the expression ‘repeat breach’ which is not specifically defined in the Glossary, but is understood to mean a ‘repeat of a previous breach’. In the case of a ‘repeat breach’ the complainant may direct a complaint to Medicines Australia without a renewal of inter-company dialogue.

Matters for consideration by the Appeals Committee include:

- Was the complaint in relation to a repeat breach? If so, there was no need to follow the intercompany dialogue procedure, and the Code Committee was entitled to consider the complaint.
- Do all elements of the complaint relate to the same claim and are they further evidence of the same alleged breach or further instances of it? It should be borne in mind that the decision in January 2009 was that the subject company should “not use the information again, or in a manner which convey the same of similar meaning.”
- If the complaint was not about a repeat breach (in the same sense of ‘repeat of a previous breach’) then were the proper procedures followed in relation to inter-company dialogue as set out at page 196 of Appendix 1 of the Code? The requirement for consensus minutes of the intercompany meeting was not adhered to, but the Appeals Committee may wish to consider whether every effort was made on the part of both the complainant and the subject company to resolve this matter by intercompany dialogue. If the subject company did not use every effort to resolve the matter, the conclusion may be open that the Code Committee was entitled to consider the complaint in any event.
- Were the Dear Doctor letter and ‘Rahman’ promotional pieces raised in intercompany dialogue? The complainant asserts that they were whereas the subject company asserts they were not.

The following outlines the appeal presentation by Servier:

The complaint shouldn’t have been heard in its entirety. The Code Committee erred in four key areas and Servier seeks that the decisions are overturned.

There are clear requirements for intercompany dialogue in the Code of Conduct. The complaint concerned four different materials; for two of these – the Dear Doctor letter and the promotional item providing the opinion of Dr Rahman (the ‘Rahman’ piece) – intercompany dialogue was not followed in its entirety. With respect to the Dear Doctor letter, there had been an exchange of correspondence with Boehringer but the intercompany dialogue process described in the Code was not followed. In relation to the Rahman piece Boehringer did not identify what aspects it alleged were in breach of the Code despite two written requests from Servier for this information.
The corrective action imposed by the Code Committee exceeds Medicines Australia’s Guidelines for determining sanctions. The Guidelines state that corrective advertising would be required in journals where an advertisement originally appeared. None of the materials subject to complaint were advertisements in Australian Doctor or Medical Observer. Further the Dear Doctor letter was sent to some 5000 doctors, whereas the sanction requires a corrective letter to be sent to all GPs and cardiologists.

Regarding the MedScape article, it was written by an experienced author who is a medical journalist and who has written more than 40 articles in the cardiovascular field since 2004. The article did not include any promotion of perindopril. It is a resource for use by Servier representatives. Section 1.10 is not relevant to the material because it is not promotional material. It should be treated as medical literature or a reprint. The content of the MedScape article MedScape reprint was fair, balanced and accurate with quotes from authors of the peer-reviewed, published studies TRANSEND and ONTARGET. The concluding sentence of the article did not favour either ARBs or ACEIs.

Servier argued that the Al Khalaf et al meta-analysis, which is quoted in the Dear Doctor letter and Rahman promotional piece, is consistent with the body of evidence.

Servier invited a Professor of Clinical Pharmacology and Therapeutics to discuss the evidence with respect to ACE Inhibitors and ARBs. Prior to commencing his presentation the Professor stated that he had received grants from, and conducted trials in association with manufacturers of both ACEI and ARB products. He had also received travel grants from both Boehringer and Servier in the past.

The Al Khalaf et al paper is a meta-analysis which separately analysed heart failure and non-heart failure trials. The authors concluded that in patients who do not have heart failure ARBs are not equivalent to ACEIs because ARBs do not confer protection against myocardial infarction (MI) in these patients. The Professor proceeded to outline the conclusions from a number of studies and meta-analyses. From this evidence he stated that there is clearly evidence to support that ACEIs confer a benefit through reduction of MI in heart failure patients over and above any reduction in blood pressure, whereas with ARBs it is difficult to demonstrate a benefit in reducing MI risk. The Professor stated that the Al Khalaf et al meta-analysis was consistent with the body of evidence.

The Professor referred to recent opinions from the European Medicines Agency (EMEA) and US Food and Drug Administration (FDA), which contrast with each other. The European “Committee for Medicinal Products for Human Use (CHMP)” has issued a positive opinion on the use of telmisartan (an ARB) use in high risk CV patients. The reasons for this decision have not been disclosed. This contrasts with the FDA Cardio-Renal Advisory Committee of July 29 2009 in consideration of an application from the sponsor for marketing approval based on the ONTARGET study for “reducing risk of CV death, MI, stroke or CHF hospitalisation inpatients ≥ 55 years at high risk of developing major cardiovascular events”. The FDA Advisory Committee concluded that:

- ONTARGET does not demonstrate superiority of telmisartan/ramipril vs ramipril (ACEI) monotherapy
- Telmisartan does not meet requirements for non-inferiority vs ramipril
- Neither TRANSEND or PROFESS studies demonstrates telmisartan superiority over placebo
The Professor concluded that the Al Khalaf et al meta-analysis is consistent with the body of evidence that it is difficult to demonstrate a benefit of ARBs in reducing MI risk in patients without heart failure and there is a demonstrable MI risk reduction with ACEI over and above reduction in blood pressure.

Servier concluded its presentation reiterating the view that the decisions of the Code Committee should be overturned or, as a minimum, the sanctions should be amended.

The following summarises the presentation in response to the appeal made by Boehringer Ingelheim:

The Professor’s presentation illustrated that this is a very complex area and the scientific community has not yet reached a conclusion on the relative benefits of ARBs and ACEIs.

Boehringer noted that in complaint 1006 from January 2009 Servier was found in breach for misleading comparison of EUROPA and TRANSCEND studies and misleading comparison of Coversyl (an ACEI) trials vs ARBs. Servier did not appeal this decision.

Boehringer discussed the procedural issues raised by Servier. It was noted that the Code Committee had been satisfied Servier had had the opportunity to fully respond to the allegations of breaches of the Code. With regard to the provision of consensus minutes, a full recording of the intercompany meeting was provided to Servier and the minutes were amended on request from Servier and a revised version was forwarded to Medicines Australia for inclusion with the complaint prior to the Code Committee considering the complaint.

Boehringer outlined the sequence of contacts between the companies leading up to the complaint and argued that:

- Boehringer from its earliest contact with Servier had raised concerns about a co-ordinated campaign, demonstrated by specific promotional pieces.
- Numerous verbatim comments had been recorded in GP Monitor from various states around Australia, indicating misleading promotion by Servier that only ACE Inhibitors have proven benefits in reducing CV events.
- Boehringer had also received reports that healthcare professionals had been detailed with materials highlighting misleading comparisons and claims concerning ARBs and ACEIs.
- Boehringer was particularly concerned at Servier’s reluctance to enter into intercompany dialogue following earlier contact in regard to the same issues, and believe this is not within the spirit of the Code.
- As soon as further supporting evidence of the misrepresentation of the body of evidence became available, Boehringer had advised Servier.
- The Dear Doctor letter from the Servier representative simply reinforced Boehringer concerns that had been raised initially with Servier. Refusing to discuss the letter at the intercompany meeting was an attempt to further delay addressing this important matter.
- All supporting materials were tabled at the intercompany meeting
- Boehringer reiterated that the materials supported its original concerns regarding misleading promotion of ACEIs in comparison to ARBs

Servier had referred to complaint 908 in which the subject company had raised a number of procedural issues in relation to the complaint where the Code Committee had determined that one aspect of the complaint was not properly brought before the Committee because it had not been the subject of proper intercompany.
dialogue. Boehringer considered that these issues were not relevant to the current complaint 1030.

Boehringer considered that the misleading promotion of ACEIs vs ARBs was not a new issue. Servier had previously used indirect comparisons to compare Coversyl and ARBs in complaint 1006.

Servier has made a sweeping generalisation from a complex therapeutic issue, where multiple studies exist, through the selective use of a single meta-analysis to support one view. Since the finding of a breach of the Code in complaint 1006, Servier has chosen to use a selective meta-analysis by Al Khalaf et al to support claims that ARBs do not reduce CV morbidity and mortality.

Boehringer pointed to study limitations reported in the Al Khalaf meta-analysis: “Our approach may, indeed, recognise some limitations because it includes very heterogeneous conditions and patients with different susceptibilities to MI. Most trials titrated doses to balance tolerability and achievement of desired effect; hence there was a wide range of dosages used even within the trials. Other limitations of our study include potential variation in the definition of MI between trials. Results are based on relatively small number of events, resulting in ORs that could be affected by small changes in the classification of events.

Furthermore, we pooled the results of trials that were not all originally intended to explore cardiovascular outcomes. In some cases, the basis used to make a diagnosis of MI was not clearly defined. We were unable to obtain data on MI events from all studies identified in our literature search. Perhaps most notably, data on MI from VALIANT, which included 14,703 patients, were not available for our analysis.”

Boehringer also noted that perindopril (Coversyl) is not identified by Al Khalaf et al as being included in any study included in the meta-analysis. This is a limitation for the study being used as the basis for the claims for the comparative benefit of Coversyl.

Boehringer outlined other relevant meta-analyses, including by Reboldi et al (2008) and Law et al (2009), which came to conclusions contrary to those of Al Khalaf et al:

- Law et al – concluded “With the exception of the extra protective effect of β blockers given shortly after a myocardial infarction and the minor additional effect of calcium channel blockers in preventing stroke, all the classes of blood pressure lowering drugs have a similar effect in reducing CHD events and stroke for a given reduction in blood pressure so excluding material pleiotropic effects.”
- Reboldi et al – concluded that ARBs are as effective as ACEIs on the risk of myocardial infarction, cardiovascular mortality and total mortality.
- Volpe et al (2009) – concluded “This meta-analysis indicates that the risk of MI is comparable with use of ARBs and other antihypertensive drugs in a wide range of clinical conditions.” Servier promotional materials had stated “A meta-analysis of heart failure trials studying the effects of ARBs, published in 2009, concluded that there is no evidence to suggest that ARBs provide protection against MI.”

Boehringer referred to the FDA Advisory Committee decision raised by Servier. It noted that the expanded indication recommended for approval by the FDA included the reduction in risk of myocardial infarction, stroke or death from cardiovascular disease. Boehringer further noted that these differing opinions from regulatory authorities indicate that this is not a clear cut issue.
Boehringer referred to the National Heart Foundation Guide to management of hypertension 2008 which states “ACE inhibitors and angiotensin II receptor antagonists have been shown to be equally efficacious in prevention of combined end points of cardiovascular disease death, myocardial infarction, stroke and heart failure admissions in patients at high risk due to past cardiovascular events”.

Boehringer stated that the varying evidence and divergent opinions concerning the relative benefits of ACEIs and ARBs in protection against cardiovascular disease demonstrate that there is continuing debate in the medical and scientific community. Boehringer considers that the single meta-analysis by Al Khalaf does not reflect the body of evidence. Other meta-analyses show different results.

Regarding the Code Committee’s statement that there was no evidence that a Servier representative had made the alleged comments or statements, Boehringer stated that every call recorded by GPs entering data into GP Monitor includes a record of the product presented and the company promoting that product. The company name for the representative is entered on the recording sheet. The records submitted as part of this complaint clearly state the verbatim comments were as a result of discussion with Coversyl representatives from Servier. Boehringer remains concerned that misleading information is being conveyed by Servier representatives.

Regarding the MedScape Article, Boehringer considers that it was used in a promotional manner. Further the article doesn’t satisfy the expected standard of high quality evidence; it is not peer-reviewed whereas there is peer-reviewed evidence available. Boehringer agrees with comments by the Code Committee in its decision with respect to the use of the item in a promotional manner. Boehringer contends that the distribution of the materials subject to complaint support its original contention that Servier was engaged in a widespread campaign distributing misinformation.

In response to a question from the Chairman regarding the requirement for a corrective letter to be sent to a wider audience than the doctors who received the Dear Doctor letter, Boehringer responded that there has been substantial activity by Servier representatives for some time using materials identified in this complaint in addition to the Dear Doctor letter. Boehringer stated that more doctors have been exposed to the misleading information than the Dear Doctor letter recipients.

In the discussion that followed Boehringer’s presentation, Servier representatives stated that they had taken a literal interpretation of the intercompany dialogue process, with the expectation that with each new piece of promotional or other material raised there should be a letter from the complainant describing the aspects considered to be contrary to the Code and then a ten day period for intercompany dialogue to occur. Boehringer did not agree with this approach, because it considered that the different pieces of promotional material were further examples of the conduct it had originally complained about.

In response to a question about whether the complaint was a repeat breach, which would have obviated the requirement for intercompany dialogue, Servier denied it was a repeat breach. Boehringer stated that it did consider that this was a repeat breach, but nevertheless it decided to engage in intercompany dialogue with Servier. It was concerned with Servier’s approach which it regarded as trying to split the complaint into three separate complaints.
The Servier and Boehringer Ingelheim representatives left the meeting following these presentations.

**GP Monitor evidence**
Appeals Committee Members reviewed the recording sheet for GP Monitor which included the requirement for the general practitioner to write the name of the company and product in addition to completing other sections on their recollections of the representative visit. The issues raised by Boehringer with respect to the activities of Servier representatives are reinforced by the GP entries into GP Monitor.

**MedScape heartwire article**
Appeals Committee Members considered that the MedScape article was an opinion piece prepared by a journalist who is not a clinician expert in cardiovascular disease. It provides a collection of extracts from published studies and editorials. It is a professional news service of WebMD and is not a peer reviewed publication. It was published in August 2008 and therefore does not take into account subsequent published articles. Although the article was originally published independently, its use by the Servier sales force was in a promotional context (particularly noting the title of the article relating to the efficacy of ARBs in cardiovascular disease). The Committee concluded that it agreed with the Code Committee’s decision.

**Dear Doctor Letter**
While noting the discrepancies between Servier and Boehringer in relation to intercompany dialogue processes, the Committee was of the view that the concerns raised by Boehringer in relation to the activities of Servier representatives was the same as that raised in relation to the Dear Doctor letter. Although the letter was not identified at the time of the original complaint, it was evidence for the promotional claims being made by Servier regarding the effectiveness of ARBs in comparison with Coversyl in cardiovascular protection. The Appeals Committee considered that Servier should have been on notice that Boehringer’s concerns were about these claims wherever they were being made. The subsequent identification of the Dear Doctor letter (and the Rahman article) was further evidence that the same or similar claims were being made. The Appeals Committee also agreed that Servier had had adequate opportunity to respond to these concerns in the intercompany dialogue and to the Code Committee.

The Committee accepted that the Al Khalaf et al meta-analysis was published in the peer-reviewed scientific literature. However, it was not convinced that the Al Khalaf et al meta-analysis represented the definitive position of the expert medical community or was fully representative of the body of evidence. The Committee accepted that there was evolving evidence of the relative efficacy of ARBs and ACEIs in offering protection in cardiovascular disease including in different sub-populations. This is also reflected by the apparently differing views of the EMEA and FDA. Members considered that this is a complex area and data relevant to the effectiveness of ACIs and ARBs was not presented in a balanced manner. Healthcare professionals should be provided with literature in a more balanced manner which discusses all evidence.

The Appeals Committee considered that the Dear Doctor letter was not balanced through its reference to the Al Khalaf et al meta-analysis as the supporting evidence for the claim concerning comparative efficacy of ARBs and ACEIs, which did not fully represent the body of evidence, and was therefore misleading. The Committee agreed with the decisions of the Code Committee.
**Rahman article**
The Appeals Committee noted Servier’s assertion that Boehringer had not lodged a formal complaint specifically in relation to the Rahman piece and that the intercompany dialogue process had not been followed. Members were of the view that the Rahman item was a Servier promotional piece, which specifically conveyed the opinion of a healthcare professional on the issue of the differential efficacy of ACE Inhibitors and ARBs on prevention of cardiovascular events. Members considered that this item was within the scope of the concerns raised by Boehringer regarding Servier’s promotion of ACE Inhibitors versus ARBs. The Appeals Committee considered that it was appropriate for the Code Committee to consider the Rahman article because it contained the same message with respect to the benefits of ACE Inhibitors over ARBs.

The Committee considered that the Rahman article conveyed the message that ARBs were less effective than ACEIs in preventing myocardial infarction and death, with reference to the Al Khalaf et al meta-analysis. For the same reasons as found regarding the Dear Doctor letter, the Committee considered that the Rahman article was not balanced, did not fully represent the body of evidence, and was therefore misleading.

The Appeals Committee concluded that it agreed with the Code Committee that the complaint concerned the manner in which Servier was promoting to healthcare professionals that ARBs were not as effective as ACEIs in reducing the risk of cardiovascular events and that these claims were not able to be adequately substantiated. These claims were evident in a number of different items and representative conduct, supported in part by the GP Monitor information.

In a unanimous decision the Appeals Committee did not uphold the Servier appeal.

**Sanctions**
Having not upheld the appeal the Appeals Committee reviewed the sanctions imposed by the Code of Conduct Committee. The Committee discussed at length the requirement for a corrective letter and corrective advertisement. In a majority decision the Committee determined that the requirement for a corrective letter to be sent to all general practitioners and cardiologists imposed by the Code Committee should remain.

In a unanimous decision the Committee determined that the requirement for a corrective advertisement should be removed.

In a unanimous decision the Committee determined that the requirement for Servier to pay a fine of $100,000 should remain.
Olmetec 1031

Subject Company: Schering-Plough

Complainant: Healthcare Professional

Complaint
The complainant stated that he was concerned about the wording of the publication ‘Hypertension News’ which is ostensibly an advertisement only. The complainant did not like the whole flavour of the item, espousing the esteemed qualifications of the ‘interviewee’ and then linking his prescribing preference for the advertised product specifically. He questioned why the ‘interviewee’ did not endorse a class of drug rather than one member of the class. Thirdly, he sought clarification on the relationship between the ‘interviewee’ and Schering-Plough and what payment was made to him or was it pro-bono because there is no disclosure on the item.

Sections of the Code
The Secretariat had asked Schering-Plough to respond to the complaint with respect to the following Sections of the Code:
- 1.1 Responsibility
- 1.9 Medical ethics
- 1.10 Distinction or promotional material
- 3.1.4 Company commissioned article
- 10.8 Discredit to and reduction of confidence in the industry

Response
Schering-Plough responded that Hypertension News is a two page promotional piece compiled to provide information to healthcare professionals about Olmetec and Olmetec Plus, using actual case studies presented by cardiologists who have prescribed the products.

The case study includes a patient profile, treatment and outcome, with general questions relating to hypertension and the products posed to the cardiologist. The cardiologist’s response is reviewed by Schering-Plough medical to ensure consistency with the Product Information.

Five Hypertension News pieces have been developed, of which three have been distributed in the field. It is intended that two such newsletters be distributed every three months, using a different cardiologist in each newsletter in order to obtain a range of clinical management strategies used with the products.

The newsletter is personally distributed by Schering-Plough sales representatives who promote the products. The sales representatives explain to the healthcare professional that the purpose of the newsletter is to provide information relation to the treatment practices of the cardiologist in the context of using the products. The newsletter is not distributed by mail to a wider audience who may not have been detailed on the products.

Schering-Plough had the approval of the cardiologist to have his name and photograph in the newsletter. Schering-Plough paid the cardiologist for his time in preparing the case study, answering the questions raised in the newsletter and reviewing the final version of the newsletter.

Schering-Plough denied that the newsletter breached any section of the Code.

Code Committee determination
- In a unanimous decision the Committee found a breach of Sections 1.1, 1.10 and 3.1.4 of the Code and no breach of Sections 1.9 and 10.8 of the Code.
Sanctions

- Withdraw the item found in breach and not use it again or in a manner that conveys the same or similar meaning
- Pay a fine of $35,000

Consideration of the complaint

It was noted that the name of the company was included on the back page of the newsletter. However, it was also noted that the newsletter states “Proudly sponsored by Schering-Plough” which may give the impression that it is an independent publication sponsored by the company. Members were of the view that the presentation of ‘independent opinion’, which included unreferenced claims about Olmetec and Olmetec Plus, in a company promotional item should not be used as an opportunity to avoid the requirements of Section 1 of the Code.

In reference to the title of the newsletter, ‘Hypertension News’, members were of the view that this was not balanced and was potentially misleading because the newsletter did not provide ‘news’ about hypertension or a discussion of a range of treatment options but was solely a promotional item for Olmetec and Olmetec Plus.

Members noted that the Code does not require a company to disclose whether a healthcare professional was paid for contributing their opinion on a topic. However a company promotional item, in this case the newsletter, should clearly identify on the front page that it is a company promotional item and not leave a reader in any doubt. Where it is clear to a reader that an item is promotional material, a healthcare professional may then weigh up the value and potential bias of the information provided therein.

In a unanimous decision the Committee found a breach of Sections 1.1, 1.10 and 3.1.4 of the Code because it was not sufficiently clear to a reader reviewing the front page that the newsletter was company promotional material. The information is not balanced because it purports to be providing news of a general nature but in fact only promotes the interests of the company with respect to their products. As the healthcare professional whose opinions were contained in the newsletter had provided his consent for information under his name to appear in the newsletter the Committee agreed that there was no breach of Section 1.9 of the Code.

The Committee also determined that there was no breach of Section 10.8 of the Code.

Sanctions

Having found several breaches of the Code the Committee determined that Schering-Plough should:

- Withdraw the item found in breach of the Code and not use it again or in a manner that conveys the same or similar meaning
- Pay a fine of $35,000.
Merck Sharp & Dohme (Australia) Educational Event 1032

<table>
<thead>
<tr>
<th>Description of function including duration of educational content delivered</th>
<th>Venue</th>
<th>Professional status of attendees</th>
<th>Hospitality provided</th>
<th>Total cost of hospitality</th>
<th>Number of attendees</th>
<th>Total cost of function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congress - European Association for the Study of Diabetes (EASD) delegate dinner</td>
<td>Entoca, Rome</td>
<td>Specialists</td>
<td>3 course dinner with alcoholic &amp; non-alcoholic beverages</td>
<td>1,098</td>
<td>6</td>
<td>1,098</td>
</tr>
</tbody>
</table>

Subject Company: Merck Sharp & Dohme (MSD)

Complainant: Medicines Australia Monitoring Committee

Complaint
The Monitoring Committee had asked MSD to provide justification for the cost of the dinner held in association with the European Association for the Study of Diabetes (EASD).

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

Response
MSD stated that the primary objective of the (EASD) was the enhancement of medical knowledge and the quality use of medicines by healthcare professionals. The conference, which brought together 18,000 delegates, provided significant high quality educational content.

MSD asserted that the hospitality provided was secondary to the educational purpose of the event and was consistent with the professional standing of the delegates. It was chosen for its central location and pricing which was within the company’s guidelines. Unfortunately due to the small number of attendees on the evening the fixed price menu was not offered to the attendees. Instead, the attendees were required to order from the à la carte menu.

The exchange rates used in this response were the rates published by the Reserve Bank of Australia on 8 September 2008.

The hospitality in question was provided by the joint venture of MSD and Schering-Plough. MSD reported this event because it was organised through its headquarters, Merck & Co. The cost of the dinner including beverages was AUD$233 per head (excluding VAT). With the exception of one bottle of wine (which was ordered without the knowledge or consent of the joint venture or its staff), this event would have been within company guidelines as the price would have been reduced by $45 per person. Staff from the organising agency signed off and settled the bill on the evening without the concurrence of the joint venture staff.
As a result of this incident MSD has changed its internal processes and it no longer permits agencies to sign off bills on its behalf or on behalf of the joint venture. This process will also be communicated to Schering-Plough.

**Code Committee determination**

In a unanimous decision the Committee found a breach of Sections 6.2 and 10.2 and no breach of Section 10.8 of the Code.

**Sanction**

- Pay a fine of $40,000

**Consideration of the complaint**

Members were of the view that the onus is always on a company to exert control over its event. It was noted that MSD had subsequently changed its policy to not permit an agency to sign off on bills. The Committee considered that a company must make it clear to its agents and the venue that nothing should be debited to the company account without the permission of the company personnel present at the event.

The Committee considered that the food consumed at the dinner was not extravagant, however the inclusion of one very expensive bottle of wine (€160) was extravagant and would not withstand public scrutiny. MSD had conceded that the level of expenditure went beyond its own guidelines. Some members expressed concern that a healthcare professional would take advantage of the company and order such an expensive bottle of wine without the permission of the company.

The Committee was particularly concerned that MSD or its agents had not exerted sufficient control over the hospitality provided at the event and in a unanimous found a breach of Sections 6.2 and 10.2 of the Code. In unanimous decision the Committee did not find a breach of Section 10.8 of the Code.
Merck Sharp & Dohme (Australia) Educational Event 1033

<table>
<thead>
<tr>
<th>Description of function including duration of educational content delivered</th>
<th>Venue</th>
<th>Professional status of attendees</th>
<th>Hospitality provided</th>
<th>Total cost of hospitality</th>
<th>Number of attendees</th>
<th>Total cost of function</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV - GP Clinic Journal Club.</td>
<td>GP Clinic, WA</td>
<td>HIV General Physicians</td>
<td>Light refreshments</td>
<td>213</td>
<td>2</td>
<td>213</td>
</tr>
</tbody>
</table>

**Subject Company:** Merck Sharp & Dohme (MSD)

**Complainant:** Medicines Australia Monitoring Committee

**Complaint**

The Monitoring Committee had requested an explanation for the cost of hospitality for a journal club meeting. MSD had advised the Monitoring Committee that the event was a representative detail meeting held over dinner. The Monitoring Committee referred the event to the Code Committee because it was concerned that representative detailing was conducted over dinner and that the balance between education and hospitality at this event was not consistent with the Code.

**Sections of the Code**

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

**Response**

MSD had stated that the event was a detail meeting attended by two MSD representatives and two doctors working in a HIV medicine GP practice. MSD referred to the Explanatory Note to Section 4.11 of the Code which states that the provision of a meal (to healthcare professionals by company representatives) which complies with the requirements of Section 10 of the Code is not a breach of this section.

MSD asserted that the hospitality provided at the restaurant was modest, consistent with the professional standing of the delegates and secondary in nature to detailed discussions between the attendees regarding the improvement of services to patients.

**Code and Appeals Committees determinations**

In a unanimous decision the Committee found a breach of Sections 6.2 and 10.2 of the Code (Decision confirmed by the Appeals Committee)

In a majority decision the Committee found a breach of Section 10.8 of the Code. (Decision overturned by the Appeals Committee)

**Sanction**

- Pay a fine of $50,000 (Fine reduced to $10,000 by the Appeals Committee)

**Consideration of the complaint**

The Committee noted that a number of errors had occurred in the reporting of this event. Firstly it had been as a journal club and secondly the cost of hospitality was incorrect. The actual cost of hospitality was $53.30 per head. Members also noted that MSD had
advised that it was providing additional training to representatives on educational event reporting requirements.

Members considered MSD’s response that the reported meeting was a two way conversation to exchange information that could not have been conducted in a standard sales call and that the dinner timeslot was selected as this was the only time the two doctors could get together.

While the venue may be popular, casual and inexpensive, the Committee considered that if the issues stated by MSD were covered in this meeting, it had been inappropriately conducted in a public restaurant rather than in a private room. The Committee considered that the restaurant in question was an inappropriate venue for conducting a sales call or educational event.

Members were of the view that there was a lack of educational purpose in the meeting and therefore was in breach of the Code for the type of hospitality provided; if the meeting was actually a sales call, it was inappropriate with regard to the venue and that hospitality in association with a sales call should be minimal and no alcohol should be provided. The Committee was of the view that this event could not withstand public scrutiny and was wholly inconsistent with the standard that was expected of the industry.

In a unanimous decision the Committee found a breach of Sections 6.2 and 10.2 of the Code. In a majority decision the event brought the industry into disrepute and was in breach of Section 10.8 of the Code.

Sanction
Having found several breaches, including a breach of 10.8 of the Code, the Committee determined that MSD should:
• Pay a fine of $50,000.

Appeal
MSD lodged an appeal stating that the educational merit of the meeting had not been adequately clarified to the Code committee. The primary purpose of the meeting was to discuss with HIV experts how MSD could help support the education of Western Australian physicians and health care workers in this highly specialised area of medicine. The majority of the meeting was devoted to discussion about data presented at a recent international conference and how important information from very recent scientific meetings could be communicated to interested physicians in a timely manner.

Consideration of the appeal
The following outlines the appeal presentation from MSD:
• MSD acknowledged that the initial reporting of the event was inaccurate. This was due to the representative, who was new to the company, being unfamiliar with the reporting procedures.
• To prevent any further errors MSD has implemented the following actions:
  ▪ Educational event reporting training
  ▪ Revisions to documents used for reporting
• Education of doctors in HIV medicine is critical. HIV medicine is a complex area. People with HIV have multiple disease conditions, require multiple medicines, and there are many drug-drug interactions. The successful management of patients with HIV requires HCPs to be well informed of recent advances and how the various treatment regimens should be used in clinical practice.
• International and local scientific meetings are important for the latest information on treatment regimens.
• Physicians consider specialist pharma representatives “an invaluable tool in
the practice of evidence based medicine”.

- The purpose of the meeting subject to complaint was to discuss the latest information from clinical trials and how this relates to clinical practice. The educational needs of WA HIV specialists were discussed. The content and purpose of the meeting was educational.
- The venue afforded privacy to the representatives and physicians for the discussion. The group was seated in a part of the restaurant away from other patrons.
- The physicians use the venue independent of industry involvement and considered it to be conducive to education.
- In a letter from the physicians who attended the meeting they noted that the time when they can see company representatives together is limited to cross over times at the surgery. The most convenient time to them is after the work day when both are present in the practice. Consulting finishes at 7.00pm and it is therefore common for the physicians to suggest a representative visit after this time.
- Having both physicians together enabled greater input and a broader clinical discussion.
- The cost of the hospitality was modest and appropriate to the professional standing of the attendees.
- Based on the further clarification provided of the educational event, MSD requested that the Appeals Committee uphold this appeal and dismiss the findings of the Code of Conduct Committee.

In response to a question from the Committee regarding the manner in which MSD had requested the doctors’ letter to the Committee, MSD advised that it had requested that the MSD representative obtain advice regarding the privacy afforded by the venue and the educational value of the meeting.

In response to a question from the Committee seeking clarification about why the description of the meeting had changed from the original report to being characterised as a detail meeting and now an educational meeting, MSD explained that the representative who reported the event was new to the company. She had originally mis-recorded the event as a journal club and later characterised the event as a detail meeting. However, there was no detailing in the meeting. The discussion included the educational requirements of WA HIV physicians, which had been described in the response to the Code Committee. As a result of the meeting two educational meetings had been arranged in WA with over 30 attendees, demonstrating that the interest in education was not limited to the two doctors who attended the event in question.

The MSD representatives left the meeting following this presentation.

Members were concerned that there had been three different descriptions provided for the purpose of this meeting. While accepting that a new representative may have initially incorrectly reported the event as a journal club, MSD should have ensured that full and correct responses were provided to the Monitoring and Code Committees. It seemed to the Appeals Committee that there was a shifting of position each time a Committee sought further information about the event.

The Committee noted that MSD had stated that papers from a recent international conference and recent clinical studies were discussed at the meeting and how MSD could assist to make the educational content from an upcoming HIV conference in Brisbane available to interested WA physicians who
are unable to attend the conference. However, MSD had not provided any documentary evidence to the Code Committee or Appeals Committee that would support MSD’s explanation, such as the papers discussed with the physicians or the program that was developed as a result of this meeting. Some members commented that if there was a planning meeting on what education would be most valuable for all HIV physicians in WA there would be consultation with a wider group than with two individual physicians.

The Committee discussed the balance between the hospitality provided, which was relatively modest at $53.00 per head, and the educational content or purpose. It was noted that the Code requires hospitality to be secondary to the educational purpose. The Committee was not persuaded that the educational content of the meeting was sufficient to satisfy the test that the hospitality was secondary to the education. Members considered that the meeting was more characteristic of a detailing meeting because it lacked any evidence of formality such as an agenda or other documentation to indicate the educational purpose. Whilst the cost of the meal was modest, the Committee considered it was not consistent with the Code to provide a meal and alcoholic beverages to health professionals in a restaurant for a meeting with sales representatives with minimal education provided.

The Committee took into consideration the letter from the two doctors who had attended the meeting. Members were not persuaded that the character of the meeting was other than a normal representative visit.

The Committee was unanimous in its view that the appeal in relation to Sections 6.2 and 10.2 should not be upheld as MSD had not provided any evidence to support its contention that the educational content of the meeting was proportionate to the hospitality provided.

The Committee considered that the meeting, whilst in breach of the Code, would not bring the industry into disrepute and upheld the appeal with respect to Section 10.8 of the Code.

Sanctions
Having upheld one aspect of the appeal the Appeals Committee reviewed the sanctions imposed by the Code of Conduct Committee. Having overturned the finding of a breach of 10.8 of the Code, which is regarded as a serious breach of the Code the Appeals Committee determined that the fine should be reduced to $10,000.
**Innovex Educational Event 1034**

<table>
<thead>
<tr>
<th>Description of function including duration of educational content delivered</th>
<th>Venue</th>
<th>Professional status of attendees</th>
<th>Hospitality provided</th>
<th>Total cost of hospitality</th>
<th>Number of attendees</th>
<th>Total cost of function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pletal Launch Meeting with an International Specialist presenting a Symposium on Intermittent Claudication. Scientific Presentation on the Diagnosis and Treatment of Patients with Peripheral Arterial Disease. Peripheral Arterial Disease Case Studies. Peripheral Arterial Disease and Diabetes epidemiology and current management guidelines. New Advances in the treatment of Intermittent Claudication. 7.5 hours of educational content.</td>
<td>The Sheraton on the Park, Sydney, NSW</td>
<td>Cardiologists, Endocrinologists, Vascular Surgeons &amp; Physicians, General Practitioners</td>
<td>Friday: Meal with alcohol/non alcoholic drinks provided. Accommodation for Regional and interstate delegates. Saturday: Meals with non alcoholic drinks provided.</td>
<td>$31,534.55</td>
<td>76</td>
<td>$98,170.58 (includes Honorarium, AV, room hire, international speaker and local speaker travel &amp; accommodation)</td>
</tr>
</tbody>
</table>

**Subject Company:** Innovex (known as Pharmalink)

**Complainant:** Medicines Australia Monitoring Committee

**Complaint**

The Monitoring Committee had asked Innovex to provide justification for the cost of the dinner associated with the educational event.

**Sections of the Code**

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

**Response**

Phormalink had stated that the intention of the launch meeting was to conduct it in a clinically and ethically responsible
manner, in a venue which has been used by the industry many times over the years. The speakers had a completely free hand in the development and delivery of their respective presentations. The format and the environment of the meeting had a significant clinical focus and was facilitated by a clinician and not one of the Pharmalink team.

Pharmalink asserted that the hospitality was modest and appropriate to the needs of the attendees. The selection of the venue was not to impress doctors but to provide a functional location, which was readily accessible by local, regional and interstate delegates.

Pharmalink denied that the educational event had breached the Code.

**Code Committee determination**

In a unanimous decision the Committee found a breach of Sections 6.2, 6.8, 10.2, 10.3 and 10.8 of the Code.

**Sanction**

- Pay a fine of $50,000

**Consideration of the complaint**

The Committee noted that there was a difference between the reported duration of education (7.5 hours) and the actual hours of education (4 hours) excluding meal breaks. The educational component is the actual hours of education, not simply the duration of the event. Members acknowledged that while there may have been discussion over dinner, this is not regarded as part of the formal educational component.

Members did not question the ethics or veracity of the presenters or education. However members questioned whether the event needed to be held over two days given the educational component was only 4 hours over the two days. The event could have been held from late morning to late afternoon on the Saturday, which would not have required accommodation for many of the delegates. For example ACT delegates could have flown to Sydney on the morning of the event. The Guidelines that accompany the Code provide guidance in relation to the appropriate balance between hours of education and provision of hospitality, accommodation and travel. The general guidance is that a minimum of 6 hours education is required to justify the provision of overnight accommodation, depending on the origin of the attendees.

The Committee was of the view that the dinner which cost $168 per delegate was extravagant and would not withstand public scrutiny. The Committee referred to previous decisions in relation to the balance between hospitality and educational content for events held in Australia and unanimously agreed that the event was in breach of Sections 6.2 and 10.2 of the Code.

Having found that the provision of overnight accommodation for all interstate and regional delegates and that the cost of hospitality was disproportionate to the education provided the Committee also found a breach of Section 10.8 of the Code.

**Sanction**

Having found several breaches, including a breach of Section 10.8 of the Code, the Committee determined that Pharmalink should:

- Pay a fine of $50,000.
Ganfort 1035

**Subject Company:** Allergan Australia Pty Ltd (Allergan)

**Complainant:** Alcon Australia (Alcon)

**Product:** Ganfort

**Complaint**

Alcon alleged that the Allergan promotional piece ‘*When Monotherapy is not enough (PB4023/05.09)*’ contained claims that are inaccurate, false and/or misleading.

Part 1: Alcon stated that the dosage claims ‘*once a day*’ and ‘*once daily*’ are not consistent with the Dosage and Administration section in the Ganfort approved Product Information (PI).

Part 2: Alcon alleged that the cited reference material does not support the Allergan claim ‘*Ganfort 0.3/5 once a day as effective as the non-fixed combination of bimatoprost and timolol*,’ which is therefore false and misleading. This major claim, which also could not be supported by the Ganfort PI, could not be supported by unequivocal evidence.

Part 3: Alcon alleged that the comparative claim ‘*When a fixed combination is needed go straight to Ganfort 0.3/5 One drop – once daily*’ was inaccurate and misleading.

**Sections of the Code**

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

- 1.1 Responsibility
- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims
- 1.7 Comparative Statements

**Response**

Part 1: Allergan responded that the TGA approved dosage regimen is ‘once daily’. Further, the full PI is reproduced within the promotional material so a healthcare professional can read the entire dosage instructions. The dosage claim ‘once daily’, with additional information contained in the PI, is an accepted style of advertisement for prescription medicines. The ability to dose an eye drop either morning or evening compared to just morning does not infer an advantage for the former. Allergan denied that the claim is misleading, false or inaccurate or in breach of Sections 1.1, 1.3 or 1.7 of the Code of Conduct.

Part 2: Allergan responded that the clinical trials section of the approved PI includes the non-inferiority study included in the marketing application. Allergan asserted it is therefore appropriate to include the PI as a reference for the claim.

Allergan further stated that the study by Hommer et al, 2007 had been accepted by the European Medicines Agency (EMEA), the TGA and the Pharmaceutical Benefits Advisory Committee (PBAC) and had been published in a peer reviewed journal. Allergan denied that the claim was in breach of Sections 1.1, 1.2.2 or 1.3 of the Code.

Allergan asserted that this complaint was frivolous and vexatious and asked the Committee to consider whether Alcon was in breach of Section 12.3 of the Code.

Part 3: Allergan responded that the claim ‘*When a fixed combination is needed go straight to Ganfort 0.3/5 One drop – once daily*’; is a call to action for healthcare professionals to consider Ganfort as part of their treatment regimen, when a fixed combination is required. Allergan stated that the claim is consistent with the approved use of Ganfort and the PBS listing and disagreed that it implied bypassing all other combination products. Allergan stated that it had agreed during inter-company dialogue not to use the claim in future.
**Code Committee determination**

- Part 1 – in a unanimous decision no breach of Sections 1.1, 1.3 and 1.7 of the Code
- Part 2 – in a majority decision no breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code
- Part 3 – in a unanimous decision no breach of Sections 1.1, 1.2.2 and 1.7 of the Code

Alleged breach of Section 12.3 by Alcon – The Committee did not find any cause to ask Alcon to respond to this allegation.

**Consideration of the complaint**

**Part 1 – Once a day**

The Committee noted the dosage stated in the Ganfort Product Information — “one drop of Ganfort in the affected eye(s) once daily, in the morning”.

Members were of the view that the ‘once daily’ claim was consistent with the approved dosage for Ganfort and with similar dose-related claims for prescription medicines. The claim appeared on printed promotional material that included the full Product Information. The Committee concluded that a health professional would not be misled by the claim and in a unanimous decision did not find a breach of Sections 1.1, 1.3 or 1.7 of the Code.

**Part 2 – Ganfort 0.3/5 once a day as effective as the non-fixed combination of bimatoprost and timolol**

Members noted that the accepted criteria to show non-inferiority in studies in glaucoma or ocular hypertension patients is that the difference in intraocular pressure (IOP) between the fixed combination product and the individual components administered concomitantly should be not more than 1.5mmHg at each time point. The Committee also noted that these criteria have been accepted by the European Medicines Agency (EMEA), the Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Advisory Committee (PBAC).

While some members commented that the relevant supporting study is a Phase 2 study, which is not referred to in the Product Information, it had been submitted to the TGA in the Ganfort marketing application. In reviewing the Hommer et al, 2007 paper members agreed that it was adequate to support the claim.

In a majority decision the Committee did not find a breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code.

The Committee noted that Allergan had acknowledged an error in the referencing for this claim on the promotional item and that this would be corrected. The Committee urged Allergan to action this correction promptly.

**Part 3 – When a fixed combination is needed go straight to Ganfort 0.3/5 One drop – once daily**

Based on the materials reviewed by the Committee in the complaint and response documents, members understood that the approved indications for Ganfort, and the PBS restrictions, are for patients who are not adequately controlled with monotherapy with either timolol maleate eye drops (0.5%) or prostaglandin or prostamide analogue. Members did not consider that the claim implied that Ganfort was the only first line fixed combination eye drop available to prescribers. The Committee considered that a prescriber would be aware of the indications and PBS restrictions for Ganfort. The Committee noted that Allergan had agreed during intercompany dialogue not to use this claim in future.

In a unanimous decision the Committee did not find a breach of Sections 1.1, 1.2.2 and 1.7 of the Code.
Subject Company: Ferring

Complainant: Healthcare Professional

Complaint
The complainant alleged that the advertisement states that Pentasa is for inflammatory bowel disease which incorporates Crohn’s disease and ulcerative colitis. Pentasa enemas and suppositories are only registered for the treatment of ulcerative colitis. It was alleged that the advertisement is therefore misleading and ambiguous.

Sections of the Code
The Secretariat asked Ferring to respond to the complaint with regard to the following Sections of the Code:
- 1.1 Responsibility
- 1.3 False and misleading claims
- 1.3.1 Unapproved products and indications

Response
Ferring stated that the advertisement had been assessed and approved as a short advertisement under Section 3.1.3 of the Code. As required in this section there were no claims only a list of all Pentasa formulations. The approved indications for the various products in the Pentasa range are all sub-sets of the therapeutic class ‘Inflammatory Bowel Disease’ (IBD).

Ferring denied that the advertisement was in breach of the Code.

Code Committee determination
- In a unanimous decision no breach of Sections 1.1, 1.3 or 1.3.1 of the Code was found.

Consideration of the complaint
The Committee was of the view that healthcare professionals would understand that not all formulations of medicines for IBD are appropriate for all sub-sets of IBD. Members noted that Pentasa tablets, sachets, suppositories and enemas are only available on the PBS as either a ‘restricted benefit’ or ‘authority required’. A healthcare professional would be sufficiently informed that Pentasa enemas are only registered to treat ulcerative proctosigmoiditis and/or left sided ulcerative colitis, the suppositories registered for the treatment of ulcerative proctitis, and the tablets and sachets are for the treatment of mild to moderate ulcerative colitis and Crohn’s disease. The Committee did not agree that the statement “For Inflammatory Bowel Disease” meant that all dosage forms were approved for all forms of IBD. The term ‘inflammatory bowel disease’ is a recognised umbrella term that is used in the PBS Schedule to encompass medicines approved for different subsets of IBD.

The Committee was of the view that the advertisement did not include any claims or state that all formulations were to treat all sub-sets of IBD and healthcare professionals would be well informed of the appropriate route of administration for different forms of IBD. The Committee unanimously determined that there was no breach of Sections 1.1, 1.3 of 1.3.1 of the Code.
**Pfizer television advertisements for a combination heart pill 1037 and 1038**

**Subject Company:** Pfizer Australia (Pfizer)

**Complainant:** Members of the general public

**Product:** Two-in-one Combination Heart Pill

**Complaint 1037**
The complainant maintained that prescription drugs should be 100% in the hands of medical practitioners without pharmaceutical companies preconditioning patients to ask for that drug. The advertisement encourages patients to doctor shop and also only adds to the blow out in the Federal Government’s Pharmaceutical Benefits Scheme. The companies will claim that these commercials are just providing patient information.

**Complaint 1038**
The complainant stated that it is wrong that Pfizer encourages people to go and talk about buying their product rather than any medical merits of their product. They should be fined for encouraging people to waste Medicare so they can potentially make a sale.

**Sections of the Code**
Materials alleged to be in breach of the following Sections of the Code:
- 9.3 General Media Articles
- 9.4 Promotion to the General Public
- 9.5 Patient Education
- 9.10 Discredit to and reduction of confidence in the industry

**Response**
Pfizer stated that the educational broadcast to members of the general public was aired on commercial TV channels. The message from this broadcast was clear and unambiguous, namely that members of the general public receiving treatment for high blood pressure or cholesterol may be suitable for combination therapy.

On a previous occasion the Code Committee reviewed a similar advertisement which ran in the West Australian newspaper and this was not found in breach of Sections 9.4, 9.5 or 9.10 of the Code.

**Code and Appeals Committee determinations**
In a majority decision the Code Committee found a breach of Sections 9.4 and 9.5 of the Code (decision overturned by the Appeals Committee) and no breach of Section 9.10 of the Code. The Code Committee determined that Section 9.3 was not applicable to this complaint.

**Sanction**
- The requirement to cease broadcasting the advertisements was removed by the Appeals Committee
- No fine (fine of $75,000 removed by the Appeals Committee)

**Consideration of the complaint**
Complaints 1037 and 1038 were considered together as they related to the same advertisement, although slightly different issues were raised by the two complainants.

Some members were of the view that the use of a combination product could potentially be advantageous to a patient in terms of convenience and compliance, and save both the patient and PBS money. These members were also of the view that in the real world compliance is a major issue where long term use is required. Also some of these members were of the view that cost to the patient is an issue for compliance with long term treatment. However the majority of members were of the view that this advertisement focused more on cost that compliance.
While it is the healthcare professional who must make the decision in consultation with a patient by discussing such things as side effects and cost, the information offers patients the opportunity to be in better control of their health by knowing what is available.

However other members stated that they are well aware of QUM and cost related issues, however this advertisement is encouraging a patient to ask their doctor for a specific prescription-only medicine.

“So next time you see your doctor, you may want to ask if a combination heart pill is right for you.”

“You may find your doctor can do something to improve your bank balance as well as your heart health.”

These members commented that it is not the role of the Code Committee to judge the merits of saving money. All decisions must be made in accordance with the provisions of the Code which states “Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is prohibited.”

The Committee noted the Pfizer response in relation to precedence of decisions pertaining to disease education activities. While the Committee did not find the company in breach with respect to complaint 1024, it was noted that this was a majority decision and on this occasion a majority of the Committee members were of the view that the television advertisement had gone further than the print advertisement. Members also agreed that the issues raised with respect to complaint 1016 differed from the complaints under consideration at this meeting.

The Committee determined that Section 9.3 was not applicable as the advertisements were not general media articles.

In a majority decision the Committee found a breach of Sections 9.4 and 9.5 of the Code as the advertisements would encourage a member of the general public to seek a prescription for a prescription only product and in this case there is only one combination treatment for high blood pressure and cholesterol. The advertisements were not balanced and there was an overemphasis on the cost.

In a majority decision the Committee did not find a breach of Section 9.10 of the Code as it would not lead to erroneous prescribing by the healthcare professional as the patient should already be on treatments for high blood pressure and high cholesterol and there was no patient harm.

The Committee determined that this was a moderate breach of the Code.

Sanctions
Having found several breaches of the Code, the Committee determined that Pfizer should:

- Cease broadcasting the advertisement
• Pay a fine of $75,000

**Appeal**
Pfizer lodged an appeal against the findings of a breach of Sections 9.4 and 9.5 of the Code. Pfizer argued that the Code Committee had erred by:

- Incorrectly interpreting the advertisement as directing patients towards a single combination antihypertensive and cholesterol lowering treatment
- Incorrectly determining that the television advertisement had gone further than the print advertisement, which was found not to breach the Code in complaint 1014
- Incorrectly determining that the advertisement was unbalanced and that it over emphasised cost
- Discounted the precedents of other complaints about direct to consumer communications that were not found in breach of the Code

One complainant responded to the appeal, reiterating that he considered the advertisement was advertising a prescription medicine to consumers.

**Consideration of the appeal**
The following outlines the appeal presentation by Pfizer.

- Pfizer considers that the Code Committee erred by determining that:
  - The broadcast directed patients towards a single treatment
  - The broadcast went further than the print advertisement subject to complaint 1014
  - The broadcast was unbalanced and over emphasised cost
  - Precedents from other relevant direct to consumer complaints differed from the subject advertisement and therefore were dismissed.
- Cardiovascular disease is an important public health issue in Australia. Compliance with treatments for chronic, asymptomatic conditions such as high blood pressure and dyslipidaemia is frequently poor. Communicating compliance messages can help improve patient outcomes.
- The television commercial specifically referred to “treatments for high blood pressure or high cholesterol”. There were three compliance messages – reducing the number of pills you have to take; combination pills save money; consult your doctor for suitable treatment options.
- No product name was mentioned in the broadcast and throughout the broadcast treatments were referred to as plural (not a single treatment). There are twenty eight different combination products available for heart conditions. These treatments include two antihypertensive medicines in combination; an antihypertensive in combination with a cholesterol lowering medicine; two cholesterol lowering medicines in combination. These medicines are used to treat medical conditions that increase the risk of cardiovascular disease such as stroke and heart attacks.
- The television commercial was a direct translation of an identical print advertisement, which was the subject of complaint 1014. The same sections of the Code were raised in the previous complaint, which determined that the advertisement did not breach the Code.
- The Code allows for direct communication with consumers (section 9.5) whilst prohibiting the provision of any information that encourages a patient to seek a prescription for a specific prescription-only medicine (section 9.4).
- The Code Committee has consistently determined that communications
with consumers are not in breach of the Code if no medicine or generic name was mentioned. Complaints 1016, 1014, 944, 828, 829, 831, 832 and 818 were cited as examples. This yardstick was applied by Pfizer in relation to the television commercial.

- The Code Committee, in considering whether the television commercial was in breach of the Code, was divided in its opinion. The decision was not unanimous.
- Pfizer disagrees that the television commercial directs patients to a single prescription medicine. The facts of the commercial script do not support this assertion. The spoken words refer to “high blood pressure or high cholesterol” and refer to medicines (plural) that are available.
- Although Pfizer is the only manufacturer of a combination medicine for both hypertension and high cholesterol, it should not be disqualified from appropriate communications with consumers. There are multiple combination products for heart disease; Pfizer also makes several combination products to treat hypertension.
- The television commercial was overwhelmingly similar to the print advertisement which was found not to breach the Code. It did not go further than the print advertisement.
- The television commercial did not over emphasise cost. Reduced pill burden and reduced cost were mentioned with equal frequency.
- Many other direct to consumer campaigns have been found not in breach of the Code. Pfizer referred to radio and television advertisements for cervical cancer vaccination. These and the combination heart pill print advertisement guided the development of the current television commercial subject to complaint.
- Pfizer argued that the Code Committee’s findings should be overturned. Otherwise the industry is left with uncertainty in how to interpret the Code.

In response to a question from the Appeals Committee regarding the PBS restrictions for Pfizer’s combination product Caduet, Pfizer responded the advertisement is not recommending that people ask for a combination pill for hypertension and high cholesterol. Rather it says that if you have one or other condition, or perhaps both conditions, there are combination pills available. Pfizer emphasised that the advertisement was not for Caduet. A consumer might be taking two medicines for hypertension (for example a diuretic and an angiotensin converting enzyme inhibitor); or two medicines for high cholesterol; or two medicines because they have both high blood pressure and high cholesterol. In each case they could take a combination pill and save money.

Another Appeals Committee member queried whether a viewer would remember that the message was about hypertension or high cholesterol; a television commercial is short, whereas in the print media there is more time to consider and remember the messaging. Pfizer responded that it had used ‘high blood pressure or high cholesterol’ only once in the advertisement.

The Chairman noted that the complaint relies on very specific provisions in the Code – Section 9.4 prohibits any communication which would encourage consumers to seek a prescription of a specific prescription-only medicine. However, Section 9.5 acknowledges that consumers should have access to information on medical conditions and the treatments that might be prescribed by their doctors. Thus the Code allows for some general information to be provided to consumers, but this cannot encourage consumers to seek a prescription for a particular product. The two provisions
coupled together allow for companies to provide educational information.

The Appeals Committee considered the television commercial for combination heart pills and agreed that it did not make reference to or direct consumers towards a particular prescription-only medicine. There are numerous combination medicines available to treat high blood pressure or high cholesterol that may lead to heart disease. The words spoken in the commercial were sufficiently general to avoid identifying a particular combination medicine. The overall message was consistent with quality use of medicines principles.

The Appeals Committee did not agree that the print advertisement considered in complaint 1014 and the broadcast television advertisement were directly comparable or that the finding of no breach in 1014 meant that the television commercial should not be found in breach.

The Appeals Committee considered that the television commercial was within the boundaries of what was permitted by the Code of Conduct under Section 9.5, and was not in breach of Section 9.4 (on the basis of identifying or directing consumers to a particular prescription medicine or a particular combination of medicines to treat a combination of conditions). On balance, having regard to the wording and the number of combination drugs potentially referred to, the television commercial was considered to be primarily educational and was not promoting a particular prescription medicine to consumers.

The Appeals Committee was unanimous that the appeal in relation to Sections 9.4 and 9.5 should be upheld.

In reviewing the television commercial the Appeals Committee considered the size of the company logo that appeared at the end of the commercial. The Committee noted that there is no restriction on the size of a company logo in consumer educational communications, but the name and address of the company should not be given prominence. Whilst not taking this matter into account in reaching its decision, the Committee recommended that some guidance should be given on compliance with this requirement when the Code is next reviewed.

Sanction

Having upheld all aspects of the appeal and finding that the television commercial did not breach the Code, the Appeals Committee determined that the fine imposed by the Code Committee should be removed.
Valtrex 1039

Subject Company: GlaxoSmithKline (GSK)

Complainant: Member of the general public

Product: Valtrex

Sections of the Code
GSK was asked to respond to the complaint under 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

Complaint
The complainant alleged that an advertisement for Valtrex which appeared in the January 2010 edition (published in December 2009) of Australian Women’s Health was in breach of the Code as it was direct to consumer advertising of a prescription medicine.

Response
GSK stated that it sincerely regretted the publication of the advertisement, which is an advertisement intended for health professionals only. GSK first became aware of the fact of the publication of the advertisement on Wednesday 16 December 2009 and had advised the TGA and Medicines Australia in writing on that day. GSK stated that the placement of the health professional advertisement in a consumer magazine was due to errors on the part of both the advertising agency engaged to run the advertisement and the publishing company responsible for its publication. The advertisement was designed for and intended only to appear in publications directed to healthcare professionals and not in publications available to consumers. The events giving rise to the placement of the advertisement occurred without GSK’s knowledge, approximately 18 months prior to this incident. Upon becoming aware of the fact GSK immediately commenced an investigation.

GSK stated that the publication of the advertisement in a publication for the general public was not intended by GSK and was the result of an error beyond GSK’s control.

Code and Appeals Committee determinations

- In a unanimous decision the Committee found a breach of Sections 9.4 and 9.5 of the Code (decision upheld by the Appeals Committee)
- In a majority decision the Committee did not find a breach of Section 9.10 of the Code.

Sanction

- Pay a fine of $20,000 (reduced from $150,000 by the Appeals Committee)

Consideration of the complaint
The Committee considered the GSK response to the complaint in which the company acknowledged that an advertisement intended for health professionals had been published in the consumer magazine Women’s Health. GSK had outlined the chronology of events leading up to the complaint. Members noted that the advertising agency acting for GSK had sent the incorrect advertisement to the magazine publishers 18 months prior to this incident and had subsequently advised the publishers of this error. However, the agency did not advise GSK of this error. The publishers of Women’s Health had published the correct advertisement (suitable for consumers) for a period of 18 months, before publishing the incorrect advertisement (intended for health professionals) in the January 2010 edition, which was released in December 2009.

Members considered that a company must have policies and procedures in place to ensure the company signs off on
Sanction

Having found two breaches of the Code the Committee determined that GSK should:

- Inform the Code Committee of all new or revised company policies and procedures that will ensure that a similar error does not occur again, including any training it will provide to agencies acting on behalf of GSK to ensure they are aware of their responsibilities with respect to company promotional material for prescription medicines.
- Pay a fine of $150,000. The Committee debated at length whether the maximum fine of $200,000 (for an activity that has ceased and cannot be corrected) should apply to this breach of the Code. In a majority decision the Committee determined that a fine of $150,000 should apply, reduced from $200,000 in consideration of the mitigating circumstances as reflected in the actions GSK had taken as described in its response to the complaint.

Appeal

GSK appealed the decision of the Code of Conduct Committee stating that it had taken this matter very seriously and had taken immediate action as soon as the matter came to its attention. The Code Committee appeared to believe that GSK’s processes and procedures were not rigorous enough to prevent the inadvertent publication of this advertisement. GSK stated that its processes are comprehensive, robust and they continually maintain strict adherence to all regulations and are supported by regular training programs. GSK asked that the Appeals Committee understand that despite the company’s rigorous adherence to controls and processes, a human error had occurred within a third party, over which GSK had no reasonable control, which resulted in the incorrect
advertisement being published in the consumer magazine.

Response to the appeal
The complainant had advised that they would not make a further submission.

Consideration of the appeal
Prior to the GSK representatives joining the meeting the Appeals Committee considered the actions taken by GSK after being advised of the publication of the advertisement and what action, if any was taken by the TGA. It was understood that TGA had not taken any action and had apparently accepted that Medicines Australia would deal with any complaint that arose regarding the advertisement.

Members noted that a breach of Section 42DL of the Therapeutic Goods Act, which prohibits promotion of prescription medicines to consumers, would be a criminal offence where the maximum fine is $6,600 and that strict liability applies to the offence. Members acknowledged that the Code may set a higher standard than the Act, to which member companies agree to abide. The Appeals Committee also noted that in comparison to other activities directed at the general public considered by the Code Committee and found in breach, in this complaint there was no evidence of deliberateness.

The Appeals Committee reviewed two prior complaints where an activity had been directed at the general public - in one matter incorrect consumer medicine information had been published inadvertently by a company employee and a fine of $5,000 imposed; in the second matter an article had been deliberately published in a consumer publication, was found to be promotional and a fine of $100,000 imposed.

The GSK representatives joined the meeting. The following summarises the key points from the GSK presentation:

- GSK understand that a pharmaceutical company is not allowed to advertise a prescription medicine to the general public.
- GSK take the reputation of the company and their responsibilities under the Act and Code very seriously.
- GSK considers the fine to be unreasonably high and inappropriately implies that GSK intentionally promoted its product to consumers.
- GSK did not deliberately or intentionally publish the health professional advertisement in the magazine which is intended for a general public audience. A human error occurred.
- GSK’s company policies go further than required by the Code – for example, it has voluntarily published its sponsorships of health consumer organisations; removed brand name reminders a year in advance of the Code changes; imposed limits on the number of starter packs which can be provided to healthcare professionals.
- GSK had adequate procedures in place with the advertising agency and publisher.
- GSK explained the sequence of events leading up to the complaint:
  - In July 2008 GSK and its agency approved the consumer advertisement.
  - 9 days later the agency sent the wrong advertisement file to Women’s Health magazine – within 1 hour the agency identified the error and sent the correct file with instructions to the publisher to delete the previous file.
  - The publisher only accepted the correct file and the correct consumer advertisement had been published nine times in the last 18 months.
  - On 14 December 2009 the (incorrect) healthcare
professional advertisement appeared in *Women’s Health*.
  o On 16 December 2009 Novartis contacted GSK advising that an advertisement for healthcare professionals was in *Women’s Health*.
  o The same day GSK sought to have the advertisement removed or the publication removed from outlets, but this was not possible. GSK also advised the TGA and Medicines Australia of the publication of the advertisement. GSK also invited Novartis to state what it required GSK to do.
  o On 18 December 2009 Novartis sent a letter of demand to GSK requiring a series of actions to rectify the error.
  o On 22 December 2009 GSK responded to Novartis stating what it had done. There has been no further correspondence from Novartis.
  o On 7 January 2010 GSK received the complaint from Medicines Australia.
  o On 14 January 2010 Pacific Magazines issued a letter stating that the error in placing the advertisement had occurred at *Women’s Health*.

- GSK processes both internally and with external clients are robust:
  o GSK’s internal approval of advertisements is through the Orbis system which requires two signatures from the medical department (copy of the original consumer advertisement signed off by GSK was included in the papers before the Appeals Committee).
  o GSK then obtains the advertising agency’s confirmation via email, which ensures the correct advertisement is approved. The agency’s internal sign off is via manual signature, which was provided in the agenda papers.
  o The agency sent the advertisement to Pacific Magazines via a program called Quick Cut through which advertising copy is formally accepted. In July 2008 the agency had sent the wrong (healthcare professional) advertisement to Pacific Magazines, but this was corrected within an hour. The publisher did not accept the incorrect advertisement, only the correct consumer advertisement. Therefore, to the agency’s knowledge Pacific Magazines had only accepted the correct advertisement. Publishers should only publish accepted advertisements. The correct advertisement was published nine times over eighteen months.
  o In answer to a question from the Committee, GSK explained that publishers of consumer magazines do not give proof copy to advertisers for approval unless the publisher has created an advertisement on behalf of a client.

- With respect to the Code Committee’s comments that GSK should be held accountable for the actions of an agency acting on its behalf, GSK asserted that it has good processes in place and exerts controls as part of its contract with agencies. The major mistake occurred within the publisher which had accepted the correct advertisement and published an advertisement which it had not formally accepted and should have deleted.
- While accepting that an advertisement for healthcare professionals was published in a consumer magazine, this was outside
the control of GSK. GSK is accountable for its advertisements but was not responsible for the error that occurred. GSK has robust processes in place to make sure this would not happen.

- GSK noted other complaints involving activities directed at the general public attracting fines as low as $5,000 where there was an error by a third party.
- GSK asked that the Appeals Committee consider the following key issues when making its decision:
  - The fine of $150,000 is exceptionally high.
  - That GSK’s processes are stringent and robust. GSK cannot see what else it could have done to avoid the error.
  - The potential damage to GSK’s reputation for an inadvertent error that occurred outside the control of GSK. The high fine gives the impression that the publication was done deliberately or recklessly.
  - That GSK acted with complete integrity throughout the process.

The Appeals Committee commented that the dialogue undertaken by GSK with Novartis was thorough and met the requirements of the Code. If Novartis was not satisfied with GSK’s response it would have submitted a complaint itself.

One member of the Appeals Committee was of the view that the consumer and healthcare professional advertisements were not sufficiently different; they used similar graphics and the identifying codes were also very similar and this may have contributed to the error that occurred at the publishers. This member also suggested that to avoid similar errors in the future a company should consider engaging two separate agencies or teams within an agency to separately handle information to healthcare professionals and the general public. Alternatively the information to the general public should be completely different in terms of colour and imagery to that provided to healthcare professionals. However, it was noted that even if the advertisements for healthcare professionals and consumers look different, an error in selecting an advertisement for publication could still occur.

The Appeals Committee was unanimous in its decision that a breach of Sections 9.4 and 9.5 of the Code had occurred because an advertisement for a prescription medicine was published in a general public magazine. The Appeals Committee accepted that the error did not involve any deliberate action by GSK.

The Code Committee did not have the benefit of level of detail about the company’s procedures and system checks or the ability to ask the company questions about its internal procedures and arrangements with third parties or whether GSK could have prevented the error from occurring. From the evidence provided to the Appeals Committee GSK does have robust processes and contracts with third parties that are at least consistent with industry best practice. The Appeals Committee concluded that although there had been two breaches of the Code, the basis for the imposition of the high fine was not correct and that the fine should be significantly reduced.

Sanction

Having upheld the Code of Conduct Committee’s determinations of a breach of Section 9.4 and 9.5 but noting the circumstances under which the advertisement was inadvertently published, the Appeals Committee determined that the fine imposed by the Code Committee should be reduced to $20,000.
The Appeals Committee also amended the requirement for GSK to inform the Committee of its actions, as follows:

GSK should inform the Code Committee of any new or revised company policies that will guard against a similar error occurring again, including any new arrangements with agencies acting on behalf of GSK to ensure they are aware of their responsibilities with respect to company promotional material for prescription medicines.
**Tysabri 1041**

**Subject Company:** Biogen Idec (Biogen)

**Complainant:** Bayer Healthcare (Bayer)

**Product:** Tysabri

**Complaint**

Bayer alleged that claims relating to multiple sclerosis disability progression, freedom from disease activity and annualised relapse rate in advertisements in *Medical Observer* for Tysabri were deceptive and may result in inappropriate prescribing and therefore interfere with the quality use of medicines. This promotional material may also reduce confidence in the pharmaceutical industry.

**Sections of the Code**

Advertisements alleged to be in breach of the following Sections of the Code:
- 1.2 Level of substantiating data
- 1.3 False and misleading claims
- 10.8 Discredit to and reduction of confidence in the industry

**Response**

Biogen contended that the Tysabri promotional material was not in breach of the Code as each claim was appropriately substantiated and accurate and was not false or misleading.

Biogen also contended that Bayer’s conduct throughout this complaint was an abuse of Edition 15 of the Code and asked that the Code Committee consider asking Bayer to justify why its action in submitting the complaint did not constitute abuse of the Code. Biogen had offered to modify its use of the claims in question and had modified its materials; however, contrary to instructions from Biogen, the media advisors ran the same advertisement as those complained about by Bayer. Biogen is following up with its media advisors on how this error had occurred.

**Code Committee determination**

*Claim 1 “... 54% risk reduction in disability progression”*

- In a unanimous decision the Committee found no breach of Section 1.2 of the Code
- In a unanimous decision the Committee found a breach of Section 1.3 of the Code.

*Claim 2 “Freedom from MS activity (5 x more patients were disease free after 2 years of Tysabri vs placebo)”*

- In a unanimous decision the Committee found no breach of Section 1.2 of the Code
- In a majority decision the Committee found a breach of Section 1.3 of the Code.

*Claim 3 “90% reduction in mean annualised relapse rate for patients who have switched to Tysabri”*

- In a unanimous decision the Committee found a breach of Sections 1.2 and 1.3 of the Code
- In a majority decision the Committee found no breach of Section 10.8 of the Code.

**Sanction**

- Withdraw materials found in breach
- Publish a corrective advertisement
- Pay a fine of $75,000

**Alleged abuse of the Code by Bayer**

In a unanimous decision the Committee determined that Bayer did not have a case to answer under Section 12.3 of the Code.

**Consideration of the complaint**

The Committee noted that these advertisements were published in *Medical Observer*, which is primarily directed at general practitioners. However Tysabri can only be prescribed by a neurologist.

Members also noted the Biogen response that these advertisements were part of an awareness campaign to general practitioners. It was also a mechanism to gauge the level of interest from general practitioners with regard to the need for further information or education on treatment options for multiple sclerosis.
**Claim 1 “54% risk reduction in disability progression”**
The Committee was of the view that as general practitioners were the target audience and their understanding of the disease and treatment options would be less than that of a specialist neurologist, the claim was not sufficiently clear to a reader in the target audience and may mislead by omission.

The Committee considered that the primary endpoint of the referenced study should have been made clear to a reader in the advertisement. The results of the study state “Natalizumab reduced the risk of sustained progression of disability by 42 percent over two years (hazard ratio, 0.58; 95 percent confidence interval, 0.43 to 0.77; p<0.001).” At two years, the primary endpoint was the cumulative probability of sustained progression of disability, defined by an increase in the Expanded Disability Status Scale (EDSS) (within specified parameters) that was sustained for 12 weeks. The claim of ‘54% reduction in disability progression’ was based on a sensitivity analysis of progression of disability that was sustained for 24 weeks, which yielded a 54% risk reduction in the natalizumab group. The Committee considered that by selecting the sensitivity analysis (54%) result without also presenting the result against the primary endpoint (42%) was misleading.

Several Committee members were also concerned that it was not clear to a reader that the result was from a study that compared Tysabri with placebo. Although there was a footnote included in the advertisement that describes the Polman, CH et al study, this footnote was linked by a symbol to the first claim and not the 54% risk reduction in disability progression claim.

Members were of the view that a busy general practitioner will take things at face value and any claim needs to be clear and not mislead through the selective use of data or omission of important and relevant information.

The Committee determined that there were adequate data to substantiate the claim of 54% risk reduction in disease progression. In a unanimous decision the Committee found no breach of Section 1.2 or 1.2.2.

However, the Committee found the claim to be misleading by omission through the selective use of data and the failure to adequately communicate to a reader the basis for the claim. In a unanimous decision the Committee found the claim to be in breach of Section 1.3 of the Code.

**Claim 2 “Freedom from MS disease activity (5 x more patients were disease free after 2 years of Tysabri vs placebo)”**
The Committee was of the view that the use of the term ‘5X more patients disease free’ to a general practitioner audience gave the impression that Tysabri was more effective than it really is; the claim “5 x more patients were disease free after 2 years of Tysabri vs placebo” gave the impression that the majority of patients would be free from MS (ie “disease free”) after two years treatment with Tysabri. The qualifying statement stated the result that 37% of Tysabri patients experienced freedom from disease activity compared to 5% of placebo patients, meaning that 63% of patients still had disease activity. Members considered that the lack of clarification and the failure to disclose the primary endpoints of that study gave a more favourable impression of the efficacy of Tysabri to a reader.

Members were also of the view that the use of the term ‘disease free’ was overstating the results of the study that evaluated disease activity on clinical, radiological and composite measures.

The Committee accepted that the study that was the basis for the claim (Havrdova, E et al 2009) was well conducted and was peer reviewed. The claim could be substantiated from this study. In a unanimous decision the Committee found no breach of Section 1.2 of the Code.
The Committee considered that the term ‘disease free’ was not equivalent to the absence or freedom from disease activity; the claim was misleading because it gave the impression of greater efficacy than could be supported by the evidence. In a majority decision the Committee found the claim to be in breach of Section 1.3 of the Code.

Claim 3 “90% reduction in mean annualised relapse rate for patients who have switched to Tysabri”

The Committee noted that the claim was based on a prospective, observational study that reported on natalizumab as a second line therapy in the treatment of relapsing remitting multiple sclerosis where patients had failed on a previous disease modifying agent. The analysis was carried out on an intent-to-treat basis. There were 31 patients, 29 of which were included in the analysis. The reference is data on file.

The claim was listed as a dot point under the same heading as the claims 1 and 2 above. The reader would then assume that claim 3 related to a study in a similar study population. This was not the case. Claim 3 related to a study in patients who had failed on a previous disease-modifying agent whereas claims 1 and 2 related to patients in the Polman CH et al study which excluded patients who had relapsed whilst on MS treatments, including disease modifying agents.

The Committee was of the view that the general practitioner audience for the advertisement would not have been aware from the advertisement that the claim was based on data from a completely different study, with a small patient sample, conducted in patients who had failed previous treatment with a disease modifying agent. Members noted Biogen’s statement that GPs cannot prescribe Tysabri, however the Committee considered that it was nevertheless misleading to make a claim to this readership, who do not have extensive knowledge of the academic papers in the field of medicine, where the claim was based on a very small study for which the company did not have access to the statistical details and the statistical significance was simply confirmed in correspondence with the author. Members were also of the view that it was inappropriate to reference an important claim to ‘data on file’ as the sole source of evidence.

In a unanimous decision the Committee found the claim to be in breach of Sections 1.2 and 1.3 of the Code.

Breach of Section 10.8

Having determined that the Tysabri advertisements published by Biogen were in breach of Sections 1.2 and 1.3 of the Code the Committee considered whether these advertisements met the criteria for bringing discredit to the industry. Some members were of the view that whilst the advertisements fell short of the standards expected within the industry, there was no patient harm because Tysabri could only be prescribed by a neurologist. However other members were of the view that any misleading information reflects negatively on the reputation of the industry. While general practitioners may not prescribe the product, they were in a position to potentially influence a patient to talk to their neurologist about Tysabri.

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

Boxed Warning

While not subject to complaint, members of the Committee noted that the advertisements state ‘See Boxed Warning’ however there is no ‘Boxed Warning’ on the advertisement to ensure a reader is cognisant of the issues with this product.

Abuse of the Code by Bayer

The Committee was of the view that despite allegations that both parties were dragging out the process and the intercompany dialogue process was not ideal, members had found the advertisements to be in breach of the Code and imposed a significant sanction. In a unanimous decision the Committee determined that there was no cause to require Bayer to respond to the allegation of breach of Section 12.3 of the Code.
Sanction
The Committee noted that Biogen had been prepared to make amendments to its advertisements; however the agency responsible for placing the advertisements did not submit the revised advertisements. Members discussed at length the option of a corrective advertisement and whether this would correct the misleading impression resulting from the advertisements. The Committee determined that this was a moderate breach with a fine up to a maximum of $100,000.

Having found several breaches of the Code the Committee determined that Biogen should:

- In a majority decision, publish a corrective advertisement in all publications where the claims found in breach of the Code had appeared. This advertisement must be of the same size and prominence in the publication as the original advertisement.
- In a unanimous decision, pay a fine of $75,000.
Seretide 1042

Subject Company: GlaxoSmithKline Australia (GSKA)

Complainant: Healthcare Professional

Product: Seretide

Complaint
The complainant alleged that the treatment for patients under his specialist care had been altered by nurses providing a practice support activity who are employed by Pretium. Some patients who were on treatment with Symbicort Turbuhalers were switched to Seretide inhalers on the advice of the nurses from Pretium. After discussion with the GP involved and perusal of the documents provided by the GP the complainant became aware that the recommendations to switch to Seretide inhalers were based on the use of the ‘In check dial’ which is a device apparently developed by GSKA sponsored investigators and is being distributed by GSKA representatives. The complainant stated that he did not believe that this device and recommendations for its use have been subjected to proper scientific trial.

Sections of the Code
GSKA was asked to respond to the complaint with reference to the following Sections of Edition 15 of the Code:

- 7.1.1 Sponsorship
- 7.1.2 Sponsorship
- 7.1.5 Sponsorship
- Preamble to Section 10 Relations with healthcare professionals
- 10.8 Discredit to and reduction of confidence in the Industry

Response
GSKA strongly rejected the allegations and asserted that there were no breaches of the provisions listed. The Respiratory Care Team is managed by Pretium and run independently of GSKA. Pretium employ nurses whose objective is to assist in the management of patients with asthma and/or COPD. No incentives are paid to Pretium or the nurses to promote switching from one product to another.

The ‘In-Check Dial’ device is registered with the TGA as a medical device and is included on the Australian Register of Therapeutic Goods. The available body of evidence supports the use of this device to determine inspiratory flow rates. Both the Asthma Management Handbook and the COPD eXacerbations (COPDX) Plan, published by the Thoracic Society of Australia and New Zealand and the Australian Lung Foundation, advise consideration of inspiratory flow rates in the choice of drug delivery systems for the management of asthma and COPD.

Code Committee decision
In a unanimous decision no breach of Sections 7.1.1, 7.1.2, 7.1.5, 10 preamble or 10.8 of Edition 15 of the Code was found.

Consideration of the complaint
The Committee noted that the Respiratory Care Team (RCT) program is provided to general practitioners. Pretium, a disease management company, was appointed by GSKA to deliver and manage the RCT. Registered nurses trained in respiratory care conduct self-contained respiratory clinics across Australia at no cost to the practice. The RCT nurse undertakes a comprehensive respiratory assessment of patients identified by the GP and provides the GP with an assessment including lung function at the end of each patient clinic. Members also noted the ‘Patient Assessment Form’ which was completed by the nurses at the patient clinic. General practitioner members of the Committee commented that the measurement of peak inspiratory flow (PIF) rate of patients is useful in determining whether the PIF is sufficient for using inhaler devices. If a patient’s asthma or COPD is not well controlled, their current inhaler device would be one factor taken into consideration by the GP.

The Committee reviewed the training program for the RCT nurses, which included extensive education on respiratory care, role of the nurse and the Medicines Australia Code
of Conduct, and relevant Australian Asthma and COPD guidelines delivered in a week long orientation program. The Committee also reviewed the material describing the conduct of the program and the patient assessment form which is presented to the doctor. The Committee did not identify any evidence that indicated that a GP’s treatment of a patient would be inappropriately influenced by the RCT program. The Committee considered that ultimately it is up to the doctor to determine the appropriate treatment or change to treatment for a patient assessed under the RCT program. The Committee also noted that the patients selected by the GP for evaluation by the RCT nurses are likely to be people whose lung condition is not well-controlled, which may result in a change of medication.

In considering the complainant’s allegation that the ‘In-check dial’ device may not be supported by adequate clinical evidence, it was noted there are a number of published studies which support the validity of the device as a predictor of inspiratory flow rates if it is used properly. The Committee concluded that there is reasonable evidence to support its use.

The Committee considered the statement by GSKA in its letter of 11 March that the RCT program is independently managed by Pretium and GSKA’s only involvement was to sponsor the services and that this sponsorship was managed through the medical department of GSKA and not any commercial part of the company. The Committee wished to remind GSKA that it nevertheless was overall responsible for the program it sponsored and that the provisions of the Code relating to medical practice activities had been expanded in the 16th edition of the Code.

The Committee concluded that it is the responsibility of the healthcare professional to refer patients to the program and make any decision on patient care having received the results of the spirometry assessment and inspiratory flow rates. On this basis the Committee unanimously did not find a breach of Sections 7.1.1, 7.1.2, 7.1.5, 10 preamble or 10.8 of Edition 15 of the Code.
Clexane 1043

Subject Company: sanofi-aventis

Complainant: Healthcare Professional

Product: Clexane

Complaint
The complainant alleged that the omission of the words “for all patients admitted to hospital” in relation to NHMRC Guidelines on venous thromboembolism (VTE) prevention in a mailer for Clexane created a misleading impression of the NHMRC guidelines and has the potential to lead to the treatment of a large number of patients who are not the subject of the NHMRC guidelines.

Sections of the Code
Sanofi-aventis was asked to respond to the complaint with reference to the following Sections of Edition 16 of the Code:
• 1.1 Responsibility
• 1.2 Substantiating Data
• 1.3 False or misleading claims

Response
Sanofi-aventis denied that the omission of the words “… for all patients admitted to hospital” was intended to mislead prescribers or imply the relevance of the guidelines to a larger number of patients. The information card had only been provided to selected healthcare professionals within hospitals – specifically orthopaedic surgeons, anaesthetists, haematologists and accident and emergency physicians.

Sanofi-aventis acknowledged that the information card could have been clearer and has distributed a corrective letter to all hospital based healthcare professionals who received the original mailing to clarify the scope of the NHMRC VTE guidelines.

Code Committee decision
• In a majority decision no breach of Sections 1.1 and 1.2 of the Code
• In a majority decision a breach of Section 1.3 of the Code

Sanction
The Committee noted that a corrective letter had been sent and did not impose any further sanction.

Consideration of the complaint
Members noted that the mailer had been sent to relevant healthcare professionals within hospitals and had not been distributed to prescribers outside hospitals. Although the mailer did correctly reference the NHMRC Guidelines with its full title, including the statement ‘in patients admitted to Australian hospitals’, this was in small print and it was not clear to a reader that the prominent claim related to patients admitted to hospital. Any statement in an item of company promotional material must be an accurate communication of the relevant context for a claim.

The Committee considered whether the omission was in breach of sections 1.1 and 1.2 of the Code. The Committee noted the Cochrane meta-analysis which was the basis for the recommendation on the treatment of venous thromboembolism in people with lower leg fractures and injuries requiring immobilisation. This meta-analysis had included studies in patients in the ambulatory setting, where low molecular weight heparin may have been started in hospital and continued after the patients were discharged. The Committee concluded that the claim could be substantiated and had been referenced to high quality evidence and was therefore not in breach of Sections 1.2 or 1.1 of the Code.

In relation to Section 1.3 of the Code, the Committee concluded that the omission of the words that the recommendation related to patients admitted to hospital was potentially misleading. The Committee was of the view that this was a minor breach as there were no safety issues for patients. Members noted that Sanofi-aventis had been proactive in distributing a corrective letter to those healthcare professionals who had received the item.

In a majority decision the Committee did not find a breach of Sections 1.1 or 1.2 of the
Code, however members considered that there was a breach of Section 1.3 as there was the potential to mislead by omission.

Sanction
The Committee noted that Sanofi-aventis had already distributed a corrective letter, which was included in the agenda papers. Members discussed whether any additional sanction should be imposed. The Committee determined that this was a minor breach with no safety implications and agreed that there should be no requirement for a fine or further corrective action. The Committee determined that Sanofi-aventis should cease using the item that has been found in breach of the Code.

While not the subject of the complaint, members commented on the size and position of the qualifying statement associated with the claim and the size of the reference citation. Section 1.3 of the Code requires a qualifying statement to be located directly below or adjacent to the relevant claim and in a font size of not less than 3mm at the lower case ‘e’. Any reference must be in a font size of not less than 1.5mm at the lower case ‘e’. The qualifying statement and reference did not comply with these requirements.
**Mobic 1044**

**Subject Company:** Boehringer Ingelheim

**Complainant:** Arthritis Australia

**Product:** Mobic

**Complaint**
Arthritis Australia alleged that despite Arthritis Australia’s verbal and written communication stating that they did not want their name or the ‘Voice of Arthritis’ study to be used for commercial purposes, the Mobic advertorial and advertisement had proceeded. Arthritis Australia accepted that the ‘Voice of Arthritis’ study is in the public domain, but BI’s advertorial, which reworded aspects from the study in the advertorial, and its linkage to the Mobic double page advertisement made it appear that Arthritis Australia was supporting the promotion of a particular company’s product which was not correct.

**Sections of the Code**
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 2.1.1.4 (with reference to Sections 1 and 2) Company Commissioned Articles
- 13 Relationship with Health Consumer Organisations (specifically 13.2 and 13.3)
- 18 Discredit to and reduction of confidence in the industry

**Response**
Boehringer Ingelheim stated that it deeply regretted these events, had apologised unreservedly to Arthritis Australia, and is reviewing its internal processes for dealing with third party providers, in particular the relationship with the advertising agency involved in this matter.

BI acknowledged that the advertorial did not include the company name and has taken immediate steps to withdraw this advertorial.

BI stated that as the quotes from ‘Voice of Arthritis’ were reported accurately and as the advertisement was directed at healthcare professionals there was no breach of Sections 13.3 or 18 of the Code.

**Code Committee decision**
- In a unanimous decision a breach of Section 2.1.1.4 of the Code
- In a majority decision a breach of Section 13 preamble and 13.2 of the Code
- In a majority decision no breach of Sections 13.3 or 18 of the Code

**Sanction**
- Publish a corrective advertisement
- Pay a fine of $50,000

**Consideration of the complaint**
The Committee noted BI’s acknowledgement that the advertorial did not meet the requirements of Section 2.1.1.4 because it did not include the name of the company. In a unanimous decision members found a breach of Section 2.1.1.4 of the Code.

Members referred to the preamble to Section 13 which states that relationships between HCOs and companies should involve the following components that are essential in any relationship:
- respect for independence
- achieving and maintaining public trust
- fairness
- openness and transparency
- accountability

The Committee noted that there had been verbal and written communication from Arthritis Australia to the agency acting on behalf of BI stating that it did not want the organisation’s name or the ‘Voice of Arthritis’ study used for commercial purposes. Members noted that the BI advertorial comprised extracts from the Introduction and Objectives of the ‘Voice of Arthritis’ study, but these were partial extracts and were out of order, which potentially obfuscated the meaning of the original text.

Members commented that whilst the ‘Voice of Arthritis’ study is in the public domain and a third party could reference this proprietary material, members are obliged by the Code to
abide by a strict set of principles which ensure that companies work together with a health consumer organisation (HCO) in an ethical manner which respects the independence of the HCO.

The majority of members were of the view that BI had used Arthritis Australia’s proprietary material without their consent and which visually linked the advertorial and the Mobic advertisement in a manner that implied the HCO’s endorsement of a particular product and was therefore in breach of the Section 13 preamble and more specifically Section 13.2 of the Code. A minority of members were of the view that a GP would not link the advertorial to the Mobic advertisement or interpret it as an endorsement of Mobic by Arthritis Australia. By a majority decision the Committee found the advertorial and the manner that it was linked to the Mobic advertisement was in breach of Section 13 preamble and Section 13.2 of the Code.

A majority of members were of the view that BI was not seeking to influence the text of HCO material in a manner favourable to its own commercial interest and was therefore not in breach of Section 13.3 of the Code. Other members were highly critical of BI for the manner in which it had used the ‘Voice of Arthritis’ study in the advertorial and using it to link to the Mobic advertisement and were of the view that BI was seeking to use the ‘Voice of Arthritis’ study for commercial purposes. By a majority decision, no breach of Section 13.3 was found.

The Committee reviewed the communications between Arthritis Australia and the agency acting for BI in which Arthritis Australia expressly stated that it did not want its study to be used in this manner. Some members were of the view that BI’s conduct by proceeding to publish the advertorial and advertisement, albeit with a minor change to the advertisement following Arthritis Australia’s communication, had the potential to damage the reputation of Arthritis Australia and the industry. Some members considered that the conduct may give the impression relationships between HCOs and the pharmaceutical industry did not maintain the independence of the HCO and may reduce the public’s trust in both the industry and the HCO. However the majority of members considered that there was no breach of Section 18 of the Code as this was conduct had been isolated to one agency and company. The Committee noted that BI had apologised to Arthritis Australia. In a majority decision, no breach of Section 18 was found.

Sanction
In a majority decision the Committee determined this should be considered a moderate breach as there were no safety implications but the materials may have an effect on how the medical profession will prescribe the product.

Having found several breaches of the Code the Committee determined that BI should:

- In a majority decision, publish a corrective advertisement in all publications where the advertorial appeared. The corrective advertisement must state that the company had acted inappropriately and used the ‘Voice of Arthritis’ study against the wishes of Arthritis Australia. This advertisement must be of the same size and prominence in the publication as the original advertorial.

- In a majority decision, pay a fine of $50,000.
Champix 1046

Subject Company: Pfizer Australia (Pfizer)

Complainant: Healthcare professionals (jointly)

Product: Champix

Complaint
The complainants alleged that the content of one page of the ‘outsmartcigarettes’ website (the ‘ways to quit’ page) was promotional rather than educational for three reasons:
1. It promotes a specific action that is repeated three times – “Talk to your doctor” – which, by implication, favours prescription only treatment rather than other options that do not require seeing a doctor.
2. Website is unbalanced because it has negative statements about all the options except Champix.
3. The website lacks more balanced and complete information that would be expected in educational material and does not provide information about the potential benefits and harms of many of the alternatives.

Sections of the Code
Website page alleged to be in breach of the following Sections of Edition 16 of the Code:
- 1.3 False and misleading claims
- 12.3 Promotion to the general public

Response
Pfizer rejected the assertion that the website is unbalanced, non-educational or promotes a prescription medicine to the public. Pfizer also stated that several assertions by the complainants are inaccurate. Pfizer has made every effort to ensure that the website was compliant with all existing laws and regulations. In addition to the one page which is referred to by the complainants as problematic there are 17 other pages of the website that provide comprehensive information. The website has been in existence for over two years and in this time there have been no other complaints about the site.

Code Committee decision
- In a unanimous decision no breach of section 1.3 of the Code
- In a majority decision no breach of section 12.3 of the Code

Consideration of the complaint
While noting that Pfizer has made some amendments to the website following its receipt of the complaint, the Chairman advised members that they must make their decision based on the complaint and the website as it was at the time of the complaint.

With respect to the complainants’ concerns that the use of statements such as “Talk to your doctor” and “Ask your doctor” encouraged patients to seek a prescription medicine smoking cessation treatment, members were of the view that recommending that smokers see their doctor in these circumstances does not constitute the promotion of a prescription product. Healthcare professionals on the Committee commented that the majority of patients seeking help from their doctor had already tried to quit smoking several times. As a healthcare professional they will discuss a range of options with a patient, which may include all the options referred to on the ‘outsmartcigarettes’ website.

The Committee considered the allegation that the webpage was unbalanced and was promoting Champix over other alternatives. It noted the complainant’s statement that the list of different smoking cessation modalities did not include the non-drug forms of abstinence such as “acceptance” and “commitment” therapy. The website included reference to ‘cold turkey’, which is akin to abstinence, as well as counselling, advice and hypnotherapy which are significant non-drug therapies. It was also noted that the drug ‘nortriptyline’ was not included as it is not approved for smoking cessation in Australia; it is only indicated for the treatment of major depression. The Committee did not agree that
the webpage suggested that Champix was the best option and did not consider this aspect of the complaint provided sufficient rationale for finding the webpage in breach of Section 12.3 of the Code.

With respect to the use of brand name and generic names for the pharmacotherapy treatment options, members accepted that there is only one brand of varenicline which is Champix, whereas there are four brands of bupropion (Zyban SR, Clorprax, Prexaton and Bupropion-RL) and did not find the manner in which these treatment options were presented unbalanced or promoted Champix over other options.

In relation to the complaint that the descriptions of the rationales for developing varenicline and bupropion were unbalanced and misleading, the Committee noted that the statement that bupropion was originally ‘developed as an antidepressant and was found to help people quit smoking’ is taken from the RACGP Smoking Cessation Pharmacotherapy Update for healthcare professionals. The webpage also includes the statement “Bupropion is available only on prescription so ask your doctor or pharmacist if it is right for you”, which is the same statement used in relation to Champix. Members were of the view that the information on Champix and bupropion on the webpage was merely a summary of the modes of action and was not favouring one type of treatment over any other.

With respect to the allegation that the company should have provided more information on the risks and benefits of each treatment option, the Committee was of the view that this would potentially lead to promotion as this could be regarded as comparing the prescription medicine options as well as the other treatment options. The Committee reviewed the specific page referred to by the complainants and also noted that there were 17 other pages on the website that included comprehensive information on how to access addiction levels, useful tips on smoking cessation, benefits of quitting smoking and quitting tools and strategies. However, there could have been more obvious information about the side-effects of Champix.

In a majority decision the Committee did not find a breach of Section 12.3 of the Code with respect to the information provided on the webpage.

In a unanimous decision the Committee did not find a breach of Section 1.3 of the Code as the information was not unbalanced, false or misleading. The Committee noted that Pfizer had undertaken to make some amendments to the website, such as the removal of the exclamation mark with the statements advising consumers to see their doctor, which would make the webpage even more balanced. However, the Committee did not consider that the unamended webpage was lacking sufficient balance or should be found in breach of the Code.
The aims of the Monitoring Committee are to encourage compliance with the Code, provide advice on compliance where necessary, obtain and publish statistical data on the degree of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code.

The Monitoring Committee may review materials across a range of therapeutic areas and types of activities. If the Committee has concerns about an activity or material, or wishes to seek further information, Committee members must direct the Secretariat to write to the company identifying the issues of concern and what additional information should be provided to the Committee. After the review of this additional information, if the Committee still has significant concerns, a formal complaint may be lodged with the Code Committee for a determination. The Monitoring Committee cannot find a company in breach of the Code.

The therapeutic classes for the Monitoring Committee reviews are derived from the Therapeutic Class Index used by MIMS Australia:

- Alimentary System
- Cardiovascular System
- Central Nervous System
- Analgesia
- Musculoskeletal System
- Endocrine and Metabolic Disorders
- Genitourinary System
- Infections and Infestations
- Neoplastic Disorders
- Immunology
- Respiratory System
- Ear, Nose and Oropharynx
- Eye
- Skin
- Surgical Preparations
- Contraceptive Agents

In each financial year the Monitoring Committee reviews three types of promotional material (for example advertisements, printed promotional material, brand name reminders) across three different therapeutic classes (for example alimentary system, eye and contraceptive agents); and three different types of conduct covered by the Code across all therapeutic classes (for example websites, education events and starter packs).

Table 10 provides a summary of the Monitoring Committee reviews of materials and activities over the past six years. Table 11 provides a snapshot of the materials and activities reviewed by the Monitoring Committee in 2009-2010.
<table>
<thead>
<tr>
<th>Table 10</th>
<th>Summary of materials and activities reviewed by the Monitoring Committee</th>
<th>2004-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alimentary System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Nervous System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analgesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endocrine &amp; Metabolic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genitourinary System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infections &amp; Infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neoplastic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ear, Nose &amp; Oropharynx</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical Preparations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contraceptive Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reviews across all therapeutic classes</td>
<td>Invitations to educational meetings Market research Prescribing software</td>
<td>Invitations to educational meetings Websites Patient education</td>
</tr>
<tr>
<td>Therapeutic Class</td>
<td>Types of material or activity subject to review</td>
<td>Number of companies</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Educational event reports (3 month random sample) July 2008 – June 2009</td>
<td>41</td>
</tr>
<tr>
<td>Genitourinary System</td>
<td>Printed promotional material</td>
<td>8</td>
</tr>
<tr>
<td>Immunology (Vaccines)</td>
<td>Advertisements</td>
<td>2</td>
</tr>
<tr>
<td>Infections &amp; Infestations</td>
<td>Printed promotional material</td>
<td>14</td>
</tr>
<tr>
<td>Alimentary System</td>
<td>Advertisements</td>
<td>4</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Media releases</td>
<td>12</td>
</tr>
<tr>
<td>Cardiovascular System</td>
<td>Brand name reminders</td>
<td>12</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Disease education activities</td>
<td>23</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>On-line advertisements</td>
<td>12</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Educational event reports (3 month random sample) July 2009 – March 2010</td>
<td>41</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>18,848</strong></td>
</tr>
</tbody>
</table>
Outcomes of the Monitoring Committee review of materials and activities 2009-2010

Educational Event Reports 2008-2009

The Committee reviewed three random months (September 2008, November 2008 and June 2009) from the period July 2008 to June 2009 over four meetings.

Educational event reports were received from the following companies:

- Abbott Australasia
- Actelion Pharmaceuticals
- Alcon Laboratories
- Allergan Australia
- Amgen Australia
- AstraZeneca
- Baxter Healthcare
- Bayer Healthcare
- Boehringer Ingelheim
- Biogen Idec Australia
- Bristol Myers Squibb (BMS)
- Celgene
- CSL
- Eli Lilly Australia
- Genzyme Australasia
- Gilead Sciences
- GileadSmithKline (GSK)
- Innovex (Pharmalink)
- iNova
- Ipsen
- Janssen-Cilag
- Lundbeck
- Merck Serono
- Merck Sharp & Dohme (Australia) (MSD)
- Mundipharma
- Norgine
- Novartis Pharmaceuticals
- Novo Nordisk
- Nycomed
- Organon
- Pfizer
- Roche
- sanofi-aventis
- Sanofi Pasteur
- Schering Plough
- Servier Laboratories
- Shire
- Smith & Nephew
- Solvay
- UCB Pharma
- Wyeth

The Monitoring Committee noted the improvement in reporting by companies and congratulated companies on the internal compliance procedures put in place to assist company staff when reporting.

<table>
<thead>
<tr>
<th>Events</th>
<th>Further information requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2008</td>
<td>3,273</td>
</tr>
<tr>
<td>November 2008</td>
<td>3,007</td>
</tr>
<tr>
<td>June 2009</td>
<td>2,691</td>
</tr>
<tr>
<td>TOTAL</td>
<td>9,120</td>
</tr>
</tbody>
</table>

The Committee requested further information regarding 119 educational events from the following companies:

- Abbott – 2 events
- Actelion – 1 event
- Allergan – 2 events
- Amgen – 1 event
- AstraZeneca – 22 events
- Bayer – 1 event
- Boehringer Ingelheim – 1 event
- Biogen – 1 event
- BMS – 1 event
- Eli Lilly – 11 events
- GSK – 2 events
- Innovex – 1 event
- Ipsen – 1 event
- Janssen-Cilag – 7 events
- Lundbeck – 1 event
- Merck Serono – 3 events
- MSD – 8 events
- Novartis – 14 events
- Nycomed – 1 event
- Pfizer – 2 events
- Roche – 3 events
- sanofi-aventis – 22 events
- Schering Plough – 5 events
- Servier – 6 event

Having reviewed the additional information five events (MSD – 3 Innovex (Pharmalink) – 1 and Janssen-Cilag – 1) were submitted to the Code Committee for a determination. Links to the outcomes and reasons for the decision with respect to these complaints can be found on pages 44-46.

**Genitourinary System**

The Committee reviewed 52 items printed promotional material from member companies with products in this therapeutic area.

Items of printed promotional material were provided by the following companies:

- Abbott
- Bayer
- CSL
- Eli Lilly Australia
- iNova
- Novartis
- Novo Nordisk
- Pfizer

The Monitoring Committee did not identify any general issues across the promotional material. The Committee sought feedback in relation to 2 items from CSL. Following the review of company responses, the Committee determined that no items of promotional material should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

**Vaccines**

The Monitoring Committee reviewed 15 advertisements for vaccines.

Advertisements were received from the following companies:

- CSK
- GlaxoSmithKline Australia

The Monitoring Committee did not identify any general issues across the promotional material. The Committee sought feedback in relation to 3 items from CSL. Following the review of company responses, the Committee determined that no items of promotional material should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

**Infections & Infestations**

The Monitoring Committee reviewed 107 items of printed promotional material.

Items of printed promotional material were received from the following companies:

- Abbott Australasia
- AstraZeneca
- Bayer Healthcare
- BMS
- Boehringer Ingelheim
- Gilead Sciences
- GSK
- Janssen-Cilag
- MSD
- Novartis
- Pfizer
- Roche
- Schering Plough
- Wyeth
The Monitoring Committee did not identify any general issues across the promotional material. The Committee sought feedback in relation to 4 items from BMS, 2 items from Boehringer Ingelheim, 3 items from GSK, 3 items from MSD, 1 item from Novartis, 2 items from Pfizer and 1 item from Schering Plough.

The Committee noted the responses and welcomed the commitment to continual improvement. Following the review of company responses, the Committee determined that no items of promotional material should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

**Alimentary System**

The Monitoring Committee reviewed 32 advertisements from the following companies:
- AstraZeneca
- Janssen-Cilag
- Nycomed
- Wyeth

The Monitoring Committee did not identify any general issues across the promotional material. The Committee sought feedback in relation to 4 advertisements from Janssen-Cilag, 4 advertisements from Nycomed and 1 advertisement from Wyeth.

Following the review of company responses, the Committee determined that no items of promotional material should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

**Media Releases**

The Monitoring Committee reviewed 30 media releases from the following companies:
- AstraZeneca
- Bayer
- Baxter
- Celgene
- CSL
- Eli Lilly Australia
- Gilead Sciences
- GSK
- Janssen-Cilag
- MSD
- Roche
- Sanofi-aventis

The Committee commented that some companies were tending towards promotion and encouraging a member of the general public to seek a prescription for a specific prescription medicine.

The Monitoring Committee sought feedback from AstraZeneca, Celgene, Janssen-Cilag, MSD, Roche and sanofi-aventis.

Following the review of company responses, the Committee determined that 4 media releases from 4 companies should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code. These complaints will be considered by the Code of Conduct Committee in July 2010 with the outcomes published in the July – September Quarterly report.
Brand Name Reminders

The Monitoring Committee reviewed 50 brand name reminders from the following companies:
- Abbott
- AstraZeneca
- Bayer
- Boehringer Ingelheim
- CSL
- Eli Lilly Australia
- Janssen-Cilag
- MSD/Schering Plough
- Novartis
- sanofi-aventis
- Servier
- Pfizer

The Committee noted the high level of compliance with the new provisions pertaining to brand name reminders and congratulated companies on their quick implementation. The Committee sought feedback on 7 items from Boehringer Ingelheim, Janssen-Cilag, Pfizer and Servier. Following the review of company responses, the Committee determined that no brand name reminders should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Disease Education Activities

The Monitoring Committee reviewed 182 items of materials for disease education activities from the following companies:
- Alcon Laboratories
- Allergan
- AstraZeneca
- Baxter
- Bayer Healthcare
- BMS
- CSL
- Eli Lilly Australia
- GSK
- Ipsen
- Janssen-Cilag
- Lundbeck
- Merck Serono
- MSD/Schering Plough
- Norgine
- Novartis
- Nycomed
- Pfizer
- Roche
- sanofi-aventis
- Servier
- Shire
- Solvay

The Monitoring Committee sought feedback from in relation to 5 items of disease education activities from Alcon, Novartis and Roche. One item reviewed by the Committee was under consideration by the Code Committee and no further information was sought from the company.

Following the review of company responses, the Committee determined that 3 items should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code. These complaints will be considered by the Code of Conduct Committee in July 2010 with the outcomes published in the July – September Quarterly report.

On-Line Advertisements

The Monitoring Committee reviewed 83 advertisements published in the on-line environment from the following companies:
- Abbott
- Abbott Products (formerly Solvay)
- AstraZeneca
- Bayer
- Boehringer Ingelheim
- BMS
- Eli Lilly Australia
- GSK
- Pfizer/Wyeth
- Roche
- sanofi-aventis
- Servier
The Committee reminded several companies that a hyperlink to the Product Information (PI) must be included in on-line advertisements where the PI is not included within the body of the advertisement. It is not acceptable to state that the PI is available from the company. The Committee also reminded several companies that Edition 16 requires qualifying statements to be directly below or adjacent to the claim in a minimum font size of 3mm.

In addition to the feedback on the hyperlinked PI the Monitoring Committee requested feedback in relation to 9 advertisements from Boehringer Ingelheim, BMS, Eli Lilly, GSK, MSD, Novartis, Pfizer and Servier.

Following the review of company responses, the Committee determined that no advertisements should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code. One advertisement reviewed by the Monitoring Committee was already subject to complaint and the Committee took no further action on this matter.

Educational Event Reports 2009/2010

The Committee reviewed three random months from the period July 2009 – March 2010 (August 2009, October 2009 and March 2010) over two meetings.

Reports were received from the following companies:

- Abbott Australasia
- Actelion Pharmaceuticals
- Alcon Laboratories
- Allergan Australia
- Amgen Australia
- AstraZeneca
- Baxter Healthcare
- Bayer Healthcare
- Boehringer Ingelheim
- Biogen Idec Australia
- Bristol Myers Squibb (BMS)
- Celgene
- CSL
- Eli Lilly Australia
- Genzyme Australasia
- Gilead Sciences
- GlaxoSmithKline (GSK)
- Innovex
- iNova
- Ipsen
- Janssen-Cilag
- Lundbeck
- Merck Serono
- Merck Sharp & Dohme (Australia) (MSD)
- Mundipharma
- Norgine
- Novartis Pharmaceuticals
- Novo Nordisk
- Nycomed
- Organon
- Pfizer
- Roche
- sanofi-aventis
- Schering Plough
- Servier
- Shire
- Smith & Nephew
- Solvay
- Stiefel
- UCB Pharma
- Wyeth
Table 13
Review of Educational Events 2009-2010

<table>
<thead>
<tr>
<th>Events</th>
<th>Further information requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 2009 3066</td>
<td>10</td>
</tr>
<tr>
<td>October 2009 3067</td>
<td>15</td>
</tr>
<tr>
<td>March 2010 3047</td>
<td>21</td>
</tr>
<tr>
<td>TOTAL 9,180</td>
<td>46</td>
</tr>
</tbody>
</table>

The Committee requested further information regarding 16 educational events from the following companies:
- Abbott Products – 5 events
- Alcon – 1 event
- Allergan – 1 event
- AstraZeneca – 1 event
- Baxter – 1 event
- BMS – 1 event
- Eli Lilly – 4 events
- Gilead – 1 event
- GSK – 1 event
- Boehringer Ingelheim – 2 events
- Ipsen – 1 event
- Novartis – 8 events
- Schering Plough – 3 events
- Pfizer – 3 events
- Roche – 1 event
- Sanofi-aventis – 12 events

Having reviewed the additional information one event was submitted to the July 2010 Code Committee for a determination. The outcome and reasons for the decision will be published in the July – September 2010 Quarterly Report.