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As Chairman and Chief Executive of Medicines Australia we are very proud of the achievements of our members and the Secretariat, who have support the ethical conduct program, over the last twelve months. These achievements are summarised here in the 2011 Code of Conduct Annual Report.

The Medicines Australia Code of Conduct 16th edition was implemented in January 2010. During 2010-2011 our members have continued to demonstrate their strong commitment to maintaining high standards of ethical conduct in all their interactions with health professionals, consumers and other stakeholders and that they have embraced the necessity to be open and transparent about these interactions.

Highlights

Fifty Years of Self-Regulation
In October 1960 the first edition of the Code of Conduct was adopted by the then Australian Association of the Ethical Pharmaceutical Industry. On 26 October 2010 more than 200 guests gathered for a celebratory dinner at Sydney’s Waters Edge to celebrate the 50th anniversary of the Medicines Australia Code of Conduct.

Fifty years ago the Association recognised that if we were going to be successful as an industry and earn the trust of the people that we were communicating and negotiating with in government, we had to behave as an ethical and responsible industry that upheld high standards for the promotion of our products. One constant in this fast-changing industry over the last half century has been its collective commitment to upholding a high standard of ethical conduct in engaging with health professionals, consumers and other stakeholders.

In his remarks at the celebratory dinner, PricewaterhouseCoopers partner Michael Daniel, one of the Code of Conduct Committee chairs, recalled some of the more quixotic provisions of the first Code of Conduct that now stand rather at odds with the current approach to transparency and independence of the complaint handling processes. Michael encouraged continued ‘glasnost’ by Medicines Australia and challenged the generic medicines sector to require equal standards of its members.

Other highlights of the celebration were a live performance by indigenous health champion and musician Jimmy Little and a ceremonial cutting of a three-tiered 50th birthday cake.

Having celebrated the long history of the Code in October 2010, the cycle of review and revision of the Code doesn’t stand still. At the end of June 2010 plans are well advanced to commence the next review of the Code in August 2011, leading to a new edition planned for January 2012.

Principles of Ethical Conduct
In late June 2010 the then Parliamentary Secretary for Health, Mark Butler issued the Government’s Position Paper on the Promotion of Therapeutic Goods. This paper challenged the therapeutic goods
industry to strengthen and standardise its self-regulation through development of consistent industry Codes incorporating high level principles for promotion, to both health professionals and consumers where this is permitted under the therapeutic goods legislation.

A Working Group was established by the Parliamentary Secretary to develop the high level principles and consider mechanisms to ensure a level playing field across all companies that supply therapeutic goods in Australia, and particularly between members and non-members of industry associations.

Dr Brendan Shaw represented Medicines Australia on the Working Group, which was chaired by Anne Trimmer, chief executive of the Medical Technology Association of Australia and included representatives for consumers, pharmacists, doctors, specialist physicians, nurses, and all sectors of the therapeutics products industry (OTC and complementary medicines, medical devices and diagnostics). The Working Group developed a high level statement of principles for incorporation into all the industry sectors’ self-regulatory Codes and identified operational and governance topics that should be included in all those Codes, along with ethical obligations on companies.

The Working Group’s Report was submitted to the new Parliamentary Secretary for Health, Catherine King on 18 March 2011. The Government has not yet responded to the Report, but is expected to be released in August 2011 along with the Government’s response to a separate consultation on regulation of therapeutic goods advertising (this latter consultation was primarily concerned with products that may be advertised directly to consumers, and therefore was not directly relevant to prescription medicines).

As Medicines Australia was an active participant in developing the Working Group’s recommendations it is our intention to include the high level principles in the Medicines Australia Code of Conduct in the next review of the Code. Also, whilst many of the operational and governance issues identified for inclusion in all self-regulatory Codes are already addressed in the Medicines Australia Code, there are one or two topics that are not currently covered (such as ‘ghost writing’), which we expect to include in the 17th edition of the Code.

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 in and support of a first class industry Code of Conduct.

In early 2011 Dr Mike Wyer, one of the Chairmen of the Monitoring Committee, decided to retire from the Committee after 5 years of service. Mike has been a dedicated contributor to the work of the Committee and we wish him every success as he concentrates more on enjoying time with his family. Following Mike’s retirement from the Committee we have welcomed two new members to the Panel of Chairs of the Monitoring Committee – Mr Wayne Strong (The Change Facilitators) and Ms Helen Maxwell-Wright (Maxwell-Wright Associates).

We also take this opportunity to remember Ms Sheila Rimmer AM who passed away in September 2010. Ms Rimmer was a long serving consumer advocate and represented the Consumers Health Forum on the Medicines Australia Monitoring Committee. She will be remembered as a passionate and committed member of the consumer family; a quiet achiever who advanced the health consumer cause through her ability to win respect and build strong relationships with stakeholders, peers and colleagues. In particular, she will be remembered for her achievements in advancing consumer participation and highlighting health consumer issues for older people, the safe use of medicines, appropriate medicines information and self-management of chronic conditions.
Executive Summary

Achievements

I am pleased to report that in 2010-2011 member companies have maintained a high level of compliance with the Code.

During the year 14 new complaints were received, which is a decrease from 2009-2010 when 39 complaints were submitted to Medicines Australia. Six of the new complaints received this year were from pharmaceutical companies, with the balance from healthcare professionals (4 complaints), members of the public (2 complaints) and the Monitoring Committee (2 complaints). Of the new complaints received, 11 were finalised by 30 June 2011. Of the finalised complaints, 7 were found not in breach of the Code and 4 were found to be in breach in relation to some or all of the alleged breaches. Details of the complaints considered and finalised in 2010-2011 and the outcomes are reported in this Code of Conduct Annual Report, which is published on the Medicines Australia website.

The Monitoring Committee undertook a substantial number of reviews of company promotional materials and other activities during the year. In 2010-11 the Monitoring Committee undertook seven reviews of materials associated with particular therapeutic areas as well as reviews of company controlled websites, prescribing software communications and market research with health professionals. The review of market research was particularly extensive, taking three meetings of the Committee to complete its examination of materials and responses from companies to questions raised by the Committee. In 2010-2011 the Monitoring Committee referred two complaints to the Code Committee, which are detailed in this Report.

In reviewing materials submitted to the Monitoring Committee for review, and companies’ responses when questions were raised, the Committee commented on the generally improved standard of submissions from member companies, which greatly assists the Committee in its work, particularly when the Committee is reviewing very large amounts of documentation. The Committee also noted a high level of compliance with the Code by members overall.

Educational Event Reports

Member companies continue to report all educational meetings and symposia that they organise or sponsor, which are published every six months on the Medicines Australia website. Companies have consistently demonstrated a high level of compliance with the Code and their ongoing commitment to improved transparency of these interactions with healthcare professionals, which deliver and support valuable education about the treatments available to Australians.

On 17 December 2010 and 25 June 2011 Medicines Australia published educational event reports for the periods April – September 2010 and October 2010 – March 2011 respectively. There were almost 17,000 events reported for April – September 2010 and almost 14,000 events reported for October 2010 – March 2011. The lower number of events in the latter period most likely reflects that it covers the December-January holiday period.
At the time of writing, the Monitoring Committee is completing its review of three randomly selected months from the last twelve months of reports. Outcomes of this review will be published in the next Code of Conduct Quarterly report.

Reporting educational events is now standard good business practice for Medicines Australia member companies. We are pleased to see that during the last year Generic Medicines Industry Association members also started reporting the events that they organise or sponsor for health professionals, as required under the GMIA’s Code of Practice.

Our people

Medicines Australia welcomed Mrs Sophie Hibburd to the Ethical Conduct Team in July 2010. Sophie has grown quickly into the role and is a valued manager of the Code of Conduct processes and Continuing Education Program. Sophie is ably supported by Mrs Romina Bognolo whose excellent administrative skills keep our Code, Appeals and Monitoring Committee’s important work running smoothly. I am very grateful to Sophie’s and Romina’s efforts during the year.

Looking ahead

The three-yearly review of the Code of Conduct seems to come around all too quickly – no sooner have we bedded down the revised edition 16 and we are starting the next review. We will be commencing the review of the Code in August 2011 with the intention of finalising a revised Code by mid-2012 ready for submission to the ACCC for consideration of authorisation.

Medicines Australia will continue to work with industry and stakeholders to take up the ACCC’s challenge to continuously enhance transparency of our activities.
Governance

Complaints received by Medicines Australia are considered by the Code Committee and, when required, by the Appeals Committee.

Neither the Medicines Australia Board nor the 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://medicinesaustralia.com.au/code-of-conduct/committee-membership/

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 matters 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://medicinesaustralia.com.au/code-of-conduct/code-and-monitoring-meeting-dates/

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nominee/s</th>
</tr>
</thead>
</table>
| **Chairman** | Mr Michael Daniel, Resolve Legal (formerly of 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)** | Professor Richard O Day AM  
Professor Paul Seale  
Professor John Miners  
Associate Professor Ken Williams |
| **Consumers Health Forum of Australia (CHF)** | Ms Anne McKenzie  
Ms Sharon Caris (Alternate) |
| **Royal Australasian College of Physicians (RACP)** | Dr Avi Lemberg  
Dr Catherine Streeton  
Dr Christian Gericke (2010) |
| **Royal Australasian College of General Practitioners (RACGP)** | Dr Harry Nespolon |
| **Medicines Australia Association Representatives (maximum of 3)** | Various, depending on complaints |
| **Medicines Australia Member Company Medical/Scientific Directors (Maximum of 2)** | Various, depending on complaints |
| **Observers (No voting rights)** | |
| Therapeutic goods Administration (TGA) (one TGA representative attends) | Dr Susan Coates (2010 - 2011)  
Mr Mick O’Connor (2011)  
Ms Marlene Keese (2011) |
| Medicines Australia member companies’ employees (Maximum 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 | Mrs Sophie Hibburd |
| Medicines Australia Chief Executive Officer or delegate | Dr Brendan Shaw |
| Medicines Australia Officer responsible for Ethical Conduct | Ms Deborah Monk |
The Code Committee held 10 meetings in 2010-2011. The attendance by permanent members of the Code Committee is shown in Figure 1.

**Figure 1**

*Code of Conduct Committee Meeting Attendance 2010-2011*

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nominee/s</th>
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<tbody>
<tr>
<td>Chairman</td>
<td>Mr Michael Daniel, Resolve Legal (formerly of PricewaterhouseCoopers Legal)</td>
</tr>
<tr>
<td></td>
<td>Mr Michael Gorton, Russell Kennedy</td>
</tr>
<tr>
<td></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>Full Members (Voting rights)</td>
<td></td>
</tr>
<tr>
<td>One independent Lawyer selected from a panel of six trade practices lawyers</td>
<td></td>
</tr>
<tr>
<td>One representative from:</td>
<td></td>
</tr>
<tr>
<td>Australian General Practice Network (AGPN), or</td>
<td></td>
</tr>
<tr>
<td>Australian Medical Association (AMA), or</td>
<td>Dr Marcela Cox</td>
</tr>
<tr>
<td>Royal Australian College of General Practitioners (RACGP)</td>
<td>Dr Martine Walker</td>
</tr>
<tr>
<td></td>
<td>Dr Brian Morton</td>
</tr>
<tr>
<td>Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)</td>
<td>Professor Richard O Day</td>
</tr>
<tr>
<td>(One ASCEPT member selected from the panel of four members)</td>
<td>Professor Paul Seale</td>
</tr>
<tr>
<td></td>
<td>Professor John Miners</td>
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<td></td>
<td>Associate Professor Ken Williams</td>
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Appeals Committee Members

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<th>Organisation</th>
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<tr>
<td>Consumers Health Forum (CHF)</td>
<td>Ms Judith Maher&lt;br&gt;Ms Patti Warn (Alternate)</td>
</tr>
<tr>
<td>(Two CHF representatives to participate in complaints where the activity is</td>
<td></td>
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<tr>
<td>directed at the general public or patients)</td>
<td></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>(Maximum 1 Medicines Australia Member Company Senior Executive and maximum</td>
<td></td>
</tr>
<tr>
<td>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><strong>Medicines Australia Advisors (No voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td>Secretary, Code of Conduct Committee</td>
<td>Mrs Sophie Hibburd</td>
</tr>
<tr>
<td>Medicines Australia Chief Executive or delegate</td>
<td>Dr Brendan Shaw</td>
</tr>
<tr>
<td>Medicines Australia Officer responsible for Ethical Conduct</td>
<td>Ms Deborah Monk</td>
</tr>
</tbody>
</table>

The Appeals Committee held 4 meetings in 2010-2011 to consider 4 appeals. As shown in Figure 2 all permanent members of the Appeals Committee attended the scheduled meetings.
Monitoring Committee

Monitoring Committee meetings are held regularly on the third Monday of each month. A list of meeting dates is available from the Medicines Australia website at: http://medicinesaustralia.com.au/code-of-conduct/code-and-monitoring-meeting-dates/

Table 3
Monitoring Committee Members

<table>
<thead>
<tr>
<th>Organisation</th>
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<tbody>
<tr>
<td><strong>Full Members (Voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td>Chairman (Selected from a panel of three consultants with industry experience in marketing and knowledge of the Code of Conduct)</td>
<td>Mr Russell Edwards</td>
</tr>
<tr>
<td></td>
<td>Dr Mike Wyer (to April 2011)</td>
</tr>
<tr>
<td></td>
<td>Ms Helen Maxwell-Wright (2011)</td>
</tr>
<tr>
<td></td>
<td>Mr Wayne Strong (2011)</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 (Two CHF representatives to participate in reviews where activities are directed at the general public or patients)</td>
<td>Ms Sheila Rimmer AM (2010)</td>
</tr>
<tr>
<td></td>
<td>Mr Henry Ko</td>
</tr>
<tr>
<td></td>
<td>Ms Patricia Greenway (Alternate)</td>
</tr>
<tr>
<td></td>
<td>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>Mrs Sophie Hibburd</td>
</tr>
<tr>
<td>Medicines Australia Officer responsible for Ethical Conduct</td>
<td>Ms Deborah Monk</td>
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</tbody>
</table>

The Committee held 11 meetings in 2010-2011. As shown in Figure 3, all permanent members of the Monitoring Committee attended the scheduled meetings. Two consumer representatives participated in the reviews 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
- Mrs Sophie Hibburd, Manager Code of Conduct
- Mrs Romina Bognolo, Code Administration Officer
Communications

Medicines Australia regularly engages in communication activities to raise awareness, promote understanding of the Code and to encourage compliance. This is done in a variety of ways; including but not limited to, meetings 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). 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.

To provide Members and the Chairmen of the Code-related Committees with an insight into industry self-regulation in the UK, Medicines Australia arranged a member briefing presented by Ms Heather Simmonds, Director – Prescription Medicines Code of Practice Authority (PMCPA) on 13 December 2010. The PMCPA is responsible for administering the Association of the British Pharmaceutical Industry’s (ABPI) Code of Practice.

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 April 2011, the IFPMA convened a ‘hands on’ marketing compliance training workshop in Seoul, Korea. Ms Monk was one of the leaders in the training workshop, which was attended by 35 delegates from the Asia Pacific region. The workshop was held on the day preceding the Asia Regulatory Conference, which was jointly organised by the IFPMA, the Drug Information Association (DIA) and the APEC Harmonisation Center. Ms Monk spoke at the Regulatory Conference on ‘The latest Developments in Ethical Business Practices in Australia’. Dr Megan Kearney, Principal Medical Adviser at the TGA co-chaired the session and spoke on ethical business practices from the regulator’s perspective.

<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>8</td>
<td>307</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td>4</td>
<td>38</td>
</tr>
<tr>
<td>Other (Exhibition Stand at Conference)</td>
<td>2</td>
<td>248</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>207</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>1</td>
<td>12</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>4</td>
<td>89</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>Others (ACCC)</td>
<td></td>
<td></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>1</td>
<td>1</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Other (TGA, DoHA, Gov’t)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>34</td>
<td>963</td>
</tr>
</tbody>
</table>
Within the Australian environment, Ms Monk and Mrs Hibburd responded to many requests for guidance and advice on code provisions and interpretations. In 2010-2011 Code Secretariat staff conducted or participated in 34 events pertaining to communication about the Code, with a combined audience of 963. See Table 4 for details on these events.

Medicines Australia Code Secretariat staff provided a Code of Conduct ‘trade display’ at the General Practice Conference & Exhibition (GPCE) in Melbourne in November 2010 and in Sydney in May 2011. The GPCE meetings are attended by over 1,200 general practitioners (GPs), practice managers and practice nurses. The theme of the trade display is to promote a ‘healthy relationship’ between the industry and health professionals and to raise awareness of the Medicines Australia Code of Conduct as a standard for encouraging healthy, ethical relationships 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 6.4 of Edition 16 of the Code).

In addition to medical representatives the Medicines Australia Code of Conduct (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

CEP Enrolments in 2010-2011
Table 5 shows the number of enrolments in Semester 2, 2010 and Semester 1, 2011. Please note some candidates may be enrolled in more than one program in the semester, for example in both Programs 1 and 2.

<table>
<thead>
<tr>
<th>Program/Introduction</th>
<th>Semester 2, 2010</th>
<th>Semester 1, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program 1</td>
<td>417</td>
<td>331</td>
</tr>
<tr>
<td>Program 2</td>
<td>159</td>
<td>166</td>
</tr>
<tr>
<td>Program 3</td>
<td>176</td>
<td>140</td>
</tr>
<tr>
<td>Program 4</td>
<td>168</td>
<td>154</td>
</tr>
<tr>
<td>Program 5</td>
<td>194</td>
<td>160</td>
</tr>
<tr>
<td>Introduction to the Human Body</td>
<td>90</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>51 (RPL)</td>
<td>64 (RPL)</td>
</tr>
<tr>
<td>Code Refresher</td>
<td>248</td>
<td>312</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1503</td>
<td>1428</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, 2010 and Semester 1, 2011 are presented in Table 6.
Table 6
Summary of Student Evaluation Responses

<table>
<thead>
<tr>
<th></th>
<th>Exceeded</th>
<th>Met</th>
<th>Did not meet</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student Kit (Student and Program Notes)</td>
<td>17.3%</td>
<td>78.5%</td>
<td>4.2%</td>
<td>0%</td>
</tr>
<tr>
<td>UQ Facilitator</td>
<td>16.2%</td>
<td>70.3%</td>
<td>1.5%</td>
<td>12.0%</td>
</tr>
<tr>
<td>On-line learning modules and activities</td>
<td>20.0%</td>
<td>73.5%</td>
<td>4.4%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Student support services</td>
<td>12.6%</td>
<td>55.1%</td>
<td>1%</td>
<td>31.3%</td>
</tr>
<tr>
<td>Assessment process</td>
<td>13.7%</td>
<td>81.8%</td>
<td>4.5%</td>
<td>0%</td>
</tr>
<tr>
<td>Overall, how did you rate the experience</td>
<td>20.0%</td>
<td>76.4%</td>
<td>3.6%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Medicines Australia is pleased with the overall satisfaction ratings (exceeded/met expectations) of 96.4%.

CEP Awards

The CEP Awards for 2010 (students enrolled between January and December 2010) were presented at an Awards Dinner in April 2010. Guest Speaker Dr Andrew Pesce, President of the Australian Medical Association 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.

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.

In his address in presenting the UQ Active Learning Prizes Dr Harry Parekh 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.
UQ Health Insitu Awards were presented by Dr Harry Parekh to:

Mr Colin Clarke
AstraZeneca
Semester 1, 2010

Ms Deborah Motta-Marques
Allergan Australia
Semester 2, 2010

On behalf of Medicines Australia, Board member Mr Bruce Goodwin joined with Dr Andrew Pesce to present the Medicines Australia Code of Conduct Award and the CEP Achievement Awards. Mr Goodwin commended the Australian pharmaceutical industry’s commitment to training and supporting our highly skilled and dedicated Medical Representatives.

The Medicines Australia Continuing Education Program has been in existence for over thirty-eight years. It started in 1973 with the Medical Representatives Education Program, or MedREP. In that first year 48 candidates sat for the inaugural exams. In 1997 the new Continuing Education Program, or CEP, commenced, first at Monash University and later at Deakin University. Since 2006, the program has been administered by the University of Queensland.

Mr Goodwin spoke about the value of Medical Representatives, who are ambassadors for the industry, providing valuable service to health professionals. It is essential that Representatives are well trained in both their company’s products as well as the environment in which they work and the ethical standards expected of the industry, which is achieved through the Continuing Education program.

**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:

Mr Paul Wilson
Janssen receiving his award from
Dr Andrew Pesce and Janssen Managing
Director Mr Bruce Goodwin

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 by Mr Bruce Goodwin (left) on behalf of Medicines Australia and Dr Andrew Pesce (right) to:

Amy Beamish
Astra Zeneca

Colin Clarke
AstraZeneca

Catherine Spencer
AMGEN Australia

Mr Paul Wilson
Janssen receiving his award from
Dr Andrew Pesce and Janssen Managing
Director Mr Bruce Goodwin
CEP Achievement Award recipients not present at the awards dinner:

- Mr Matthew Lisle – Novo Nordisk
- Ms Pearl-Li Chong – Merck Sharp & Dohme

*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.*
Code Guidelines Update

Guidelines Working Group

After the Code of Conduct Guidelines had been in operation for 12 months, Medicines Australia commenced a review of the Guidelines. The Guidelines Working Group were once again engaged to assist in updating the Guidelines.

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 in the Guidelines; for example, use of social media.

Greater detail on provisions relating to Social Media and Educational Event responsibilities are among provisions requiring clarification. At time of reporting, version two of the Guidelines for Edition 16 of the Code are still in production, with expected release in late July 2011.

Guidelines Working Group Members

- Ms Marlene Arens – Merck, Sharp & Dohme (Australia)
- Mr Alistair Barkhouse – Gilead Sciences
- Mr Antony Beard – Eli Lilly Australia
- Dr Steevie Chan – Janssen
- Ms Deborah Drummond – AstraZeneca
- Mr Aaron Guttmann – Roche Products
- Ms Petra Klaunzer – AstraZeneca
- Ms Maria McManus – Roche Products
- Ms Shane McSpedden – Pfizer Australia
- Dr Mathieu Miehe – Novartis Pharmaceuticals
- Dr Shaun O’Mara – Novo Nordisk Pharmaceuticals
- Mr Andrew Roberts – Boehringer Ingelheim
- Mr Gavin Walsh – Princeton Publishing
- Mrs Sophie Hibburt – Medicines Australia
- Ms Deborah Monk – Medicines Australia

Medicines Australia would like to thank the members of the Guidelines Working Group for their continued 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
Educational Event Reporting

Medicines Australia is pleased to report a continued 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 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 7 provides a summary of the number of educational meetings reported in each of the eight 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>Jan – Jun 2008 (Report 2)</td>
<td>15,836</td>
<td></td>
</tr>
<tr>
<td>Jan- Jun 2009 (Report 4)</td>
<td>16,020</td>
<td></td>
</tr>
<tr>
<td>Jan – Mar 2010 (Report 6)</td>
<td>5,857</td>
<td></td>
</tr>
<tr>
<td>Note: 3 month report only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>October – March 2011 (Report 8)</td>
<td>13,873</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>117,949</td>
<td>36</td>
</tr>
</tbody>
</table>

Member Company educational event reports can be found on the Medicines Australia website at http://medicinesaustralia.com.au/code-of-conduct/education-events-reports/member-company-reports/
Complaints Process

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.


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.

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 2010-2011, 14 new complaints were received by Medicines Australia. As shown in Table 8, the majority of complaints were submitted by Pharmaceutical Companies (6 complaints = 42%) and 28% (4 complaints) submitted by healthcare professionals. Table 8 provides details on the source of all new complaints received in 2010-2011.

<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>4</td>
</tr>
<tr>
<td>• Hospital physicians/pharmacists</td>
<td></td>
</tr>
<tr>
<td>• Specialists</td>
<td></td>
</tr>
<tr>
<td>Organisations</td>
<td></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></td>
</tr>
<tr>
<td>• Member of the general public</td>
<td>2</td>
</tr>
<tr>
<td>• Academic</td>
<td></td>
</tr>
<tr>
<td>Monitoring Committee</td>
<td>2</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td></td>
</tr>
<tr>
<td>• Member Company</td>
<td>6</td>
</tr>
<tr>
<td>• Non-Member Company</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>14</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 carried over from 2009-2010

Thirteen complaints were carried over from 2009-2010 – these are complaints received in 2009-2010 but were not finalised before 30 June 2010. The decisions with respect to ten complaints found all or some aspects of the allegations to be in breach of the Code. In three of the complaints, none of the aspects of the allegations were found to be in breach. Figure 4 provides details of the final decisions of the Code and Appeals Committees with respect to the thirteen complaints carried over from 2009-2010. Links to the reasons for the decisions for the complaints carried over from 2009-2010 can be found on pages 35-38.
**Complaints received in 2010-2011**

Of the 14 new complaints received in 2010-2011, 11 complaints were considered and finalised by the end of the financial year. The 3 complaints received and not finalised or considered by the Code and/or Appeals Committees in 2010-2011 were withdrawn by the complainants.

As shown in Figure 5, 7 of the 11 new complaints finalised in 2010-2011 were found not in breach of the Code and 4 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 35-38.
**Appeals**

In 2010-2011, 28% of complaints considered by the Code Committee were appealed. Figure 6 shows the outcomes of the 4 appeals held in 2010-2011. This includes two appeals from complaints carried over from 2009-2010 and two appeals from complaints lodged in 2010-2011.

![Figure 6 - Outcomes of 2010/2011 Appeals](image)

**Sanctions**

Sanctions may be imposed on a company where breaches of the Code have been established. Under the provisions of Edition 16, 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 on companies by the Code and Appeals Committees for the ten complaints carried over from 2009-2010 where all or some of the allegations were found in breach of the Code and the four complaints received and finalised in 2010-2011 where all or some of the allegations were found in breach of the Code.

![Figure 7 - Sanctions imposed by the Code & Appeals Committees on companies found in breach of the Code](image)
**Monetary fines**

Figure 8 shows the financial penalties imposed on companies found in breach of the Code. The majority of the fines imposed were under $75,000, with one fine in the $75,000 - $99,999 bracket and two fines in the $150,000 - $200,000 bracket.

**Figure 8**

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

- Complaints received in 2009-2010 & finalised in 2010-2011
- Complaints received & finalised in 2010-2011

<table>
<thead>
<tr>
<th>Fines Range</th>
<th>2009-2010</th>
<th>2010-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0 - $24,999</td>
<td>5</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>1</td>
<td>2</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>2</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 2010-2011 was 28 working days. This time was reduced where the complaint was not subject to appeal to 22 working days. The shortest time to resolve a complaint remained at 16 working days.

The average time to resolve a complaint in 2010-2011 was considerably less than 2009-2010 where the average time was 41 working days.
Figure 9
Length of time to resolve all finalised complaints
- Complaints received in 2009-2010 & finalised in 2010-2011
- Complaints received & finalised in 2010-2011

Code provisions subject to complaint
Figure 10 provides a snapshot of the alleged and actual breaches by section of the Code for complaints carried over from 2009-2010 and those received and finalised in 2010-2011.

Figure 10
Number of alleged and actual breaches of the Code for complaints received in 2009-2010 and finalised in 2010-2011
- Number of alleged breaches of the Code
- Breach
- No breach

Figure 11 provides a snapshot of the alleged and actual breaches by section of the Code for complaints received and finalised in 2010-2011.
**Definitions**

The definitions in this list apply only to terms used in this Annual Report. A more extensive glossary of terms is included in Edition 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 specialists 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.
Complaint determinations

This section of the Code of Conduct Annual Report provides the decisions and reasons for decisions of all complaints considered by the Code Committee and finalised in 2010-2011. Table 9 provides a summary of each complaint finalised in 2010-2011. To view the detailed reasons for the decision please click on the complaint number in column 1.

Complaints received and finalised in 2010-2011 were all considered under Edition 16 of the Code. There were 4 complaints (relating to media releases) received in 2009-2010 and finalised in 2010-2011 which were considered under Edition 15 of the Code, the relevant Code at the time the media releases were issued. The complaints that were considered under Edition 15 of the Code are so identified in Table 9.

This section includes 4 complaints relating to media releases, 3 complaints relating to disease education activities or materials and 1 complaint relating to an educational event that were referred to the Code Committee by the Monitoring Committee following its reviews of these activities in 2009-2010. This section also includes two complaints relating to an advertisement and promotional material referred by the Monitoring Committee following its reviews in 2010-2011.

Complaints that were withdrawn are not included in Table 9 as they were not considered by the Code Committee.

### Table 9

<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>1045</td>
<td>Bayer Australia</td>
<td>Advertising campaign to the general public</td>
<td>N/A</td>
<td>Member of the general public</td>
<td>No breach of 9.4 and 9.10</td>
<td>Breach of 9.5.1 and 9.5.6 Edition 15</td>
</tr>
<tr>
<td>1047</td>
<td>Schering Plough Pty Ltd (subsidiary company of Merck &amp; Co Inc, known in Australia as Merck Sharp &amp; Dohme Australia Pty Ltd [MSD])</td>
<td>Printed Promotional Material</td>
<td>Simponi</td>
<td>Roche Products</td>
<td>Breach of Sections 1.2 and 1.3. No breach of section 1.5.</td>
<td>Send a corrective letter to all rheumatologists in Australia and publish a corrective advertisement in Rheumatology Update and any other publication which included an advertisement in which the claim found in breach was used. Pay a fine of $50,000</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>
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</tr>
<tr>
<td>1048</td>
<td>Novartis Australia</td>
<td>Television advertising campaign to general public</td>
<td>Lucentis</td>
<td>Healthcare Professional</td>
<td>No Breach of the Code</td>
<td>* Not Applicable</td>
</tr>
<tr>
<td>1049</td>
<td>AstraZeneca Media Release</td>
<td>Nexium</td>
<td>Monitoring Committee</td>
<td>Edition 15: Breach 9.2 No breach 9.10</td>
<td>* Do not distribute the media release again in the same or similar form * Pay a fine of $75,000</td>
<td></td>
</tr>
<tr>
<td>1050</td>
<td>Janssen-Cilag Media Release</td>
<td>Concerta</td>
<td>Monitoring Committee</td>
<td>Edition 15: Breach 9.2 No breach 9.10</td>
<td>* Do not distribute the media release again * Pay a fine of $15,000</td>
<td></td>
</tr>
<tr>
<td>1051</td>
<td>Roche Products Media Release</td>
<td>MabThera</td>
<td>Monitoring Committee</td>
<td>Edition 15: Breach 9.2.1 Breach 9.2.3 No breach 9.10</td>
<td>* Pay a fine of $30,000</td>
<td></td>
</tr>
<tr>
<td>1052</td>
<td>Sanofi-aventis Media Release</td>
<td>Actonel</td>
<td>Monitoring Committee</td>
<td>Edition 15: Breach 9.2 No breach 9.10</td>
<td>* Do not distribute the media release again * Pay a fine of $20,000</td>
<td></td>
</tr>
<tr>
<td>1053</td>
<td>Roche Products Financial support for medical practice activities</td>
<td>Pegasys</td>
<td>Healthcare Professional</td>
<td>Breach 9.10 Breach 9.11</td>
<td>* Pay a fine of $200,000</td>
<td></td>
</tr>
<tr>
<td>1054</td>
<td>Alcon Laboratories Australia Disease education booklet</td>
<td>N/A</td>
<td>Monitoring Committee</td>
<td>No breach 12.7.2 Breach 12.7.5 No breach 16</td>
<td>* Withdraw the Glaucoma Information booklet and not use it again in the same or similar form * Pay a fine of $5,000</td>
<td></td>
</tr>
<tr>
<td>1055</td>
<td>Roche Products * Printed promotional material * Website * Dosing Card</td>
<td>Mircera Amgen Australia Posters Breach 1.1, 1.2, 1.3, 1.5 Website Breach 1.1, 1.2, 1.3, 1.5, 1.7</td>
<td>Monitoring Committee</td>
<td>Posters Breach 1.1, 1.2, 1.3, 1.5 Website Breach 1.1, 1.2, 1.3, 1.5, 1.7</td>
<td>* Cease use of all materials and website * Pay a fine of $200,000 * Send a corrective letter to all</td>
<td></td>
</tr>
</tbody>
</table>
### Table 9
Complaints finalised in 2010-2011

<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>1056</td>
<td>Novartis Australia</td>
<td>DVD</td>
<td>Clozaril Monitoring Committee</td>
<td>No breach 9.13, Breach 1.1, 1.2, 1.3, 1.5</td>
<td>* Not applicable</td>
<td></td>
</tr>
<tr>
<td>1057</td>
<td>Roche Products</td>
<td>Website</td>
<td>Pegasys RBV Monitoring Committee</td>
<td>No breach 1.3, No breach 12.7, No breach 12.7.4</td>
<td>* Not applicable</td>
<td></td>
</tr>
<tr>
<td>1058</td>
<td>AstraZeneca</td>
<td>Educational Event N/A Monitoring Committee</td>
<td>Breach 9.3, Breach 9.4.3, No breach 9.13</td>
<td>* Pay a fine of $15,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1059</td>
<td>Roche Products</td>
<td>Patient Access Program</td>
<td>Pegasys RBV Merck Sharp &amp; Dohme</td>
<td>No breach 8, No breach 9.12, No breach 9.13</td>
<td>* Not applicable</td>
<td></td>
</tr>
<tr>
<td>1060</td>
<td>Boehringer Ingelheim</td>
<td>Printed promotional material</td>
<td>Spiriva GlaxoSmithKline</td>
<td>No breach 1.3</td>
<td>* Not applicable</td>
<td></td>
</tr>
<tr>
<td>1061</td>
<td>Pfizer</td>
<td>Advertisement</td>
<td>Lipitor Dr Ken Harvey</td>
<td>Breach of 1.3, No breach of 9.13</td>
<td>* Cease publication of the advertisements, Pay a fine of $20,000.</td>
<td></td>
</tr>
<tr>
<td>1062</td>
<td>MSD</td>
<td>Unsolicited email breach of privacy regulations and used to advertise rather than educate</td>
<td>Maxalt Healthcare professional</td>
<td>No Breach of 2.1.3, 2.4.4 and 9.1</td>
<td>* Not applicable</td>
<td></td>
</tr>
<tr>
<td>1065</td>
<td>MSD</td>
<td>Relationship with General Public</td>
<td>Diprosone Member of the General Public</td>
<td>No breach of 9.13 and 12.1</td>
<td>* Not applicable</td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Subject Company</td>
<td>Material or information subject to complaint</td>
<td>Product</td>
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</tr>
<tr>
<td>1066</td>
<td>Sanofi Pasteur</td>
<td>Promotional material</td>
<td>Adacel and Acel Range of Vaccines</td>
<td>GSK</td>
<td>Breach of 1.1, 1.2.2, 1.3 and 1.5</td>
<td>* Pay a fine of $50,000</td>
</tr>
<tr>
<td>1068</td>
<td>Bayer Australia</td>
<td>Promotional material</td>
<td>Testogel and Reandron 1000</td>
<td>Monitoring Committee</td>
<td>No breach of Section 1.3 or 1.7</td>
<td>* Not applicable</td>
</tr>
<tr>
<td>1069</td>
<td>Roche Products</td>
<td>Advertisement</td>
<td>N/A</td>
<td>Health care Professional</td>
<td>No breach of 1.1, 1.3, 12.6, 12.7, 12.7, 12.8 and 18</td>
<td>* Not applicable</td>
</tr>
<tr>
<td>1070</td>
<td>Merck Serono Australia</td>
<td>News item</td>
<td>Movectro</td>
<td>Member of the General Public</td>
<td>Breach of 12.5, No breach of 12.1, 12.3, 12.6, 12.7 and 18</td>
<td>* Pay a fine $20,000</td>
</tr>
<tr>
<td>1071</td>
<td>Ipsen</td>
<td>Advertisement</td>
<td>Somatuline Autogel</td>
<td>Monitoring Committee</td>
<td>No breach of 1.2, 1.2.2 and 1.3</td>
<td>* N/A</td>
</tr>
<tr>
<td>1072</td>
<td>Novartis Australia</td>
<td>Advertising Campaign</td>
<td>Exforge and Exforge HCT</td>
<td>MSD</td>
<td>Breach of 1.1, 1.3 and 1.5. No breach of 1.7</td>
<td>* Cease using claim * Pay a fine $50,000</td>
</tr>
</tbody>
</table>
Testosterone – 1045

Subject Company: Bayer Australia (Bayer)

Complainant: Member of the general public

Product: N/A

Complaint
The complainant alleged that the advertisement was advertising a prescription medicine for a serious condition to the general public. The complainant also stated that the symptoms described in the advertisement could be the result of many other things including normal ageing. The image in the advertisement was dark and menacing and may raise undue concern for consumers, especially in association with the final dramatic statement in large capitals stating “Low testosterone can take the life out of you”.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 15 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
Bayer disagreed that the patient education advertisement was promoting a prescription product to the general public. There is no mention of any product in the advertisement and Bayer’s testosterone replacement therapy is among 11 formulations available in Australia. The information fulfils the requirements of Sections 9.4 and 9.5 of the Code as it is raising awareness of a condition. Bayer denied that the advertisement would reduce confidence in the industry.

Code and Appeals Committee determinations
In a unanimous decision the Code Committee found no breach of Sections 9.4 and 9.10 of the Code (decisions confirmed by the Appeals Committee). In a majority decision the Code Committee found a breach of Sections 9.5.1 and 9.5.6 of the Code.

Sanction
- Pay a fine of $10,000 (sanctions not considered by the Appeals Committee)

Consideration of the complaint by the Code Committee
The Committee noted that the advertisement had been published in August 2009 and had previously been referred to another complaints panel and the TGA prior to being forwarded to Medicines Australia by the TGA in March 2010.

The Committee discussed the incidence of low testosterone in the community and whether it is a major health issue. Members noted that the incidence is between 1 and 3 percent and is age dependent. Some members were of the view that if the advertisement encouraged men to visit their general practitioner (GP) it may offer the GP an opportunity to talk to the patient about a range of health issues. Many patients presenting to the GP may have health and lifestyle issues which could contribute to a lack of vitality or tiredness other than a low testosterone level. Members were of the view that the advertisement created an over emphasis on testing when this may not be required.

The Committee noted that the advertisement did not refer to a specific prescription medicine or type of treatment solution but encouraged a reader to see their doctor for review and a testosterone test if required. In a unanimous decision the Committee did not find a breach of Section 9.4 of the Code as the advertisement did not encourage a member of the public to seek a prescription for a particular prescription medicine.

Some members were of the view that the advertisement was not balanced as it implied that low testosterone was the most prevalent cause of the symptoms described in the advertisement and that there is a high incidence of low testosterone whereas this is not an accurate reflection of the incidence across all ages. In a majority decision the
Committee found a breach of Section 9.5.1 of the Code.

Section 9.5.6 of the Code states that the tone of a patient education message must not unnecessarily cause alarm or misunderstanding in the community. The Committee considered that the tone of the advertisement and imagery was alarmist, particularly in consideration of the relatively low incidence of the condition. Members considered that the tone was unnecessarily dramatic. In a majority decision the Committee found that the advertisement was in breach of Section 9.5.6 of the Code as the incidence of the condition doesn’t warrant this level of alarm. While a minority of members were of the view that the advertisement was relatively innocuous, these members agreed that it would have been more informative to put the condition into a more balanced context.

The Committee was unanimous in its view that the advertisement was not of such a nature that it would bring the industry into disrepute and found no breach of Section 9.10 of the Code.

**Appeal**

The complainant lodged an appeal against the finding that the advertisement does not breach Section 9.4 of the Code. The complainant also recommended that the Committee reconsider the finding that there had been no breach of Section 9.10 of the Code. The complainant provided a detailed explanation of the provisions of the Therapeutic Goods Act 1989 and argued that the advertisement did not comply with those provisions or with the Code of Conduct.

**Response to the appeal**

Bayer Australia denied that it had breached Section 9.4 of the Code. It argued that the advertisement was intended only to encourage men to see their doctor if they have any of the identified symptoms and did not make any reference to the possibility of treatment with a prescription-only medicine. Bayer Australia denied that it had breached Section 9.10 of the Code, but also argued that any appeal with respect to Section 9.10 of the Code had not been properly made in the timeframe required by the Code.

**Consideration of the Appeal**

Prior to the Bayer and complainant’s representatives joining the meeting the Appeals Committee considered the procedural issues that had been raised with respect to the appeal. The appeal by the complainant is clearly in relation to the finding there was no breach of Section 9.4 of the Code. The complainant also states in the appeal submission that she considers the advertisement was misleading, but it is not open to the Appeals Committee to consider this, because a breach of Section 1.3 False or Misleading Claims was not examined by the Code of Conduct Committee. However, the advertisement was found in breach of Section 9.5.1 of the Code because it was not sufficiently balanced.

In an email of 25 June 2010 to Medicines Australia, following her review of Bayer Australia’s response to the appeal, the complainant stated that she recommends that the Committee reconsider its decision to find no breach of Section 9.10 of the Code. Bayer Australia, in its response to Medicines Australia regarding this further email communication, stated that it considers that the only matter before the Appeals Committee should be an appeal concerning the finding of no breach of Section 9.4 because the appeal submission clearly stated that the appeal concerns Section 9.4 and no appeal was made with respect to Section 9.10 of the Code. The Appeals Committee agreed that the only matter of appeal that it should consider was with respect to the finding of no breach of Section 9.4 of the Code.

The Appeals Committee noted that the complainant had addressed the appeal to a wide range of individuals and organisations, including the ACCC and two Members of Parliament. The appeal submission raised questions about the adequacy of the regulation of advertising prescription medicines to the general public and asserted that the Bayer advertisement contravened the
Therapeutic Goods Act 1989 and Trade Practices Act 1974. However, it is not the remit of the Appeals Committee to consider breaches of Commonwealth legislation. The Committee is strictly confined to determining whether the Code of Conduct Committee had erred in its findings, and in this instance its finding that the Bayer Australia advertisement about low testosterone levels did not breach Section 9.4 of the Code.

It was noted that the Code of Conduct and Appeals Committee had made previous decisions in other complaints with respect to Section 9.4 of the Code. It has been generally held that if there was no reference to a specific medicine or therapeutic good in an advertisement concerning disease awareness it would not offend Section 9.4 of the Code.

The primary question for the Appeals Committee concerns whether the Bayer Australia advertisement is encouraging a member of the public to seek a prescription for a specific prescription-only medicine.

The complainant, her representative and the Bayer Australia representatives joined the meeting.

The Chairman clarified for the complainant and Bayer Australia representatives, that in relation to the appeal letter of 15 June 2010 which raised a number of issues about government regulation of advertising of therapeutic goods, the Appeals Committee and Code of Conduct Committee only have jurisdiction to consider matters under the provenance of the Code of Conduct. Further the Committee considers that the appeal arises only in relation to Section 9.4 of the Code. Whilst there was reference to other provisions of the Code, including that the advertisement was misleading, these issues were not considered by the Code Committee and therefore cannot be considered by the Appeals Committee. Regarding Section 9.10 of the Code, this matter was considered by the Code Committee and no breach was found. Because this decision was not appealed in the appeal letter it would not provide procedural fairness to Bayer if the Appeals Committee now reviewed that decision. The Appeals Committee will therefore only consider whether the Code Committee had erred in finding no breach of Section 9.4 of the Code.

The following summarises the appeal presentation by the complainant.

- The complainant is primarily concerned with having the law upheld. Section 9.4 of the Code prohibits any activity directed to the general public which encourages a patient to seek a prescription for a specific prescription-only medicine. The complainant considers that the Bayer advertisement does encourage a consumer to seek a prescription for a prescription-only medicine.

- Overall the advertisement is an encouragement to seek a prescription for testosterone. The advertisement encourages a reader to think that declining testosterone is a significant problem in older men, and lists symptoms of low testosterone levels. It encourages people to self-diagnose. It explicitly states that there is a simple and practical solution. The advertisement states the generic name of a particular prescription medicine. It is implied that testosterone is the solution to the problem. It encourages a person to see their doctor for a check up or to visit the website.

- Bayer has argued that the advertisement doesn’t encourage a patient to seek a prescription for a specific prescription medicine. There are twelve products that contain testosterone and Bayer supplies 5 of these. Testosterone is the name of a specific prescription-only ‘medicine’. The Code (Section 9.4) does not refer to a prescription-only ‘product’.

- The encouragement to seek a prescription for a prescription-only medicine does not have to be explicit to breach the Code. The definition of promotion in the Code refers to ‘any statement’ made by a company for the purpose of encouraging use of that product.
Elements that support the argument that the advertisement is promotional rather than educational include:

- Some readers will have gone to their doctor and asked for testosterone
- Readers expect glossy advertisements to be selling something – this looks like it is selling something; it has Bayer’s name on it and Bayer is known to sell medicines.
- The name of the medicine testosterone is in the largest lettering on the page.
- A global website concerning body building, which includes a sub-site for Australians, includes a reader’s comment that he interpreted the advertisement as promoting a particular product, testosterone.

Bayer claims the advertisement is educational and not promotional; the complainant questioned whether this was likely to be Bayer’s sole interest because:

- Bayer is not known primarily as a provider of education.
- If the advertisement was genuinely educational, it would not have been produced in the form it was. The advertisement lacked information. For example there was no information distinguishing between low testosterone as a cause for the symptoms mentioned and other causes; there was no information on lifestyle interventions to help manage the symptoms; the imagery inspired anxiety and confusion.
- A reader is unlikely to be more knowledgeable after reading the advertisement but is more likely to think that his symptoms were due to low testosterone.
- Is there a real need for this type of educational message?

The complainant suggested that the advertisement could encourage illegal drug seeking behaviour for performance enhancing use and cited a 2005 study in Sydney in which 23 percent of performance and image enhancing drug users were men over 40.

The complainant stated that testosterone is over prescribed in older men. Overprescribing of testosterone exposes men to potential adverse consequences of testosterone. The complainant referred to a study published in the New England Journal of Medicine in the last 2 weeks which described the cessation of a trial in older men prescribed testosterone because there was an increase in the rate of cardiovascular events in the testosterone treated group compared with the placebo group.

Bayer sells testosterone products and stood to gain from the advertisement. It could reasonably have expected that the advertisement would increase prescriptions for testosterone. The intent of the advertisement was promotion and not education.

The complainant questioned whether the omission of a brand name, the inclusion of a direction to see your doctor and an assertion that an advertisement is educational is sufficient to meet the requirements of the Code. The most probable purpose of the advertisement was to encourage readers to seek a prescription for testosterone.

The complainant added that the advertisement is one type of consumer advertising described by the US FDA – disease awareness advertisements that are unbranded but are part of a campaign to increase sales. The complainant stated that there is harm to public health from this type of marketing activity.

The complainant questioned the validity of encouraging men to have their testosterone levels tested. Testosterone naturally declines with age. If testosterone levels are being compared with normal levels derived from younger men, this does not signify that low testosterone levels in older men is a medical condition.

The Bayer representatives then presented the response to the appeal, which is summarised as follows:
- Section 9.4 of the Code prohibits the promotion of a ‘specific’ prescription-only medicine to the general public and requires that any information provided to the general public must be educational. The print advertisement did not mention the brand name of any specific prescription-only medicine; it did not include any product branding; it did not include any reference directly or indirectly to a specific prescription medicine.
- Testosterone is the name of the hormone. There are eleven products supplied by 4 companies that contain testosterone; the products are different formulations and dosage forms. Bayer does not market the product with the highest market share by volume.
- The information in the advertisement is essentially similar to fact sheets published by Andrology Australia and published literature. Bayer referred to relevant parts of the facts sheets. There are no claims included in the advertisement.
- Low testosterone levels is a relevant public health issue. It is relevant in elderly men, with an incidence of 10 percent in men over 60 years of age. 43 percent of men with type 2 diabetes have low testosterone. There is higher mortality in men with low testosterone.
- The target group for the advertisement is recommended to go and get a health check. There are many other reasons for these older men to have their health reviewed by a GP which go beyond testosterone deficiency. The symptoms could be due to another medical condition.
- The advertisement does not breach Section 9.4 of the Code – it is educational and does not mention a specific prescription-only medicine. Bayer referred to other examples of disease education activities in the general media that are not promoting prescription medicines to the general public.

A member of the Committee questioned Bayer’s statement that it is not the market leader in testosterone products. Bayer responded that the highest volume product is Sustanon, which is not Bayer’s product. All of Bayer’s testosterone products together might exceed Sustanon sales by value.

A member of the Committee questioned Bayer’s statement that low testosterone is a public health issue and that there is a higher mortality associated with low testosterone. The member noted that testosterone levels naturally decline with age and there is not a cause and effect relationship between low testosterone and mortality.

The Committee discussed with the complainant and Bayer representatives the interpretation of Section 9.4 of the Code and its reference to ‘a specific prescription-only medicine’. Bayer argued that the advertisement did not promote a specific prescription product – the health professional will decide which product and dose form to prescribe. The complainant argued that a doctor can prescribe using the active ingredient name and the pharmacist will select which brand or product. A Committee member noted that the advertisement, as required by the Code, is branded with Bayer Australia which could signify a specific product.

In answer to a question about whether the advertisement had an educational purpose, considering that the commonest cause of death in males is cardiovascular disease or prostate cancer and not low testosterone, Bayer responded that Andrology Australia also sees a reason to raise awareness of the condition; the advertisement encourages men to get a checkup, for which there is a positive health benefit. A member of the Committee disputed that non-specific health promotion had any public health benefit.

Following this discussion the complainant made her closing comments:
- The complainant disputed some statistics used by Bayer, stating that Bayer had overstated the incidence of testosterone deficiency in Australia and was trying to
leave an impression that was not supported by the evidence.

- The definition of promotion encompasses whether the purpose, actual effect or likely effect is to encourage a member of the public to seek a prescription for a prescription-only medicine.
- The Committee should find that Bayer had advertised a prescription-only medicine to the general public.

The Chairman invited the parties to consider that if the proposed interpretation of a ‘specific prescription-only medicine’ in Section 9.4 of the Code was that it prohibits disease awareness communications if there are a number of different products for the condition where the active ingredient is the same, but permitted disease awareness communications as long as there are products with different active ingredients to treat a medical condition, this would impose a prohibition that is arbitrary.

The Committee also noted that provisions of the Code cannot be taken in isolation. Section 9.5 of the Code explicitly permits education of the general public about medical conditions and the treatments that may be prescribed by their doctors. The educational material must encourage patients to seek further information or explanation from their healthcare practitioner.

The Chairman thanked the complainant and her representative and the Bayer representatives for their presentations. The two parties left the meeting to allow the Committee to consider its decision.

The Committee discussed the interpretation of ‘a specific prescription-only medicine’ in Section 9.4. Whilst there may be legitimate concerns by members about whether low testosterone levels in older men is a public health issue, or encouraging men to see their doctor and have their testosterone level tested is a waste of public resources, these issues are not relevant to whether the advertisement encourages a patient to seek a prescription for a specific prescription-only medicine.

Members noted that the advertisement did not state that a patient can have testosterone replacement as a treatment.

Previous decisions of the Code of Conduct and Appeals Committees have held that as long as there is more than one medicine available to treat a condition, disease awareness advertising is permitted if it does not refer to a specific product by brand or active ingredient name. A majority of members considered that the use of the word ‘testosterone’ in the advertisement was referring to the human hormone, which is generally known and familiar to the public, and was not referring to a specific prescription-only medicine or product. A minority of members considered that the advertisement was referring to both the hormone and to the generic prescription-only medicine testosterone and by encouraging men to see their doctor for a testosterone test was encouraging a patient to seek a prescription for a specific prescription-only medicine.

The complaint before the Appeals Committee threw a new light on how the prohibition on promoting prescription-only medicines to the general public might be interpreted where there is more than one product available to treat a condition but the active ingredient is the same (or very similar) in the different products; also where an active ingredient name has alternative meaning to describe the condition the medicine is used treat such as a hormone.

The Committee concluded in a majority decision not to uphold the appeal and to confirm the Code Committee’s decision not to find the advertisement in breach of Section 9.4 of the Code. However, the Committee advised that the complaint had raised interpretive and practical issues that warrant a review and clarification of the prohibition as it is expressed in Section 9.4, noting that the prohibition is intended to mirror the therapeutic goods legislation prohibition.
against advertising prescription medicines to consumers.

It was noted that whilst no breach of Section 9.4 of the Code had been found, the advertisement was found in breach of Sections 9.5.1 and 9.5.6 of the Code and must be withdrawn and no longer used in its present form.

Sanction
Having confirmed the Code of Conduct Committee’s determination that there was no breach of Section 9.4, there was no need for the Appeals Committee to Review the sanctions imposed.

Simoni – 1047

Subject Company: Schering-Plough Pty Limited (a subsidiary of Merck & Co Inc, known in Australia as Merck Sharp & Dohme Australia Pty Ltd [MSD])

Complainant: Roche Products Pty Ltd

Product: Simponi

Complaint
The complainant alleged that Simponi promotional material for health care professionals was misleading. It was alleged that the claim ‘patient-friendly anti-TNF’ had not been adequately substantiated, was false and misleading, and implied some special merit that could not be related to a clinical outcome or be adequately substantiated.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 1.2 Substantiating data
- 1.3 False and misleading claims
- 1.5 Unqualified superlatives

Response
Merck Sharp & Dohme (MSD) responded that the claim was not false or misleading, and could be substantiated by reference to the ease of administration attributes described in the Product Information, Consumer Medicine Information and patient instruction leaflet. MSD also denied that the claim implied special merit for the product. MSD asserted that the claim was not comparative with other products and did not imply superiority over other products or features.

Code Committee decision
- In a unanimous decision a breach of Section 1.2 of the Code
- In a unanimous decision a breach of Section 1.3 of the Code
- In a majority decision no breach of section 1.5 of the Code

Sanction
- Send a corrective letter to all rheumatologists in Australia and publish a corrective advertisement in Rheumatology Update and any other publication which included an advertisement in which the claim found in breach was used.
- Pay a fine of $50,000.

Consideration of the complaint
The Committee considered MSD’s response to the complaint, which asserted that the claim ‘patient-friendly’ was based on the administration device for the anti-TNF medicine, that this product is administered once a month, was easy to administer, and had a low sting formulation when injected. The Committee noted that of the series of three advertisements in which the claim appears, two do not refer to the delivery device. Members did not consider that it could be reasonably inferred from the advertisements that the claim of ‘patient-friendly anti-TNF’ was referring to the delivery device or the frequency of injections and not to the medicine itself. Members considered that a reader would infer from the claim that it referred to the medicine, Simponi, and not the delivery device or dosing regimen. The Committee referred to the Product Information for Simponi and noted that the side effects from Simponi were similar to that of other anti-TNF medicines. It was noted that some side effects from this medicine are very
serious, like other anti-TNF medicines, and therefore it was considered inappropriate to claim that this medicine was ‘patient-friendly’. Members considered that the claim could suggest to a prescriber that Simponi had some advantages for patients, which could not be substantiated. The Committee considered that there was no evidence to support the claim that Simponi was a ‘patient-friendly’ anti-TNF medicine. Members considered that the claim lacked specificity about what was ‘patient-friendly’ about Simponi, which could be easily misinterpreted and was therefore misleading.

The Committee considered the assertion by MSD that the ‘patient-friendly’ claim related to the ease-of-use delivery system and the low sting formulation. Members reviewed the references provided to support the claim. Members did not accept that the ‘Ease-of-use’ commendation from the US Arthritis Foundation in relation to other medication delivery systems was relevant to the Simponi pre-filled syringe or Smart-ject autoinjector. In relation to the low sting upon injection with Simponi, the Committee could not identify any evidence to support this assertion. Whilst the Simponi Product Information included information on the rate of injection site reactions, the Committee did not agree that this was adequate substantiation for the claim of ‘patient-friendly anti-TNF’. In addition, the Committee reiterated that it did not agree that the claim was specific to the delivery mechanism.

The Committee determined that the claim ‘patient-friendly’ anti-TNF was misleading and could not be substantiated. Within the advertisements and as a tagline the claim is not specific to its delivery device or frequency of administration. In unanimous decisions the Committee determined that the claim was in breach of Sections 1.2 and 1.3 of the Code.

Some members of the Committee considered that the claim was implying that Simponi has some special merit which could not be substantiated. However, a majority of members considered that the claim was not implying that other anti-TNF products are not patient-friendly, or that Simponi will provide a better clinical outcome. In a majority decision no breach of Section 1.5 of the Code was found.

Sanction
The Committee determined that the breaches found were moderate, having no safety implications for patients but which may have an effect on how the medical professional will prescribe the product.

The Code Committee determined that MSD should:
- Send a corrective letter to all rheumatologists in Australia
- Publish a corrective advertisement in Rheumatology Update and any other publication which included an advertisement for Simponi in which the claim found in breach was used. The corrective action must be completed in accordance with Section 24.2 of the Code.
- Pay a fine of $50,000.

Lucentis – 1048

Subject Company: Novartis Australia
Complainant: Healthcare professional
Product: Lucentis

Complaint
The complainant alleged that Novartis is promoting the prescription medicine Lucentis in a television advertising campaign to the general public through the Macular Degeneration Foundation. The complainant also alleged that the education campaign is misleading by exaggerating the incidence of age related macular degeneration (ARMD) and suggesting that early detection of ARMD can change the clinical outcome.
Sections of the Code
Website page alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.2 Substantiating data
- 1.3 False and misleading claims
- 9.4 (in particular 9.4.1, 9.4.2, 9.4.3, 9.4.4, 9.4.5) Company educational events in Australia
- 12.1 Relationship with the General Public - General principles
- 12.3 Promotion to the general public
- 12.5 General media articles
- 12.6 Educational information to the general public
- 12.7 Disease education activities in any media
- 18 Discredit to and reduction of confidence in the industry

Response
Novartis responded that the current marketing campaign for Lucentis and Visudyne is compliant with the Medicines Australia Code, consistent with the approved Product Information and the body of evidence and denied that the awareness campaign was misleading or lacked balance. Novartis further denied that it was promoting a prescription medicine to the general public. It also asserted that the literature supports that early detection of ARMD can improve the treatment outcome.

Code Committee decision
In a unanimous decision no breach of any section of the Code was found.

Consideration of the complaint
Prior to considering the complaint the Committee viewed the television advertisement that was the subject of the complaint. The advertisement did not refer to any prescription medicine treatment for macular degeneration; it was a call to action for people to have an eye test, including a check of the macula; it emphasised that early detection was important; it advised seeking further information from the Macular Degeneration Foundation. Novartis was identified as the supporter of the advertisement.

The Committee considered one of the main arguments from the complainant – the prevalence of macular degeneration in people aged 50 years or more is low and the necessity for early detection had been overstated. Members noted the Clinical Evidence review by Arnold and Heriot published in the British Medical Journal in 2006, which stated that “Sight-threatening (late) age related macular degeneration (AMD) occurs in 2% of people aged over 50 years in industrialised countries, with prevalence increasing with age”. An editorial by R H Guymmer published in the Medical Journal of Australia on 19 March 2007 stated that around 15% of Australians over 50 years of age have some signs of AMD and between 1 and 2 percent of people in this age group lose significant vision as a result of AMD. In light of this evidence, the Committee did not agree with the complainant’s argument that it was misleading to draw attention to macular degeneration in people over 50 years. The Committee considered that there was good clinical evidence to substantiate that people over 50 are at some risk of AMD, and the risk increases with age.

The Committee did not consider that the television advertisement was misleading or promoting unnecessary concern or alarm in the community. It was appropriate to recommend to consumers to have an eye test, have their macular checked and to seek further information from the Macular Degeneration Foundation. The advertisement advised consumers to seek advice from their healthcare professional who can evaluate whether any intervention is required. There was no content in the advertisement which would encourage a member of the public to seek a prescription for Lucentis or any other prescription medicine.

The Committee considered the complainant’s assertion that Novartis had sponsored an educational talk in Newcastle about macular degeneration that was sensationalist and alarmist. The Committee considered that it was not inappropriate to provide an educational talk for doctors about AMD in light of the evidence of its prevalence. The
complainant had also alleged that Novartis had provided inappropriate travel and hospitality to doctors who adopted use of Visudyne. The Committee considered that there was no evidence of the conduct alleged by the complainant.

In a unanimous decision the Committee determined that there was no breach of the Code in relation to any conduct alleged by the complainant. Novartis was not engaged in promoting a prescription medicine to consumers. Its support of a disease awareness television advertisement published by the Macular Degeneration Foundation was compliant with the Code.

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AstraZeneca Media Release – 1049

Subject Company: AstraZeneca

Complainant: Monitoring Committee

Product: Nexium

Complaint

The Monitoring Committee was of the view that the AstraZeneca media release relating to Nexium was promoting the product to the general public and that the indications for Nexium stated in the media release were not fully consistent with the newly approved indications.

Sections of the Code

Media release alleged to be in breach of the following Sections of Edition 15 of the Code:

- 9.2 Product Specific Media Statements
- 10.8 Discredit to and reduction of confidence in the Industry

Response

AstraZeneca strongly disagreed that the Media Release was promotional or linked Nexium with the reduction of GI risks from aspirin. AstraZeneca’s intention for the media release was educational — to announce the new indication for Nexium for the prevention of gastric/duodenal ulcer re-bleeding and to inform the public of the known risks associated with the prolonged use of low dose aspirin. AstraZeneca also argued that the messages that were picked up by the media could not be construed as bringing discredit to the industry.

Code Committee decision

- By a unanimous decision, breach of Section 9.2
- By a majority decision, no breach of Section 9.10

Sanction

- Do not distribute the media release again in the same or similar form to that found in breach of the Code
- Pay a fine of $75,000

Consideration of the complaint

The Committee noted that the media release was issued following TGA approval of a new indication for the intravenous (IV) and tablet forms of Nexium to be used following therapeutic gastroscopy for acute, bleeding gastric or duodenal ulcers to prevent re-bleeding. In this indication the oral form of Nexium would follow IV treatment. However, the media release on 9 November 2009 focussed on the use of proton pump inhibitors (PPI) to reduce the risk of peptic ulcers in patients taking low dose aspirin, which is not a new indication for Nexium.

The Committee agreed with the Monitoring Committee that the media release was promoting a prescription-only medicine to the general public. The media release referred to the use of PPIs to reduce the risk of peptic ulcers in people taking aspirin and specifically identified Nexium as a PPI. The media release encouraged consumers to talk to their doctor about minimising the risk of peptic ulcers if they are taking aspirin, and the included reference to Nexium made a link to a specific PPI, which may have the effect of encouraging members of the public to seek a prescription for Nexium if they are taking aspirin. The Committee considered that AstraZeneca had used the opportunity of the approval of a new indication for Nexium oral and IV to promote a different use of their product – for the
prevention of peptic ulcers in people taking non-steroidal anti-inflammatory medicines, such as aspirin.

The Committee reviewed the new approved indication for Nexium oral and IV and agreed with the Monitoring Committee that the new approved indication had not been adequately communicated in the body of the media release. The media release stated that Nexium was approved for use in adults with a peptic ulcer to prevent re-bleeding whereas the actual indication for prevention of re-bleeding is only following therapeutic endoscopy. The Committee considered that this was an important qualification of the indication which had not been accurately reflected in the media release. Whilst the Minimum Product Information for Nexium oral and Nexium IV had been attached to the media release, the indication should have been fully and accurately stated in the body of the release. The Committee did not accept AstraZeneca’s explanation that the indication had been abbreviated to avoid formal or technical terms. The Committee considered that the media release gave a misleading impression of the approved use of Nexium.

The Committee unanimously determined that the AstraZeneca media release was not accurate or balanced and included statements that could be considered to be promotion of a prescription-only medicine to the general public. In a unanimous decision a breach of Section 9.2.1 was found.

The Committee discussed whether the media release would bring the industry into disrepute. In a majority decision the Committee determined that no breach of Section 9.10 should be found.

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

Sanction
The Committee noted that the media release was an activity that had been concluded. The Committee determined that AstraZeneca should:

- Not distribute the media release again in the same or similar form to that found in breach of the Code
- Pay a fine of $75,000

Janssen-Cilag Media Release – 1050

Subject Company: Janssen-Cilag

Complainant: Monitoring Committee

Product: Concerta

Complaint
The Monitoring Committee was of the view that by issuing two product specific media releases to the general public about the PBS availability of Concerta, on 1 October and 18 December 2009, Janssen Cilag was potentially in breach of Section 9.2 of the Medicines Australia Code of Conduct.

Sections of the Code
Media Releases alleged to be in breach of the following Sections of Edition 15 of the Code:
- 9.2 Product Specific Media Statements
- 9.10 Discredit to and reduction of confidence in the Industry

Response
Janssen-Cilag responded that it had not breached the Code and that the information contained within the media release was appropriate, non-promotional and educational in tone and substance. The first media release was issued on the day of the Asian tsunami, and all media engagement was therefore halted. The second media release in December was issued following Janssen-Cilag’s analysis that there was a very small risk of the general public hearing the same message twice. It was in the public interest to be informed of the PBS listing changes for Concerta.

Sanction
The Committee noted that the media release was an activity that had been concluded. The Committee determined that AstraZeneca should:
Code Committee decision
 By a unanimous decision, breach of Section 9.2
 By a unanimous decision, no breach of Section 9.10

Sanction
 Do not distribute the media release again
 Pay a fine of $15,000

Consideration of the complaint
The Committee noted that two media releases had been issued by Janssen-Cilag – one on 1 October 2009 and the second on 18 December 2009. Whilst the content of the two releases differed, each refers to the PBS listing of Concerta for adults with ADHD from 1 October 2009. Janssen-Cilag’s response acknowledged that the two media releases were part of the one attempt to inform the public of the PBS reimbursement of Concerta.

Section 9.2.1 of the Code permits the publication of a media release to announce to the public the availability of a new product or major indication approval. This announcement occurred with the publication of the media release on 1 October 2009. Section 9.2.2 of the Code states that no other media releases relating to a specific medicine are permitted.

The Committee considered Janssen-Cilag’s response that it had halted media engagement following the release of the media release on 1 October when it became aware of the Samoan tsunami tragedy. The Committee did not accept that the cessation of further media engagement in October was adequate justification for issuing a second media release two and a half months later.

The Committee noted that the first media release had received some media coverage, primarily in regional NSW and Queensland and on Sydney radio and in the West Australian. The Committee considered that the limited coverage of the first media release did not justify the publication of the second release.

The Committee unanimously determined that the publication of a second media release regarding the PBS listing of Concerta was a breach of Section 9.2 of the Code. The Committee unanimously determined that the conduct would not bring the industry into disrepute and was not in breach of Section 9.10 of the Code.

Sanction
The Committee considered that this was a minor breach of the Code. The limited media coverage was taken into consideration and was a mitigating factor in determining the sanction. The Committee determined that Janssen-Cilag should:
 Not distribute the media release again
 Pay a fine of $15,000

Roche Media Release – 1051

Subject Company: Roche Products
Complainant: Monitoring Committee
Product: MabThera

Complaint
The Monitoring Committee considered that some statements included in the Media Alert and Media Release issued by Roche on 8 September 2009 were false and misleading. These statements were the use of ‘new hope’ in the Media Release “New hope for people with most common form of adult leukaemia”, which the Monitoring Committee considered created a false impression of the likelihood of achieving a cure, and statements that the use of MabThera in combination with chemotherapy extended time in remission compared with chemotherapy alone.

The Monitoring Committee also considered that a number of statements in the Media Release were promotional and may encourage a patient with CLL to seek treatment with MabThera.

The Monitoring Committee considered that the Media Alert and Media Release were in
breach of Sections 9.2.1 and 9.2.3 of the Code and may bring discredit to the industry and was therefore in breach of Section 9.10.

Sections of the Code
Material was alleged to be in breach of the following Sections of Edition 15 of the Code:
- 9.2 Product Specific Media Releases
- 9.10 Discredit to and reduction of confidence in the Industry

Response
Roche did not agree that the Media Alert and Media Release (released on 8 September 2009) were promotional or that it is likely that the average audience would be prompted by it to seek a prescription for MabThera. Roche contended that the Media Alert and Media Release documents should not be read in isolation, but rather form part of the same package of material.

Roche argued that the statements identified by the Monitoring Committee were taken out of context by reading the two documents in isolation, and therefore the statements could not be regarded as being promotional.

Roche denied that the use of the word “hope” is misleading as “hope” did not refer to cure but an extended remission time. Additionally “hope” is commonly used when reporting on advances in the treatment of cancer.

Code Committee decision
- In a majority decision a breach of Sections 9.2.1 and 9.2.3 of the Code
- In a majority decision no breach of Section 9.10 of the Code

Sanction
- In a majority decision, pay a fine of $30,000.

Consideration of the complaint
The Committee discussed whether the words ‘new hope’ would be understood by members of the general public to mean MabThera would provide a cure for CLL. Some members of the Committee considered that the term would have its generally understood meaning – that there was another treatment option that offered some chance of successful treatment, which was a factual statement. Other members considered that the words would be read as making a stronger claim about the chance of being cured. By majority decision, the Committee accepted that the statement ‘new hope’ did not imply that patients with CLL would be cured with MabThera and it was found not to be in breach of the Code.

The Committee considered the statement that ‘MabThera in combination with chemotherapy prolongs the time patients battling CLL remain in remission compared to chemotherapy alone’. The Committee accepted that the statement was consistent with the clinical evidence, which was also included in the approved Product Information. The Committee therefore concluded that the statement was not false or misleading. Whilst the statement was not false or misleading, the Committee considered that the statement was promotional because it would encourage patients to seek treatment with MabThera in addition to chemotherapy. The statement was found to be in breach of Section 9.2.1. This statement was also included in the Media Alert which accompanied the Media Release. The Media Alert was therefore found to be in breach of Section 9.2.3 of the Code.

In relation to the statement ‘The hundreds of Australians living with this often life-threatening disease can now be offered a treatment proven to prolong time in remission’, the Committee accepted that this statement was also consistent with the clinical evidence and the approved Product Information. The Committee concluded that the statement was not false or misleading.

The Committee considered the four statements in the Media Release which the Monitoring Committee had considered were promotional:
- The hundreds of Australians living with this often life-threatening disease can now be offered a treatment proven to prolong time in remission
- MabThera allows previously untreated patients with CLL to live symptom free for...
longer, helping them to rebuild their lives and start looking to the future.

• **MabThera presents a long-awaited advance in CLL management and a significant step forward for people battling this deadly disease.**

• **We have seen how MabThera has greatly improved the treatment of other blood cancers, and through what we have seen by participating in these important clinical studies, we are confident it will achieve similar benefits for patients with CLL.**

The Code Committee agreed that the statements were promotional because they conveyed the positive attributes and benefits of MabThera treatment and may encourage patients with CLL to seek treatment with this medicine. The Committee did not accept Roche’s arguments that these statements were taken out of context by the Monitoring Committee. In context the statements remain promotional. The Committee was also concerned that the fourth statement (above) implied that the efficacy of MabThera in CLL will be equal to its efficacy in blood cancers such as non-Hodgkin’s lymphoma, whereas there was no evidence to support this. The Committee determined by a majority decision that the Media Information was promotional and in breach of Section 9.2.1 of the Code.

The Committee determined that there was no evidence that the Media Release or Media Alert had brought discredit to the industry. No breach of Section 9.10 of the Code was found.

**Sanction**

The Committee determined in a majority decision that the breach was moderate to minor and determined that Roche should:

- Pay a fine of $30,000.

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**Sanofi-aventis Media Release – 1052**

**Subject Company:** Sanofi-aventis

**Complainant:** Monitoring Committee

**Product:** Actonel

**Complaint**

The Monitoring Committee was of the view that the sanofi-aventis media release for Actonel dated 21 July 2009 was promotional when considered under the definition of promotion in the Code. The Monitoring Committee considered that whilst comparisons made in the media release were between sanofi-aventis’ products, statements in the media release could encourage a member of the public to seek a prescription for a specific prescription-only product which was in breach of Section 9.2 of the Code.

**Sections of the Code**

Material alleged to be in breach of the following Sections of Edition 15 of the Code:

- 9.2 Product Specific Media Statements
- 9.10 Discredit to and reduction of confidence in the Industry

**Response**

Sanofi-aventis did not agree that the media release was promotional or that it is likely that the average audience would be prompted by it to seek a prescription for Actonel. Rather sanofi-aventis believe it would prompt a reader to ask their doctor if they are at risk of osteoporosis.

Sanofi-aventis disagreed that the statements in the media release have the potential to bring discredit to the industry because the statements are accurate and provide useful information about an under-diagnosed and under-treated condition.

**Code Committee decision**

- By a unanimous decision, breach of Section 9.2
- By a majority decision, no breach of Section 9.10
Sanction
- Do not distribute the media release again
- Pay a fine of $20,000

Consideration of the complaint
The Committee considered that the media release issued on 21 July 2009 included a number of statements that would be regarded as promotional under the definition of promotion in the Code. The Committee regarded the statements such as ‘first once-a-month osteoporosis treatment now on PBS’, ‘a simpler and more convenient dosing regimen’, ‘a once a month treatment on the PBS, that is as well tolerated and just as effective as its daily counterpart’ and ‘the advantage of a once a month treatment ... rather than 52 tablets per year for a weekly treatment or 365 tablets per year for a daily treatment’ as clearly promotional.

The Committee considered that the content of the media release may encourage a member of the general public to seek a prescription for the specific ‘monthly’ Actonel Once-a-Month prescription-only medicine. In a unanimous decision the Committee determined that the media release was in breach of Section 9.2 of the Code.

The Committee also noted that the media release did not include information about the product’s precautions, adverse reactions, contraindications or interactions, as is required under Section 9.2.1 of the Code, however this was not raised by the Monitoring Committee as part of the complaint and was therefore only noted to provide feedback to sanofi-aventis. It was subsequently brought to the attention of the Committee that the media release did in fact contain the required safety information. However due to a photocopying error it had appeared, from the materials before the Committee, that the release did not include such information. The Committee was pleased that such information was in fact included as required, but noted that the absence of the information was not taken into account in its original decision.

The Committee determined by a majority decision that the conduct would not bring the industry into disrepute and was not in breach of Section 9.10 of the Code.

Sanction
The Committee unanimously determined that sanofi-aventis should:
- Not distribute the media release again
- Pay a fine of $20,000

Pegasys – 1053

Subject Company: Roche Products Pty Ltd
Complainant: Health Care Professional
Product: Pegasys

Complaint
The complainant alleged that Roche Products Pty Ltd has provided a financial benefit to an Area Health Service (AHS) in return for achieving a certain number of patients prescribed Pegasys.

Sections of the Code
Conduct alleged to be in breach of the following Sections of Edition 16 of the Code:
- 9.10 Company supported medical practice activities
- 9.11 Grants and financial support

Response
Roche provided an initial response (dated 25 June) and a further response (dated 5 July) following its own internal investigation of the alleged conduct. Roche stated that it had not provided, nor has it agreed to provide, a financial benefit to the AHS in return for individuals in the AHS being treated with Pegasys or with ribavirin in combination therapy. Such an agreement would be contrary to Roche’s SOP for the award of grants, scholarships and donations to healthcare providers and patient organisations.
Roche initiated an internal investigation of the alleged conduct, which found that there had been discussions between Roche employees and the AHS in relation to Roche providing funds to support a nursing position at the AHS. A proposal had been put to AHS in a manner which was capable of being construed as being contingent upon the level of sales of Pegasys RBV to AHS. Roche had advised that when the employees realised that the proposal could be construed in a way that was contrary to the Code, it was withdrawn. Roche submitted that because the offer was withdrawn there was no breach of the Code.

The Code of Conduct Committee reviewed this complaint at the 19 July 2010 meeting, and requested further information from Roche before further consideration and determination. The further information was received on 6 August 2010 and provided an unsigned copy of the letter sent to AHS as well as a spreadsheet listing all financial transactions Roche has had with the AHS in 2009-10.

**Code Committee decision**

By majority decision the Committee found that the offer breached Sections 9.10 and 9.11 of Edition 16 of the Code of Conduct.

**Sanction**

- In a unanimous decision, pay a fine of $200,000

**Consideration of the complaint**

The Committee considered the letter of offer made to the AHS, which Roche had stated had been withdrawn before the agreement was signed. The letter clearly made an offer of funding to the AHS that was contingent on the number of patients treated with Pegasys, with a sliding scale of increased funding for more patients treated.

It was noted that Sections 9.10 and 9.11 of the Code state that “Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional’s professional practice”. Therefore a breach may be found for an offer being made, even if it was subsequently withdrawn and not implemented.

The Committee noted that it had no evidence that the offer had not been implemented, although Roche had clearly stated that it had been withdrawn prior to implementation. Whilst the offer may not have been implemented, the complainant was of the understanding that it had been implemented, and he claims that other staff at the AHS have a similar understanding.

The Committee concluded that the fact that the offer was made was sufficient to find a breach of the Code. The Committee unanimously determined that the offer as outlined in the letter sent to AHS was in breach of section 9.10 and 9.11 of the Code as the offer contained conditions that would interfere with the independence of a healthcare professional’s professional practice.

The Committee noted that the complainant had not raised a complaint in respect of Section 9.13, Discredit to and Reduction of Confidence in the Industry. The Committee considered that the conduct may have been found in breach of this Section had it been raised in the complaint, but natural justice prevented the Committee making any finding in relation to this Section.

**Sanction**

The Committee unanimously determined that the breach found was severe and that Roche should:

- Not make any similar offer to a healthcare professional organisation or institution
- Pay a fine of $200,000
Subject Company: Alcon Laboratories Australia
Complainant: Monitoring Committee
Product: N/A

Complaint
The Monitoring Committee considered that certain text in the Glaucoma Information booklet was potentially making a claim and a comparison between different products for the treatment of glaucoma.

The Monitoring Committee noted that Section 12.7.2 of the Code allows that a disease education activity may make reference to the availability of different treatment options, but this information should not be of such a nature that an individual would be encouraged to seek a prescription for a prescription-only product. Further, the Monitoring Committee noted Section 12.7.5 of the Code requires that management options should be presented in a comprehensive, balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment. The Committee considered that the identified passage of text was not consistent with these requirements.

If the booklet was to be regarded as a patient aid, the Monitoring Committee did not consider that the booklet was compliant with Section 16 which requires that patient aids must not make comparisons between products or include promotional claims.

Sections of the Code
Material was alleged to be in breach of the following Sections of Edition 16 of the Code:
- 12.7.2 Disease education activities in any media
- 12.7.5 Disease education activities in any media
- 16 Materials for use with patients (patient aids)

Response
Alcon in its response contended:
- that the relevant section of the booklet does not refer to any specific product and no product claims are made.
- The statements about new treatments should be considered in the context of the whole booklet, where different treatment options are discussed, both pharmacological and surgical.
- The first line treatment option is prostaglandin eye drops in the majority of patients.
- No direct comparisons between different products or product specific promotional claims were made.

Notwithstanding its disagreement that the booklet had breached the Code, Alcon had advised that the section on new treatments will be deleted from the booklet and Alcon has ceased supplying the booklet and all current stock has been destroyed.

Code Committee decision
- In a majority decision no breach of Section 12.7.2 of the Code
- In a majority decision a breach of Section 12.7.5 of the Code
- In a unanimous decision no breach of section 16 of the Code

Sanction
- Withdraw the Glaucoma Information booklet and not use it again in the same or similar form.
- Pay a fine of $5,000.

Consideration of the complaint
The Committee noted Alcon’s advice that the booklet was made available to doctors and ophthalmologists for them to give to patients with glaucoma. A patient does not need to be prescribed a particular medicine to receive the booklet.

Page 10 of the booklet, under the heading ‘New treatments for Glaucoma’ refers to ‘a powerful class of drugs (prostaglandins)’, being able to ‘manage glaucoma more effectively’ and that ‘these newer drops ... used just once a day ...easier for people to
remember to use them’. The Committee noted that there are a number of eye drops available which contain prostaglandin, supplied by Alcon and other companies. The booklet did not refer to a product by brand name; it only referred to the class of medicines.

The Committee considered whether the booklet would encourage a person to seek a prescription for a prescription-only product. A minority of members of the Committee considered that the statements on page 10 (identified above) would encourage a person to seek a prescription for prostaglandin eye drops for their glaucoma. These members thought that because there are other classes of eye drop available to treat glaucoma, members of the public with glaucoma would be encouraged to ask for prostaglandin eye drops. The majority of members of the Committee considered that the statements referring to new treatments for glaucoma should be considered in light of the entire contents of the booklet, which referred generally to the management of glaucoma with eye drops. These members did not consider that the text on page 10 of the booklet encouraged a member of the public to seek a prescription for a prescription-only medicine. These members considered that the reference to prostaglandin eye drops was sufficiently general and it was understood that most people newly diagnosed with glaucoma will be prescribed a prostaglandin eye drop.

In a majority decision, no breach of Section 12.7.2 of the Code was found.

In relation to Section 12.7.5 of the Code, a majority of members considered that the booklet was not balanced. These members considered that the booklet unduly emphasised treatment with prostaglandin eye drops and did not mention other treatment options such as other classes of eye drop. Surgical management of glaucoma was also inadequately covered. Members considered that whilst the booklet emphasised one treatment approach, this was not sufficient to encourage a member of the public to seek a prescription for a prescription-only product. In a majority decision a breach of section 12.7.5 of the Code was found.

The Committee noted that Alcon had withdrawn the booklet from distribution.

Sanction
The Committee determined that the breach found was minor, having no safety implications for patients and no effect on how the medical professional would prescribe any product.

The Code Committee determined that Alcon Laboratories should:
- Withdraw the Glaucoma Information booklet and not use it again in the same or similar form.
- Pay a fine of $5,000

Mircera – 1055
Subject Company: Roche Products
Complainant: Amgen Australia
Product: Mircera

Complaint
Amgen alleged several breaches of the Code in relation to the promotion of Mircera in:
- A poster presentation at the Home Therapies Conference in Brisbane
- A website promoting Mircera to health professionals
- A Mircera dosing card

Amgen considered that the promotional claims were misleading, inadequately qualified, used unqualified superlatives and
implied superiority over other products. Amgen also alleged that the claims were not fully consistent with the Mircera approved Product Information. Amgen also alleged that the website was of such poor scientific quality that it was in breach of Sections 1.3 and 9.13 of the Code.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 1.1 Responsibility
- 1.2 Substantiating data
- 1.3 False or misleading claims
- 1.5 Unqualified superlatives
- 1.7 Comparative statements
- 9.13 Discredit to and reduction of confidence in the industry

Response
Roche responded that there were a number of procedural issues with the complaint. It had responded to the complaint in relation to the claims made in the poster for which there had been intercompany dialogue. However, Roche stated that intercompany dialogue for complaints relating to the website and dosing card had not been completed and it argued that the Code Committee should not consider these complaints.

Roche denied that it had breached the Code in relation to the Mircera materials. It considers that the information presented in the Mircera promotional materials was current, accurate, balanced and not misleading. Roche considers that Amgen has sought to imply into Roche’s statements about Mircera meaning which are not present or implied by those statement and a reasonable healthcare professional would not read such meaning into the statements.

Code and Appeals Committee determinations

Posters at Home Therapies Conference
- By a unanimous decision, breach of Section 1.1
- By a unanimous decision, breach of Section 1.2
- By a unanimous decision, breach of Section 1.3

Website (various pages as described in the complaint)
- By a unanimous decision, breach of Section 1.1
- By a unanimous decision, breach of Section 1.2
- By a unanimous decision, breach of Section 1.3
- By a unanimous decision, breach of Section 1.5
- By a unanimous decision, breach of Section 1.7
- By a majority decision, no breach of Section 9.13

Dosing card (‘a new way of working’ claim and unique receptor interaction claim/qualifier, which also appeared on the website and poster)
- By a unanimous decision, breach of Section 1.1
- By a unanimous decision, breach of Section 1.2
- By a unanimous decision, breach of Section 1.3
- By a unanimous decision, breach of Section 1.5

Sanction
- Cease use of all materials and website found in breach of the Code
- Pay a fine of $200,000
- Send a corrective letter to all healthcare professionals with a password to the website
- Place the corrective letter on the website page thereby informing visitors that the website has been found in breach of the Code and has been taken down.

Consideration of the complaint by the Code Committee
The Committee discussed which of the materials subject to complaint should be considered by the Committee. In its response Roche had submitted that there had been no intercompany dialogue with respect to the dosing card, and that the intercompany dialogue had not been completed with respect to the website. The Committee

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reviewed the discourse between the two companies and the various claims subject to complaint.

The Committee concluded that the claims subject to complaint on the dosing card are the same as those on the poster from the Home Therapies Conference, concerning the ‘continuous stimulation of erythropoiesis’ claim and ‘unique receptor interaction’ claim, and that these had been discussed through intercompany dialogue on the poster. The Committee therefore determined it was appropriate to consider the complaints about the dosing card.

With regard to the website, the Committee noted that there had been an exchange of letters between Amgen and Roche concerning detailed alleged breaches of the Code with respect to a number of claims on different pages of the website. Roche had undertaken to make some changes to the website, but not on every issue raised by Amgen. Roche had undertaken to make the proposed changes within 10 working days, but this had taken longer than that time. The Committee accepted that Amgen was entitled to expect that the issues should have been resolved within the required time frame, but they had not been. The Committee therefore determined that it was appropriate for it to consider the complaints concerning the ‘nephrology.com.au’ website.

The Committee determined to consider the complaint by reviewing each issue in the letter of complaint from Amgen dated 24 June 2010.

A. ‘It’s about time an ESA could be home delivered with once monthly convenience’ (Poster at the Home Therapies Conference)

The Committee considered whether the claim could imply that Mircera was the first erythropoiesis stimulating agent (ESA) available with monthly dosing. The Committee did not agree that the claim would only be interpreted to refer to the ‘home delivery’ service; it agreed that the claim may also be interpreted to imply that Mircera was the first ESA with a monthly dosing schedule. The Committee considered that the claim was ambiguous and may mislead a prescriber to think that Mircera was the only ESA that can be administered once a month, which is not correct.

In a unanimous decision the Committee determined that the claim was misleading and in breach of Section 1.3 of the Code.

B. ‘first continuous stimulating agent’ (Poster at the Home Therapies Conference and website)

The claims relating to Mircera being the ‘first continuous stimulating agent’ also appeared on the nephrology.com.au website. The claim on the Poster implied that Mircera is the first ESA with this property through the qualifying statement and the claim ‘A new way of working’ on the Mircera Dosing Card in which the medicine is described as having a unique receptor interaction.

The Committee noted that the term Continuous Erythropoietin Receptor Activator or CERA was coined by Roche and was not a widely accepted or used term in the scientific literature. The Australian Approved Name for the active ingredient is methoxy polyethylene glycol-epoetin beta. The term CERA does not appear in the Product Information for Mircera. Nor does it appear in the European regulatory documentation. The Committee noted that Mircera has a longer half life than other ESA products, but this does not have any implications for clinical outcomes for patients and there is no evidence of better efficacy from Mircera.

The Committee considered that the claim that Mircera can ‘mimic the body’s natural process of continuous stimulation’ was misleading. The Committee agreed with the complainant that it was not correct that because of its long half life of 6 days Mircera results in continuous stimulation of erythropoiesis. There was no evidence to support the claims of ‘continuous stimulation’. It was noted that Mircera can be dosed at two-weekly intervals in the initiation phase and at monthly intervals once the desired haemoglobin level
is reached. This further supports the contention that the effect of Mircera is not continuous.

The Committee considered that the claim that Mircera has a ‘unique’ receptor interaction could not be substantiated. It was noted that the Product Information describes Mircera having a slower association to the receptor and faster dissociation from the receptor which may contribute to its slower elimination and longer half-life, but there is no evidence to support the assertion of a unique receptor interaction. Further, there is no evidence to demonstrate that this interaction with the receptor has any relevance to clinical outcome.

The Committee unanimously concluded that the claims that Mircera is the first continuous stimulating agent, mimics the body’s natural process of continuous stimulation, and has a unique receptor interaction that leads to continuous stimulation of erythropoiesis were misleading, could not be substantiated, and were not accurate or correct or consistent with the approved Product Information. The claims were found in breach of Sections 1.1, 1.2 and 1.3 of the Code. The claim of ‘unique receptor interaction’ was found to be in breach of Section 1.5 of the Code.

C. ‘A new way of working’

The claim ‘a new way of working’ was a tagline associated with the product name and appeared on the Posters at the Home Therapies Conference, the website and the Dosing Card. It was qualified with the statement relating to the ‘unique receptor interaction’, which was referenced to studies by Jarsch et al and Saueressig et al.

The Committee noted that the study by Jarsch et al compared the receptor binding properties of Mircera with epoetin β; there had been no comparison with or examination of the receptor binding property of epoetin alfa or darbepoetin alfa. The study by Saueressig et al was an observational study of personnel time associated with anaemia treatment using ESAs. This study did not include Mircera, and therefore did not directly measure the personnel time associated with anaemia treatment using Mircera. The Committee therefore considered it was misleading to claim that Mircera had a ‘new way of working’ or ‘unique receptor interaction’. The Committee unanimously determined that the claim was in breach of Section 1.3 of the Code. The Committee also considered that the claim of ‘unique’ in the qualifying statement was in breach of Section 1.5 of the Code for the reasons already discussed. The Committee noted that a breach of Section 1.5 of the Code in relation to the ‘new way of working’ claim had not been raised in intercompany dialogue and therefore the Committee determined to make no finding in relation to this alleged breach.

D. Comparisons between Aranesp and Mircera (‘nephrology.com.au’ website)

D.1 ‘Less overshoots with Mircera during correction (compared to darbepoetin alfa)’

The Committee considered whether the claim of ‘less overshoots with Mircera during correction’ which was referenced to the Macdougall et al (2008) study was in breach of the Code. The Macdougall study compared Mircera to darbepoetin alfa treatment in ESA-naïve patients. The study consisted of an 18-week correction period (weeks 1 to 18) for dosage titration followed by an evaluation phase (weeks 19 to 28).

The Committee was of the view that Roche had selectively presented the overshoot data to portray a greater difference between the two treatments by referring only to the 8-week timepoint data, and should have presented the data for the entire 18-week correction period. Furthermore, the graphical representation of the change to haemoglobin (Hb) levels on the website page is not an accurate depiction of Figure 5 in the Macdougall study publication, with the Y axis in the graph on the website starting at 100 (ie mean Hb 10), whereas in the paper the Y axis begins at 7, and the length of the X axis is different (6 months on the website graph vs 7 months in the study figure). Starting the Y axis at 100, and increasing the axis intervals by 10
fold visually increases the apparent difference between the two treatment lines. In addition, the confidence intervals which appear on the graph in the study publication are absent from the graph on the website, which, if they had been included, indicate no statistical difference between treatment groups.

The Committee determined that the claim was not accurate or balanced, was misleading and made an unfair comparison with darbepoetin alfa. The Committee unanimously found the claim in breach of Sections 1.1, 1.3 and 1.7 of the Code.

D.2 ‘65% less overshoot than darbepoetin alfa’

This claim also related to the Macdougall et al study and was a graphical representation of the overshoot data. For the same reasons as stated above (i.e. that the 65 percent represents the difference at one timepoint only), the Committee unanimously found the graph was misleading and made an unfair comparison with darbepoetin and was in breach of Sections 1.3 and 1.7 of the Code.

D.3 ‘Fewer dose changes with Mircera’

The Committee considered that there was insufficient information presented in the abstract of the Mann et al paper to adequately assess the validity of the claim. It was noted that in the pooled data from four Phase III studies in patients on dialysis, the comparator to Mircera was either darbepoetin or epoetin at the prescribed dose and administration interval, but it was not specified which drug was used. The Committee unanimously found that the claim was in breach of Section 1.2 of the Code because the data to substantiate the claim was a poster presentation.

The Committee considered that the web page and graph made an unfair comparison between Mircera and other ESA medicines. This was a selective analysis of studies in dialysis patients presented in a manner that gave the impression it was applicable to all renal patients treated with an ESA (i.e. whether treated by dialysis or not). Darbepoetin can be administered at weekly, two-weekly or monthly intervals, but the poster presentation does not distinguish between different doses of darbepoetin or epoetin, simply pooling all doses together. The Committee agreed with the complainant that this was an unfair comparison.

The Committee unanimously determined that the claim and graphical representation on the web page were in breach of Sections 1.1, 1.3 and 1.7 of the Code. The Committee further considered that the claim ‘less dose hunting’ implied some special merit that could not be adequately substantiated and no relevance to clinical outcome had been demonstrated. The Committee unanimously found that the claim was in breach of Section 1.5 of the Code.

D.4 ‘Injections per year with Mircera vs short-acting ESAs’;

As noted in the Committee’s discussion of the ‘Fewer dose changes with Mircera’ claim, the ESA darbepoetin can be administered once a month in certain (non-dialysis) patients. The web page and graphical representation only refers to once weekly injections of darbepoetin as a comparison with once monthly Mircera. Further, as Roche had conceded in intercompany dialogue, there is no qualification of the claim on this web page that Mircera is only dosed once a month in the maintenance phase and is given more frequently in the titration phase of treatment. The Committee therefore concluded that the claim that Mircera required fewer injections per year was misleading and made an unsubstantiated and unfair comparison with darbepoetin and epoetin. The Committee unanimously found that the claim was in breach of Sections 1.3 and 1.7 of the Code.

D.5 ‘14% of subjects rated sc darbepoetin alfa injections as ‘very painful’”

The claim was based on a study by Pannier et al, which was an acceptable, although small, study. However the Committee considered that the data from the study had been misrepresented by Roche in the claim. Roche
had selected just one aspect of the study – the number of subjects who had rated the pain immediately following subcutaneous injection as ‘very painful’ – and had simplistically represented this as a percentage of the total number of subjects, with a p-value, which could not be identified from the statistical analyses presented in the study report. By selecting the subset of patients who reported ‘very painful’ immediately following the injection Roche had presented more negative view of the outcome than the overall results of the study would suggest. The Committee considered that the claim was misleading by omission, was not representative of the body of evidence and made an unfair comparison.

The Committee unanimously determined that the claim was in breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code.

D.6 ‘Conversion to Mircera saves time – compared to darbepoetin alfa or epoetin’

The Committee considered whether the claim of ‘conversion to Mircera saves time – compared to darbepoetin alfa or epoetin’ was too definitive. The discussion in the paper used more general terms such as ‘suggests’ and ‘may be possible’.

The Committee concluded that the claim that conversion to Mircera saves time was unbalanced, could not be adequately substantiated, was misleading and made an unfair comparison with darbepoetin and epoetin. The Committee unanimously concluded that the claim was in breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code.

E. ‘Simplifying anaemia’

The Committee considered whether the umbrella claim of ‘simplifying anaemia’, which appeared on a number of the web pages that the Committee had found in breach of the Code but also on pages where no breach had been alleged, should be found in breach of the Code. The Committee noted that Roche had agreed to amend the website. The Committee concluded that given that it had found various claims and pages of the website in breach of the Code under separate complaints for the reasons stated for those complaints, there was no case to find the claim ‘simplifying anaemia’ in breach of the Code as it related to pages and claims on the website that had not been found in breach.

No breach of Section 1.1, 1.2, 1.3, 1.5 or 1.7 of the Code was found.

F. Roche website – breach of Section 1.3 and 9.13

The Committee discussed whether the website overall was in breach of Section 9.13 of the Code. The Committee considered that the website had demonstrated inadequate attention to detail which suggested insufficient care had been taken in its design paper, but had not been accurately presented – the (modelled) results for Mircera in the study were 6.5 and 6.7 which were represented on the web page as 7 and the data for the other ESAs had also been rounded. No error bars for the data had been included on the graph.

The Committee considered that the claim that ‘conversion to Mircera saves time’ was too definitive. The discussion in the paper used more general terms such as ‘suggests’ and ‘may be possible’.

The Committee concluded that the claim that conversion to Mircera saves time was unbalanced, could not be adequately substantiated, was misleading and made an unfair comparison with darbepoetin and epoetin. The Committee unanimously concluded that the claim was in breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code.
and review. The Committee considered that overall the claims for Mircera shown in the posters, website and dosing card constituted a severe breach of the Code because the materials had the potential to effect how the medical profession would prescribe the product and have a significant commercial impact on the market for ESA products. However, by a majority decision the Committee determined that the website would not bring the industry into disrepute or reduce confidence in the industry. In a majority decision no breach of Section 9.13 was found.

The Committee determined that no breach of Section 1.3 of the Code should be found for the whole website beyond the individual breaches of Section 1.3 found with respect to individual complaints about claims and pages of the website.

The Committee noted that Roche Products had stated that the nephrology.com.au website had been reviewed by the Monitoring Committee, which had raised no issues with it. The Code Committee was advised that the Monitoring Committee had recently reviewed advertisements published in electronic media (websites, e-newsletters, audiovisual media). It had not regarded the nephrology.com.au website as an advertisement and had not reviewed every claim and supporting reference on the website. Nevertheless, the Code Committee noted that it may form its own view of materials regardless of any prior review by the Monitoring Committee.

**Appeal**

Roche lodged an appeal against:

1. The findings of the Code Committee concerning promotional material for Mircera in relation to:
   a) The claim “it’s about time an ESA could be home delivered with once monthly convenience” (Code Committee Consideration A)
   b) Some, but not all, of the Code Committee’s findings in relation to the claim “first continuous stimulating agent” (Code Committee Consideration B)

2. The Committee’s decision to consider Amgen’s complaints in relation to the website before intercompany dialogue and resolution had been concluded

3. Fine imposed was disproportionate to the seriousness of the breach.

**Response to the Appeal**

Amgen responded that the required process for intercompany dialogue did occur. Amgen supported the Code Committee’s determination that the three promotional pieces constituted a severe breach of the Code and saw no reason to modify the sanction imposed.

**Consideration of the Appeal**

The following summarises Roche’s appeal presentation:

The messages and promotional claims in the Mircera materials are targeted at a specialist physician group who understand the important differences between the various Erythropoiesis Stimulating Agents (ESAs) available. Roche believe that these claims are clear and unambiguous.

‘First continuous stimulating agent’ claim

The claim of “continuous stimulation” requires an understanding of the mode of action of Mircera in order to understand it. Mircera is different to other ESAs available. Roche argued that Amgen had oversimplified the mode of action of Mircera. The physical and chemical properties of Mircera are of significant difference and justify the claims. In its complaint, Amgen had contended that the term “continuous stimulation” implies that Mircera is permanently bound to the
receptor. Roche stated that Mircera is a large molecule, which is pegylated, in comparison to other ESAs. Mircera has a low receptor affinity compared with erythropoietin alfa and beta and has a slower rate of elimination. This leads to Mircera having a very long half-life. The molecule remains in the patient’s system, interacting with the receptor. This allows for monthly injections across all patient groups. The term CERA means that it continuously activates the erythropoietin receptor leading to an even level of stimulation over time; not overstimulation.

A Committee member questioned Roche’s statements concerning the relevance of the receptor interaction to a monthly dosing schedule, as Amgen’s product darbepoetin is also dosed once a month. Roche responded that in pre-dialysis patients both products are given once a month, but for patients on dialysis only Mircera can be given monthly.

A Committee member questioned the clinical relevance of the half life of Mircera, considering that the medicine is intended to stimulate formation of red blood cells. The half life of a red blood cell is about 56 days. If an ESA medicine stimulates the production of red blood cells, the length of half life of the medicine is not clinically relevant. Further, the Committee member questioned whether there was any evidence that the long half life of Mircera resulted in ‘continuous’ receptor stimulation.

Roche challenged the Code Committee’s statement that Continuous Erythropoietin Receptor Activator (CERA) was not a widely accepted term in the scientific literature. Roche argued that the development of a product name and its use in scientific literature is not a new concept. The term CERA is used in scientific literature published in peer-reviewed journals and is an accepted term. Roche provided evidence that Amgen had similarly coined the term NESP (Novel Erythropoiesis Stimulating Agent) which is used in their product’s name Aranesp.

“**It’s about time an ESA could be home delivered with once monthly convenience**” claim
Roche argued that in the context of the banner at the Home Therapies Conference, which is a conference about the home delivery of dialysis services, the claim would lead the audience to conclude that it referred only to the home delivery of the product, rather than the monthly dosing schedule.

**Website claims**
Roche stated that of the 6 claims on the website the Code Committee found in breach of the Code, 3 of them had been conceded by Roche during intercompany dialogue. Roche argued that the claims which it had conceded to change should not have been considered in the original complaint.

One of these claims had now been conceded and was not subject to appeal.

**Less overshoots with Mircera during correction (compared to darbopoietin alfa)**
The graph was clearly labelled to indicate that it represented the 8 week timepoint, which is a clinically relevant timepoint referenced in the study.

Members of the Committee discussed the graphical presentation of the Macdougall et al study Figure 5 on the website page. Members noted that the y-axis started at 7 g/dL (70 g/L) in the published paper, which had been changed to starting at 10 g/dL (100 g/L) on the website; the duration on the x-axis had omitted the 7 month data on the website; and the error bars shown in the published paper, which were overlapping, had been omitted. These elements created a significantly different impression of the data on the website compared with the original paper.

**14% of subjects rated sc darbopoietin alfa injections as ‘very painful’**
Roche disagreed with the Code Committee’s finding that this claim was misleading by omission. The title of this page of the website was ‘with less injection site pain overall’ (compared with darbopoietin alfa). The referenced study by Pannier et al was an
acceptable basis for the claim although it was a small study. The differences identified in this study were highly significant for Mircera. The study referenced by Amgen to dispute the claim was a meta-analysis by Locatelli et al, which was not designed to report on pain at injection sites.

Roche outlined the timeline of the complaints and intercompany dialogue with Amgen. There were three complaints brought by Amgen over a two month period. Roche questioned the validity of the complaint lodged with Medicines Australia in relation to the website. Roche considered that intercompany dialogue had not been concluded in relation to the website claims and therefore the Code Committee should not have reviewed the complaints in relation to the website.

Sanction
Roche questioned the severity of the fine imposed by the Code Committee. Roche had not attempted to deliberately mislead physicians. All claims subject to complaint were based on appropriate data that had been presented at scientific meetings or published in peer-reviewed journals. Roche had been responsive to Amgen’s concerns and had made amendments to materials in question and had shut down pages of the website. Of the 44 individual complaints made by Amgen, in 24 Roche had agreed to make some changes; in one Roche had agreed to cease using the claim; in the other 19 matters there was continuing dispute.

Roche provided a list of complaints from 2007 to 2010 which showed that the highest sanction of $200,000 had only been imposed once for what was considered to be a much more severe breach of the Code. Roche asked the Appeals Committee to consider a reduction in the fine.

An Appeals Committee member questioned what the route of elimination of Mircera is. The Product Information states that it is unknown if a significant proportion of the drug is catabolised and there is no animal data on its route of metabolism. Roche responded that the drug is eliminated by endocytosis at the erythropoietin receptor. No degradation products of Mircera are detected in the urine or faeces, as compared to darbepoetin (Aranesp) where a significant amount of degraded product is found in urine and faeces.

Amgen representatives then provided their response to the Appeal:

Amgen consider that no new evidence was presented by Roche which would justify the decisions of the Code Committee being overturned.

Amgen consider that the statement “it’s about time an ESA could be home delivered with once monthly convenience” as used in context at the Home Therapies Conference was ambiguous and misleading. The emphasis in the graphic was through underlining key words and larger font sizes which gave prominence to about time and once monthly rather than emphasising the home delivery aspect of the claim as argued by Roche.

In regard to the comparisons between Mircera and Aranesp (darbepoetin alfa) on the website, the Code requires claims to be supported by appropriate data which do not mislead by distortion or undue emphasis. Roche had manipulated published graphs and selectively reported data which was misleading. Roche had not demonstrated that it had taken remedial action to correct the website. It was therefore appropriate for Amgen to make the complaint to the Code Committee.

In relation to the “less overshoots” claim and supporting graph, Amgen outlined how Roche had selectively represented the data. The graph from the referenced study showed that Mircera was no better than darbepoetin alfa. Roche removed error bars which compounded the issue. The graph had been deliberately changed to portray the evidence in a more favourable light for Mircera, which was misleading.
Amgen has reviewed all the referenced material and could not find any scientific evidence to support the claim of “continuous stimulation” of the erythropoietin receptor. The half life of the drug is irrelevant – there is no evidence that it works in a different way to other ESAs. The pegylation of the molecule gives a longer half life, but to claim it is continuously stimulating the receptor is misleading.

Amgen consider that the deliberate choice not to use the WHO international naming conventions for the active ingredient was intended to force clinicians to use the trade name and thus emphasise the ‘CERA’ claim.

Amgen consider that the intercompany dialogue was followed appropriately and that due process did occur before lodging the complaint with Medicines Australia. The length of time taken to resolve the issues during the intercompany dialogue showed reticence from Roche to make any changes to the material.

Amgen agrees with the Code of Conduct Committee’s view that the breach was severe and support the sanction imposed.

Following this presentation, Roche made its closing statement:

Roche reiterated that it was not its intention to mislead physicians. Once it had been notified by Amgen that there were errors in its materials it had agreed to make certain changes.

The website had been deactivated from the time that Roche were notified of the complaint.

During intercompany dialogue, Roche had agreed to amend 24 of the 44 claims subject to complaint, cease using one claim completely which left 19 claims subject to complaint. One of the changes agreed to was the alteration of the graph in question.

Roche questioned how Amgen were able to access the website as it was password protected. Access to the website had to be approved by Roche.

The Chairman thanked the Roche and Amgen representatives for their presentations who then left the meeting to allow the Committee to consider its decision.

The Appeals Committee discussed the intercompany dialogue process between Roche and Amgen and the timelines between commencement of dialogue and lodgement of the complaint. The Appeals Committee noted that there were initially a large number of complaints discussed during the intercompany dialogue, and while a significant proportion had been resolved, it showed that Roche’s campaign was aggressive. The Committee also noted that a number of the claims in dispute were duplicated across the three pieces of material - the website, dosing card and poster.

The Appeals Committee noted that Amgen were not granted access to Roche’s website as requested during the intercompany dialogue and therefore were not able to verify if any of the changes offered by Roche had been made. Further, Amgen had stated that the amendments to the website had not been completed within the time in which a complaint should be considered resolved as described in the intercompany dialogue procedures. The Appeals Committee agreed with the Code Committee that Amgen were within their rights to submit the complaint. On this basis the Appeals Committee unanimously agreed that the Code Committee’s consideration of the complaints in relation to the claims on the website was appropriate.

One Appeals Committee member argued that the primary issue of concern should be patient safety and whether this had been compromised by the misrepresentation of data. The Appeals Committee considered that if a physician took the scientific evidence as represented at face value, there was a possibility that patient safety could be compromised.
The Appeals Committee discussed the complaint in relation to the claim “It’s about time an ESA could be home delivered with once monthly convenience”. The Appeals Committee considered that Roche had deliberately associated the two statements – home delivery and once monthly convenience – with ‘It’s about time’ through equal prominence given to both features so that the statement became ambiguous and could equally be interpreted as ‘It’s about time’ referring to home delivery being once a month or the medicine being administered once a month. Mircera is not the only ESA that can be given once a month. The Appeals Committee agreed with the Code Committee’s decision that the claim was misleading and was in breach of Section 1.3 of the Code.

The Appeals Committee discussed the claim for “continuous stimulation” and concluded that there was no scientific evidence to support that Mircera continuously stimulated the erythropoietin receptor. The long half life of approximately 6 days and the pharmacological properties of the drug do not lead to the conclusion that continuous stimulation of the receptor is occurring. The Appeals Committee agreed with the Code Committee that there was no evidence to support the claim of ‘continuous stimulation’. The Appeals Committee confirmed the decision of the Code Committee that the claim was in breach of Section 1.1, 1.2 and 1.3 of the Code.

Roche had not appealed the Code Committee’s decisions in relation to the ‘unique receptor interaction’, ‘mimics the body’s natural process of continuous stimulation’ or ‘new way of working’ claims.

The Appeals Committee discussed the claims on the Mircera website. Overall the Appeals Committee considered that it was a well presented website and once the information was corrected would be beneficial to physicians. However, in its form where the graphical representations omitted key information and made unfair comparisons, it was disparaging and was in breach of the Code as alleged by Amgen. The Committee considered that the effect of the incorrect depiction of scale and timelines and the omission of error bars on the graphical representation was to exaggerate differences which were not significant. In addition, the Appeals Committee recognised that the website may be more heavily relied upon by regional and remote renal physicians and therefore could compromise patient safety. The Appeals Committee unanimously agreed to uphold the Code Committee’s findings.

Specifically, the claims:

- ‘Less overshoots with Mircera during correction (compared to darbepoetin alfa)’ and associated graph was in breach of Sections 1.1, 1.3 and 1.7 of the Code.
- ‘65% less overshoots than darbepoetin alfa’ was in breach of Section 1.3 and 1.7 of the Code.
- ‘Injections per year with Mircera vs. short-acting ESAs’ and associated graphical representation was in breach of Sections 1.3 and 1.7 of the Code.
- ‘14% of subjects rated sc darbepoetin as ‘very painful’ was in breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code.

The Appeals Committee was not persuaded by the Roche appeal that the Code Committee had erred in its reasons for its decisions or its findings in relation to these claims and associated graphical representations. The appeal was not upheld in relation to any aspect.

Roche had not appealed the Code Committee’s decisions concerning the claim ‘Fewer dose changes with Mircera’ and the associated graphical representation or concerning the claim “Conversion to Mircera saves time – compared to darbepoetin alfa or epoetin.

In discussing the severity of the fine, the Appeals Committee stated that there should be processes within the organisation to avoid these kinds of errors. The Appeals Committee did not find it acceptable to retroactively amend claims once they had been complained about by a competitor. The materials were
statistically misleading due to the inaccurate depiction of scales and timelines and the omission of error bars, and clinically misleading (the half life of the drug is not relevant – the production of RBC which have a half life of about 56 days is what matters). The claims in the material were found to be misleading and implied clinical relevance that could not be justified. As a result the Appeals Committee also considered that there was a degree of risk to patient safety as a result of the claims that had been found in breach of the Code and there was the potential to have a major effect on how physicians would prescribe the product. Together these constitute a severe breach of the Code of Conduct.

The Appeals Committee determined by majority decision to uphold the sanctions as determined by the Code of Conduct Committee.

Sanction

Having found a number of breaches of the Code in regard to the poster presentations, the website and the dosing card, which were determined to be severe breaches, the Committee discussed an appropriate sanction. The Committee unanimously resolved that Roche Products should

- Cease use of all materials and website found in breach of the Code
- Pay a fine of $200,000
- Send a corrective letter to all healthcare professionals with a password to the website. The corrective letter must be approved by the Chairman of the Code Committee and must be sent to the specified recipients within 30 calendar days of receiving the reasons for the decision.
- Place the corrective letter on the website page thereby informing visitors that the website has been found in breach of the Code and has been taken down.

The Appeals Committee confirmed the sanctions imposed by the Code of Conduct Committee.

‘An Early Psychosis’ DVD – 1056

Subject Company: Novartis Australia
Complainant: Monitoring Committee
Product: Clozaril

Complaint

The Monitoring Committee considered that the DVD included statements and testimonials that were praising the product Clozaril which were promotional in nature in a material intended for distribution to consumers.

Novartis had stated that the DVD is not currently being distributed. However, the Committee was concerned that the VHS (videotape) version containing the same content had been distributed to healthcare professionals to give to consumers and was potentially in breach of the Code.

If the DVD/tape was intended to be given to a patient after the decision to prescribe Clozaril has been made, the Monitoring Committee considered that the content of the DVD/tape was not just educational but included statements that were promotional and may be in breach of Section 12.6 of the Code.

If the DVD/tape should be regarded as a patient aid, the Monitoring Committee did not consider that it was compliant with Section 16 of the Code. Section 16 requires that patient aids must not make comparisons between products or include promotional claims.

Sections of the Code

Material alleged to be in breach of the following Sections of Edition 16 of the Code:

- 12.6 Educational information to the general public
- 16 Materials for use with patients (patient aids)

Response

Novartis apologised for any confusion regarding the DVD, which it said should not
have been submitted to the Monitoring Committee because it had not been in use within the last 24 months. Novartis stated that the VHS version of the material had been produced in 2003, but hasn’t been available for a number of years.

In its response, Novartis referred to Appendix 1 of the Code, which states that complaints will not be accepted where the promotional material or activity had occurred at a time more than 24 months before the lodgement of the complaint.

Novartis stated that the DVD had been produced and had been under review through the internal copy clearance system when it was provided to the Monitoring Committee. The DVD has never been distributed.

**Code Committee decision**
No breach of Section 12.6 or 16 was found, in recognition that the videotape had not been distributed for more than two years and the DVD version had not yet been distributed. The complaint exceeded the limitation period stated in the Code.

**Consideration of the complaint**
The Committee considered the circumstances that led to the DVD being reviewed by the Monitoring Committee.

The Committee understood that the videotape version of ‘An Early Psychosis’ had not been distributed by Novartis since 2007. The Committee was also of the understanding that the DVD version of the videotape was undergoing internal company review prior to further distribution and had been provided in error to the Monitoring Committee for its review of disease education activities. In its response, Novartis had referred to the Limitations on complaints in Appendix 1 of the Code, which states that complaints will not be accepted where the promotional material or activity occurred in a period greater than 24 months from the date of lodgement of the complaint.

The Committee was very concerned by the content of the VHS/DVD and would be inclined to find it in breach of the Code if the complaint had been properly before the Committee.

The Committee concluded that it would accept that the limitation period for complaints had expired if Novartis could provide an assurance that the videotape was no longer in use or being given to patients by clinics. The Committee requested that Novartis write to all clinics which prescribe Clozaril for patients and request that they return any copy of the video to Novartis and that Novartis destroy all copies of the videotape that are returned. Novartis should advise the Committee of the completion of this action by Friday 6 August 2010.

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**‘BeatHepC’ website – 1057**

**Subject Company:** Roche Products

**Complainant:** Monitoring Committee

**Product:** Pegasys RBV

**Complaint**
The Monitoring Committee considered that the term ‘cure’ on the website would have a different meaning for consumers in relation to Hepatitis C than it would for physicians; physicians may understand that a ‘cure’ means a sustained virological response, whereas a member of the general public may understand ‘cure’ to mean that they have fully overcome the condition. A member of the general public is unlikely to understand that the term ‘cure’ is relevant to only 50 to 80 percent of treated people, or that it means a sustained viral response for a period of time demonstrated in clinical trials.

The Monitoring Committee considered that the website was potentially misleading and was not balanced.
**Sections of the Code**

Website alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.3 False or misleading claims
- 12.7 Disease education activities in any media
- 12.7.4 Disease education activities in any media

**Response**

Roche had responded that a successful cure from hepatitis C is possible – the disease can be completely overcome and this effect can be sustained. Roche contended that the word ‘cure’ in the context of hepatitis C treatment is appropriate terminology for a general public audience. This contention was supported by publicly-available material using the word ‘cure’ in the same context.

Roche had denied that the website was in breach of the Code. Roche argued that the website was balanced, informative and promoted awareness of all aspects of the disease and its management.

Roche had supported its response to the complaint with advice from Hepatitis Australia that the use of the word ‘cure’ was entirely appropriate and that the website contents were fair, accurate, balanced, was not misleading and provided appropriate hepatitis C disease education information.

**Code Committee decision**

- By a majority decision, no breach of Section 1.3
- By a majority decision, no breach of Section 12.7
- By a majority decision, no breach of Section 12.7.4

**Consideration of the complaint**

The Committee discussed what would be meant by ‘cure’ in relation to hepatitis C in the mind of consumers. It was noted that the medical literature consistently used the term ‘sustained virological response’ which is defined as the absence of hepatitis C virus RNA in the serum 24 weeks after therapy has ceased. Most medical literature did not use the term ‘cure’. Few studies have followed subjects for longer than 24 weeks after treatment cessation. One abstract included in the response from Roche, a study by Swain et al, had followed patients for a mean of 4.1 years after cessation of treatment, with 99 percent remaining serologically negative for the hepatitis C virus. This study claims it validates the use of the term ‘cured’ for people achieving a sustained viral response.

However, the Committee was primarily interested in consumers’ interpretation of the term ‘cure’ in relation to hepatitis C. The BeatHepC website used the term ‘cure’ and stated ‘being cured of hepatitis C means clearing the hepatitis C virus from your blood’. Some members of the Committee considered that members of the public are likely to understand that the term ‘cured’ as having the commonly understood meaning of ‘no longer having the problem’. The Committee was unable to identify any systematic investigation by Roche or another organisation of what consumers would understand by the term ‘cure’ in relation to hepatitis C. Some members also considered that the name of the website ‘beatHepC.com.au’ reinforced the impression that the problems associated with hepatitis C can be ‘beaten’ or eliminated, which they considered was misleading. However, the term ‘beat hepatitis C’ was also used by independent community organisations such as Hepatitis Australia in their communications with the general public.

Members were also concerned that the term ‘cured’ might not convey to members of the general public that they may still have liver damage that will not be ‘cured’ by treatment. The Committee noted that the paper by Ghany et al acknowledged that liver cancer has been identified years after a ‘virological cure’, especially if liver cirrhosis existed at the time of achieving a sustained virological response. Whilst the medical and professional community might properly understand that ‘cure’ means a sustained virological response but the risk of liver disease progression
remains, a consumer might not gain this understanding from the term ‘cure’ or ‘cured’.

The Committee considered Roche’s advice that many publications from both State and Federal Governments and from community organisations have adopted the term ‘cured’ in relation to hepatitis C treatment. Although the Committee recognised the importance of pharmaceutical companies aligning their health promotion messages to those communicated by both health departments and peak national community organisations, a pharmaceutical company should not adopt a term without being cognisant of the Code and other standards that apply to their communications.

The Committee reviewed each page of the ‘BeatHepC’ website, particularly the page headed ‘The Chance of a Cure’. A majority of the Committee accepted that this page made it clear to a reader that achieving a ‘cure’ was not guaranteed and depended on a number of factors, including the degree of liver damage when treatment is started. The use of the word ‘chance’ with ‘cure’ provided some moderation of the understanding of the likely outcome of treatment.

The Committee concluded in a majority decision that the use of the terms ‘cure’ or ‘cured’ on the BeatHepC website was not misleading and was not in breach of Section 1.3 of the Code. The Committee also concluded by a majority decision that the website was not in breach of Section 12.7.4 or 12.7 of the Code. The Committee accepted that within the environment of hepatitis C treatment the key characteristics of the condition were covered on the BeatHepC website and that the implications of the disease were not alarmist.

Whilst concluding that the website was not in breach of the Code, the Committee wished to convey to Roche that some members of the Committee, particularly the consumer members, had significant concerns about consumers’ understanding of the meaning of a ‘cure’ in relation to hepatitis C. Members encouraged Roche to investigate what consumers actually understand from the term, particularly in populations more vulnerable to hepatitis C such as injecting drug users, prisoners and the culturally and linguistically diverse community, in order to be confident that a realistic understanding of the outcome of treatment is conveyed.

AstraZeneca Educational Event – 1058

Subject Company: AstraZeneca

Complainant: Monitoring Committee

Product: N/A

Complaint
The Monitoring Committee had reviewed an amended educational event report voluntarily submitted by AstraZeneca in relation to an event held at a medical centre in Queensland in the three month period January to March 2010. The amended report detailed hospitality at a cost of $160.35 per person in association with a one hour presentation held within the medical centre. The hospitality provided included a private chef and waiter.

The Monitoring Committee considered that the hospitality provided was not secondary to the educational content provided at the educational event and was therefore potentially in breach of Section 9.3 and 9.4.3 of the Code. The educational event costs had exceeded AstraZeneca’s internal company policy for the conduct of educational meetings. The Monitoring Committee also considered that this event may bring discredit to the industry and may be in breach of Section 9.13 of the Code.

Sections of the Code
Conduct alleged to be in breach of the following Sections of Edition 16 of the Code:
- 9.3 Educational events
- 9.4.3 Meals and beverages (at company educational events in Australia)
- 9.13 Discredit to and reduction of confidence in the industry

**Response**
AstraZeneca asserted the value of the educational content provided at the meeting, but acknowledged that the hospitality provided involved a per-head cost that exceeded what would be considered acceptable for a pharmaceutical company educational event and which exceeded its own company limits. The actual hospitality provided was not lavish or excessive and was within normal business standards, although the costs may not have been.

AstraZeneca asked the Committee to take into consideration that it had taken appropriate corrective action to ensure that in future hospitality is always appropriate for its educational events and that the company had proactively disclosed the meeting to the Monitoring Committee, which demonstrates the company’s strong commitment to Code compliance.

**Code Committee decision**
- By a unanimous decision, breach Section 9.3
- By a unanimous decision, breach Section 9.4.3
- By a majority decision, no breach Section 9.13

**Sanction**
- By a majority decision, pay a fine of $15,000

**Consideration of the complaint**
The Committee considered the balance between the educational content of the meeting and the hospitality provided. The Committee considered that the education provided was relatively basic whereas the hospitality on a per-head cost was excessive and not an appropriate form of hospitality for an educational event held in the workplace.

AstraZeneca had acknowledged that the hospitality had exceeded its own company limits and exceeded what would be considered appropriate for pharmaceutical company educational event of this type.

The Committee unanimously determined that the educational event was in breach of Section 9.3 and Section 9.4.3 because there was not an appropriate balance between the educational content and the hospitality provided and the hospitality was not secondary to the educational content. In relation to Section 9.13, the Committee determined by a majority decision that the event did not bring discredit to or reduce confidence in the industry.

**Sanction**
The Committee debated what would be an appropriate sanction. The Committee agreed that the fine should be reduced from that which would normally be imposed for this conduct because AstraZeneca had openly and proactively self-reported the event, which originally had been misreported. The Committee determined by a majority decision that AstraZeneca should:
- Pay a fine of $15,000

**Pegasys “Free of Charge” RBV Program – 1059**

**Subject Company:** Roche Products

**Complainant:** Merck Sharp & Dohme

**Product:** Pegasys RBV

**Complaint**
The complainant alleged that the Pegasys “Free of Charge” RBV Program conducted by Roche Products Pty Ltd for the treatment of chronic hepatitis C is a disguised Patient Familiarisation Program (PFP) or seeding program.
Sections of the Code
Conduct alleged to be in breach of the following Sections of Edition 16 of the Code:
- 8 Product Familiarisation Programs (PFPs)
- 9.12 Gifts and Offers
- 9.13 Discredit to and reduction of confidence in the industry

Response
Roche denied that the Pegasys “Free of Charge” RBV Program is a PFP; rather it is a patient access program which builds on a Compassionate Access Scheme for the initial indication of Pegasys (Hepatitis C treatment).

Code Committee decision
- By a majority decision, no breach of Section 8
- By a majority decision, no breach of Section 9.12
- By a majority decision, no breach of Section 9.13

Consideration of the complaint
The Committee discussed the patient access program in consideration of the provisions of the Code. The Committee determined that the provision of Pegasys RBV through the normal supply channel but at no cost did not constitute a gift or benefit to healthcare professionals or associated staff. It was therefore not a gift or offer and Section 9.12 of the Code did not apply. No breach of Section 9.12 was found.

The Committee considered whether Section 8 of the Code applied to the Program. It was noted that the product is supplied on physician request through the usual supply channel of the hospital pharmacy. It is not provided directly from Roche Products to the physician or to the patient. The purpose of the Program is not to enable a physician to gain familiarity with the product; the prescribers would be physicians experienced in the use of Pegasys RBV. Roche has argued that the purpose of the Program is similar to a compassionate access program. The Committee noted that the program was aimed at specific patients with a defined virological profile and that the product was supplied by the hospital pharmacist on specific request from a clinician. The hospital pharmacy applies for further supply against the amount dispensed for these patients. The Committee concluded that the Program was not a Product Familiarisation Program and Section 8 of the Code did not apply. No breach of Section 8 was found. Having found no breach of either Section 9.12 or Section 8, the Committee unanimously concluded that no breach of Section 9.13 should be found.

One member of the Committee raised a concern that personal information was collected (date of birth and initials) on the sample order form provided for clinicians to order the product to be supplied by the pharmacy. Whilst it appeared that these patient details were communicated between the clinician and pharmacy and were not provided to Roche, the Committee cautioned that the company should ensure that it did not receive any personal information about patients receiving the product under the Program. It was noted that the hospitals and clinicians are responsible for ensuring they meet their obligations for maintaining patient privacy.

The Committee recommended that Medicines Australia should review the conduct of programs such as the one subject to complaint in order to clarify how such conduct fits within the Code, in consideration that the Committee did not agree it should be regarded as a Product Familiarisation Program.
Spiriva Leave Behind – 1060

Subject Company: Boehringer-Ingelheim/Pfizer (BI/Pfizer)

Complainant: GlaxoSmithKline (GSK)

Product: Spiriva

Complaint
GSK alleged that the claim “early treatment, active tomorrow” in the promotion of Spiriva was misleading. GSK argued that this statement has the potential to result in healthcare professionals having unrealistic expectations of the onset and effect of Spiriva as well as encouraging prescribing Spiriva in preference to other agents for asthma.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 1.3 False and misleading claims

Response
BI/Pfizer disagreed with GSKs assertion that the advertisement including the tag line “early treatment, active tomorrow” implies onset of treatment benefits within 24 hours of administration. BI/Pfizer disputed that the material containing this tagline is in breach of the Code, or has the potential to mislead prescribers and compromise patient safety.

Code Committee decision
- In a majority decision no breach of Section 1.3 of the Code was found

Consideration of the complaint
The Committee considered whether the claim “early treatment, active tomorrow” could be construed as misleading. The Committee noted that during intercompany dialogue concerning Spiriva promotional materials the two companies had resolved all but one issue, which related to the interpretation of the word “tomorrow” in the claim.

The Committee contemplated the definition of “tomorrow” in the context of its ordinary meanings, as well as in the context of the advertisement subject to complaint.

A minority of members of the Committee interpreted “tomorrow” to mean “in the next 24 hours” in the context of the advertisement and therefore felt that the claim was misleading. The clinical evidence for tiotropium (Spiriva) supports its use for long term maintenance therapy for chronic obstructive pulmonary disease (COPD) and not for short term or immediate relief. Some members questioned why the wording used in the German and Dutch advertisements for Spiriva (translated for the Committee), which did not use the word “tomorrow. They felt that the taglines used in the overseas ads were less ambiguous.

A majority of the members of the Committee understood “tomorrow” to mean “into the future”, noting that the clinical evidence supported the effectiveness of long term treatment. In addition the imagery used in the advertisement supported “tomorrow” as being “into the future”. Members also noted that there are a number of examples of the use of the word “tomorrow” in a range of advertisements and media which consistently refer to the longer term future and not “the next day”. The advertisement included a clear statement of the PBS restriction, which is for the long term maintenance treatment of bronchospasm and dyspnoea associated with COPD. Further, the promotion of Spiriva has always been along the lines of long term decrease in the frequency of exacerbations of the COPD.

The Committee determined by a majority decision that the word “tomorrow” as used in the context of the advertisement means “into the future” and not “in the next 24 hours”. No breach of Section 1.3 of the Code was found.

The Committee contemplated the definition of “tomorrow” in the context of its ordinary
Lipitor Advertisement – 1061

Subject Company: Pfizer Australia

Complainant: Dr Ken Harvey

Product: Lipitor

Complaint
Dr Harvey requested the Code of Conduct Committee review Pfizer’s advertisements for Lipitor alleging that the advertisements are false and misleading. The series of three advertisements, which appeared in the electronic publication 6minutes, includes the image of a person dressed in barrister’s robes overlaid with the statement in bold print “It’s all about the evidence”. The second and third advertisements also state “Barry Andrews. Judge since 1999. On Lipitor since 2005”. In all three advertisements the small print below the image notes that Barry Andrews is not a real judge or patient. Dr Harvey alleged that the large print statements and illustrations are false and misleading as shown by the small print disclaimer.

Dr Harvey submitted that the purpose of the picture of the “judge” and the associated statements is to falsely imply that a member of the judiciary (and/or his doctor) has weighed the evidence and chosen Lipitor as the statin of choice.

Dr Harvey further alleged that the advertisements also were in breach of Section 9.13 of the Code as they brought discredit to and reduced confidence in the industry.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 1.3 - False and misleading claims
- 9.13 - Discredit to and reduction of confidence in the industry

Response
Pfizer stated that the current Lipitor promotional campaign aims to highlight that Lipitor has a wealth of evidence that supports its efficacy in studies of up to 5 years duration, and to encourage doctors to make evidence-based prescription decisions. Pfizer argued that readers of medical publications would appreciate that images used in pharmaceutical advertising are not intended to be interpreted literally. The image of the judge is representative of a profession that evaluates evidence and a reasonable reader will extrapolate this to the evaluation of medical evidence. To provide further clarity Pfizer had included the footnote that ‘Barry Andrews is not a real judge’, but this footnote does not contradict the text on the advertisement as alleged by the complainant.

In its response Pfizer had proposed that to minimise any chance of ambiguity it would move the footnote to a more prominent position in the advertisement.

Code Committee decision
- In a majority decision a breach of Section 1.3 of the Code was found
- In a majority decision no breach of Section 9.13 of the Code was found

Sanction
- Cease publication of the advertisements that include the statement ‘Barry Andrews. Judge since 1999. On Lipitor since 2005’
- Pay a fine of $20,000.

Consideration of the complaint
The Committee unanimously agreed that the first of the three advertisements, which did not include the statement ‘Barry Andrews. Judge since 1999. On Lipitor since 2005’, was not in breach of the Code. The Committee did not consider that the image of the judge associated with the claim “It’s all about the evidence”, absent any identification of the image as a real person, was false or misleading.

The majority of the Committee considered that naming of the fictitious person in the advertisement, stating that he is a judge and
taking Lipitor, could lead the reader to believe that he is an actual person who held the position of a judge who had reviewed the evidence and provided an endorsement. These Committee members considered that the qualifying statement that Barry Andrews is not a real judge or patient demonstrated that the statement about Barry Andrews being a judge and taking Lipitor was false and misleading.

Members considered that it was unacceptable when advertising medicines to prescribers to make a statement and then retract or contradict it through the use of a qualifier. A qualifying statement is normally used to explain the circumstances in which a statement may be regarded as true and factual. In this case the qualifying statement clarified that the statement it referred to was not true in any circumstance. The majority of members considered that it was irrelevant that the statement in question was not a direct product claim because the overall effect of the statement and image was to promote the product.

A minority of members of the Committee did not consider that health care professionals would be misled by the advertisement or statements and would understand that the imagery and identification of the judge was merely an artifice of advertising.

In a majority decision, the use of the tag line ‘Barry Andrews. Judge since 1999. On Lipitor since 2005’ in combination with the image of a judge and the qualifier that he isn’t a real judge or patient was false and misleading. The Committee agreed by majority decision that the half- and full-page advertisements were in breach of Section 1.3 of the Code.

The Committee discussed whether the advertisement would bring the industry into disrepute or reduce confidence. A majority of members considered this to be a minor breach, which would have no implications for prescribers or patients. In a majority decision no breach of Section 9.13 of the Code was found.

Sanction
The Committee determined that the breach found was a minor breach because it had no safety implications for patients and would have no major effect on how the medical profession would prescribe the product.

The Code Committee determined that Pfizer should:
- Cease use of the advertisements that included the statement ‘Barry Andrews. Judge since 1999. On Lipitor since 2005’
- By a majority decision, pay a fine of $20,000.

Maxalt – 1062

Subject Company: Merck, Sharp & Dohme Australia (MSD)

Complainant: Healthcare professional

Product: Maxalt

Complaint
The healthcare professional alleged that MSD had sent them an unsolicited promotional email which suggested a requirement for urgent attention and used the email to promote the product Maxalt under the guise of winning an award rather than enhancing medical knowledge.

Sections of the Code
Material alleged to be in breach of the following Sections of Edition 16 of the Code:
- 2.1.3 – Mailing of printed promotional material to healthcare professionals
- 2.4.4 – Distribution of promotional material to healthcare professionals via email or facsimile
- 9.1 – Relationship with healthcare professionals

Response
MSD responded that it had complied with all privacy legislation. It stated that the healthcare professional had registered as a
user of the MSD4GPs website and the email subject to this complaint had been sent to them as a registered user. MSD further stated that it considered that the information in the email was relevant to the practice of medicine and included all mandatory information required for a promotional item including referencing, PBS information, the Minimum PI and a link to the full Product Information.

**Code Committee decision**

- In a unanimous decision no breach of Sections 2.1.3, 2.4.4 and 9.1 of the Code was found

**Consideration of the complaint**

The Committee reviewed the complaint and noted that Section 2.1.3 of the Code of Conduct refers to the mailing of printed promotional material (i.e. via Australia Post) only and therefore was not relevant to this complaint. The Committee unanimously agreed that there was no breach of Section 2.1.3.

The Committee noted that the healthcare professional had an extensive and long-standing business relationship with MSD, which included attendances by sales representatives and that the healthcare professional would have been offered promotional material on a regular basis. The Committee noted that the healthcare professional had registered voluntarily as a user of MSD’s website for healthcare professionals MSD4GPs in January 2010 and that he had received the email concerning Maxalt as a result of that registration. Other emails had been sent to the healthcare professional prior to the Maxalt email of 27 September 2010.

The Committee accepted that MSD had adequate privacy statements associated with the registration for the MSD4GPs website. The privacy statement states that MSD may use the contact information provided by a registrant to provide information on MSD products and services, and this will continue indefinitely. The email concerning Maxalt included a link to a fuller company website privacy statement and an ‘unsubscribe’ link. The Committee acknowledged that MSD had promptly removed the healthcare professional from the mailing list following their request on 27 September 2010.

The Committee was satisfied that the email sent to the healthcare professional on 27 September 2010 concerning Maxalt had complied with Section 2.4.4 of the Code and with the relevant provisions of Section 2.1.4 (as required by Section 2.4.4). The Committee did not agree with the complainant that the email directly or indirectly implied that urgent attention was required or was a replica of urgent media. However, the Committee accepted that the MSD4GPs website was intended to provide clinical and practice-related educational information to GPs and the healthcare professional appeared to be concerned that they had received an email communication that was both promotional and educational (such as the information on the new formulation availability and PBS listing) rather than purely educational. MSD had promptly unsubscribed the healthcare professional on their request.

The Committee concluded that the email was not unsolicited and complied with the requirements of Section 2.4.4.

In relation to Section 9.1, the Committee considered that it was reasonable for MSD to communicate to the healthcare professional, who was a registered user of the MSD4GPs, about the availability of a new formulation of a migraine treatment, and its PBS listing. Information about the appropriate use of Maxalt had been included in the email.

In a unanimous decision, no breach was found of Sections 2.4.4 and 9.1.

The Committee cautioned MSD with regard to the content and purpose of the email and some of the promotional statements. Whilst not raised as part of this complaint, the Committee reminded MSD that all promotional materials must comply with Section 1 of the Code of Conduct and must be balanced, accurate, correct and fully supported by the Product Information. The
Committee had some concerns about the balance of the Maxalt email and its emphasis on the AJP Award as a basis for promoting the product to health professionals and the clinical claim “Are your patients benefitting from this treatment?” being based on a patient preference study.

Sanction
The Committee determined by unanimous decision that there was no breach of Sections 2.1.3, 2.4.4 and 9.1 and therefore no sanction was imposed

Diprosone – 1065

Subject Company: Merck Sharp & Dohme Australia (MSD)
Complainant: Member of the general public
Product: Diprosone

Complaint
A member of the general public made a complaint about how Merck Sharp and Dohme responded to her report of an adverse reaction experienced after using Diprosone. The complainant considered that the company had not adequately responded to her concerns or in a timely manner.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 9.13 – Discredit to and reduction of confidence in the industry
- 12.1 – Relationship with the General Public

Response
MSD responded that its investigation of the patient’s concerns and checking the product quality of the batch of Diprosone that the patient had used had shown that there no problems with product quality or meeting specifications. The patient had experienced an adverse reaction; all prescription medicines may have unwanted side effects.

MSD stated that the patient had requested a refund but this had been declined. MSD argued that not providing a refund does not bring discredit to the industry and it is not aware of any pharmaceutical company that regularly provides refunds to patients if they experience a side effect to a prescription medicine.

MSD further stated that it considered that the patient’s complaint had been taken seriously, a check of product quality had been undertaken and appropriate patient information had been sent to the patient. MSD denied that it had breached either Section 9.13 or 12.1 of the Code.

Sanction
- In a unanimous decision no breach of Sections 9.13 and 12.1 of the Code was found

Consideration of the complaint
The Committee considered that whilst it was unfortunate that the complainant had experienced an adverse reaction to the prescribed cream, it is something that can occur; all prescription medicines can cause side effects. It cannot be known at the time of prescribing whether a patient might have an adverse reaction.

The Committee agreed that the pharmacist who dispensed the product should have provided the patient a CMI for Diprosone as is required under the Community Pharmacy Agreement between the Pharmacy Guild and the Commonwealth Government. Under the Agreement a pharmacist is required to provide a CMI whenever a patient is newly initiated on a treatment. The Committee noted it was unfortunate that the patient apparently wasn’t counselled by either the
prescribing GP or the pharmacist that if any adverse reaction occurred she should return to the GP in the first instance. The Committee considered that this complaint might have been avoided if the pharmacist had provided the CMI to the patient at the time of dispensing and counselled the patient to see her GP if any side effects were experienced. The Committee suggested that the complainant could refer this matter to the Pharmacy Board of Australia in relation to the conduct of the pharmacist.

The Committee discussed MSD’s handling of the complaint and agreed that their complaint handling processes could have been better. The Committee noted that it was the patient’s perceived lack of response from the company that led to the complaint. However, the Committee noted that when MSD did call the complainant back it offered to test the cream and had obtained the product batch number, it had provided the CMI and made some efforts to resolve the issue. MSD may have been slow to respond to the complainant, but it had been thorough in its investigation.

The Committee suggested that MSD should conduct a review of its complaint handling processes. In this instance the complainant had expected a response from MSD after her initial call, but this had not occurred because MSD had understood that it had agreed to call the patient only if could provide a refund for the product, which it did not. The Committee recommended that MSD should consider improving its follow up procedures for complaints.

The Committee also requested confirmation from MSD that it had reported the Adverse Event as required by the TGA’s pharmacovigilance requirements.

Sanction
The Committee determined by unanimous decision that there was no breach of Sections 9.13 and 12.1, therefore no sanction was imposed.

Adacel and Acel Range – 1066

Subject Company: Sanofi Pasteur

Complainant: GlaxoSmithKline

Product: Adacel and Acel range of products

Complaint
GlaxoSmithKline (GSK) originally alleged that promotional materials pertaining to Adacel and the Acel range of products are in breach of the Medicines Australia Code of Conduct. The letter of complaint to Medicines Australia (17 February 2011) referred to 3 statements/claims at issue and concluded with 5 ‘requests’ to Sanofi Pasteur.

Following lodgement of the complaint, intercompany dialogue between GSK and Sanofi Pasteur had continued, including a meeting between the Managing Directors. On 14 March 2011, GSK informed Medicines Australia that four of the 5 original ‘requests’ had been satisfactorily resolved; the remaining matter was ‘request 2’, which related to Sanofi Pasteur’s use of claims which infer that its 5 component pertussis vaccines have a clinical advantage over (GSK’s) 3 component pertussis vaccines. GSK asserted that the emphasis on the ‘5’ components, whether or not a comparison is directly drawn, is misleading because it is not balanced or accurate, is unsubstantiated, not consistent with the body of evidence, and misleads by implication and omission.

Sections of the Code
Material alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.1 – Nature and availability of information and claims - Responsibility
- 1.2.2 – Substantiating data - Level of substantiating data
- 1.3 – False or misleading claims
- 1.5 – Unqualified superlatives
Response
Sanofi Pasteur responded to the original complaint and the additional correspondence submitted by GSK on 14 March 2011. It specifically responded to the remaining matter subject to complaint, ‘request 2’.

Sanofi Pasteur responded that it had given undertakings to GSK to withdraw the materials subject to complaint and to use a qualifying statement if any future promotional piece draws any comparison between 3 and 5 component pertussis vaccines, but considered it to be inappropriate to require such qualification in every instance where Sanofi Pasteur draws attention to the 5 components of its pertussis vaccine regardless of whether a comparison with 3 component vaccines is made. Sanofi Pasteur considers that to do so would be inappropriate and itself potentially misleading or confusing.

Sanofi Pasteur denied that it had breached the Code of Conduct.

Code Committee decision
- In a unanimous decision a breach of Sections 1.1, 1.2.2, 1.3 and 1.5 of the Code was found.

Consideration of the complaint
The Committee noted the history of the complaint and the intercompany dialogue between GSK and Sanofi Pasteur. The Committee considered that it was very difficult for it to understand the scope of what remained unresolved between GSK and Sanofi Pasteur. In most complaints the Committee is asked to determine whether specific claims or statements made in promotional materials are consistent with the Code, whereas in this complaint it was asked to adjudicate on a request from GSK for actions by Sanofi Pasteur in relation to its promotion of the Adacel vaccine, which then related to the three claims or statements in dispute between the companies.

The Committee discussed complaints 1 and 2 in the original complaint from GSK. These complaints related to claims that the two additional antigenic components in Adacel, fimbriae 2 and 3, have a role in protecting against pertussis. GSK did not accept that a clinical advantage could be demonstrated from the inclusion of the fimbriae 2 and 3 components. The reference relied on by Sanofi Pasteur for these claims was a study by P. Olin et al, published in The Lancet in November 1997.

The Committee reviewed the Olin et al paper, which was a large randomized, controlled trial of over 80,000 infants comparing 4 types of vaccine: a two component acellular diphtheria-tetanus-pertussis (DTP) vaccine, a three component acellular DTP vaccine, a five component acellular DTP vaccine and a whole-cell DTP vaccine. The study results examined both rates of symptomatic pertussis (paroxysmal cough for at least 21 days) and culture-confirmed pertussis with the four types of vaccine. The two 3 and 5 component acellular vaccines were more effective than the 2 component or whole cell vaccines, but there was no clinically significant difference between the 3 and 5 component vaccines – there were numerically fewer cases of pertussis with the 5 component vaccine, but the confidence intervals overlapped between the 3 and 5 component vaccines indicating there was no statistical difference. There had been a statistical difference between the 3 and 5 component vaccines in the subgroup of culture-confirmed pertussis, but not in the group with symptomatic but not culture-proven pertussis.

The Committee noted that the 3 and 5 component acellular vaccine products used in the Olin et al study contained different amounts of antigen to Sanofi Pasteur’s Adacel vaccine and GSK’s product, and in particular had included significantly more antigen than Sanofi Pasteur’s Adacel product for adult vaccination, which was the product in the advertising subject to the complaint.

The Committee concluded that the Olin study, albeit a robust study and with a good methodology and large study population, was not a reasonable basis for any claims of superior efficacy of 5 component pertussis vaccines over 3 component pertussis vaccines.
The Olin study did not demonstrate clinical superiority of 5 component vaccines. Further, the Committee did not consider that the study could adequately substantiate that any observed difference in the culture-confirmed pertussis sub-group was due to the presence of fimbriae 2 and 3. This was merely a speculation by the authors in the discussion in the study paper with reference to antibody levels in vitro and ex vivo and had no basis in clinical efficacy.

The Committee noted the graphs in Figure 2 of the Olin study, which show that for antibodies to pertussis toxin, the 3 component vaccine performed better than the 5 component. Whilst in the graph of antibodies to fimbriae 2 and 3 the 5 component vaccine performed better than the 2 or 3 component, the selection of just this result was insufficient to justify the claim that fimbriae in 5 component vaccines provide a clinical advantage over 3 component vaccines.

The Committee noted that the US FDA had written to all manufacturers of acellular pertussis vaccines stating that there is no direct correlation between clinical efficacy and the number of pertussis antigens and that a qualifying statement should appear on all advertising when manufacturers refer to the number of antigens in a vaccine.

The Committee considered that the ‘Maybe it’s time to take 5’ claim, like claims 1 and 2, was unable to be substantiated because it implied that there was a clinical advantage from 5 component vaccines which could not be demonstrated from the referenced literature and was therefore unbalanced and misleading.

The Committee discussed what aspects of GSK’s original complaint of 17 February 2011 remained unresolved following the ongoing intercompany dialogue with Sanofi Pasteur. Through intercompany dialogue Sanofi Pasteur had given a number of undertakings to GSK concerning its promotion of its acellular pertussis and diphtheria/tetanus vaccine. The Committee considered that the fundamental issue at dispute between the companies was Sanofi Pasteur’s claims that its 5 component pertussis vaccine is clinically superior to a 3 component vaccine. This was summarised in Sanofi Pasteur’s response to the complaint where it was stated “… GSK has alleged that in the promotional materials used on 17 to 19 August 2010, Sanofi Pasteur made claims that 5 component vaccines have greater clinical efficacy than 3 component vaccines. This allegation arises out of what is said to be the juxtaposition of various aspects of the materials such that they inferred the claimed comparison. Sanofi Pasteur firmly rejects that construction of the materials as artificial and contrived for the reasons set out in Appendix 1.”

The Committee reviewed the communications between GSK and Sanofi Pasteur during intercompany dialogue, and particularly Sanofi Pasteur’s proposal of 9 March 2011 and its detailed response to Complaint 3. The Committee concluded that the advertising materials for Adacel had claimed a clinical advantage for 5 component vaccines over 3 component vaccines which was false and misleading and could not be substantiated with evidence of adequate quality. Although Sanofi Pasteur had given undertakings to not make any future direct comparisons between 5 and 3 component vaccines, it sought to achieve a position in which it could promote the concept of a 5 component vaccine, which inferred a clinical advantage whether or not directly compared with 3 component vaccines.

Sanction
Having found several breaches of the Code the Committee considered an appropriate sanction. The Committee considered that this was a moderate breach of the Code, having no safety implications for patients.

The Committee determined that Sanofi Pasteur should not make the claims that have been found in breach of the Code again in the same or similar form. It was noted that Sanofi Pasteur had stated that it had already withdrawn the materials subject to complaint.
The Committee unanimously determined that Sanofi Pasteur should pay a fine of $50,000.

The Committee discussed whether corrective action was required. As the advertisements found in breach of the Code were used at a three day conference in August 2010, and no subsequent instances of use of the same claims had been alleged by GSK, no corrective action was required.

Testogel and Reandron 1000 – 1068

Subject Company: Bayer Australia

Complainant: Monitoring Committee

Product: Testogel and Reandron 1000

Complaint
The Monitoring Committee had reviewed advertisements in the Endocrine and Metabolic disorders therapeutic class published in the period April – June 2010. It had asked for a further explanation from Bayer regarding the claim ‘the gimmicks can go’ in advertisements for Testogel and Reandron 1000. The Monitoring Committee considered that the claim was unclear as to its meaning. Did it refer to other treatments that ‘can go’? The claim was unreferenced, therefore the Committee could not identify its source or meaning. The Committee requested that Bayer supply the references or evidence to support the claim which appeared in both advertisements.

The Monitoring Committee had reviewed Bayer’s response to these concerns but remained of the view that Bayer had not fully addressed them.

The Committee was of the view that the Bayer advertisements for Testogel and Reandron 1000 may not comply with the Medicines Australia Code of Conduct.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 1.3 – False or misleading claims
- 1.7 – Comparative statements

Response
Bayer Healthcare denied the advertisements breached either Section 1.3 or 1.7 of the Code. The tagline “When testosterone is restored, the gimmicks can go” is not a comparative claim. The gimmicks referred to in the claim are shown in an unambiguous manner and there is no suggestion in either advertisement that other testosterone replacements are not equally effective to Testogel and Reandron 1000. The tagline is not comparative. Bayer further stated that the tagline is not a claim and is substantiated through market research with GPs.

Bayer had provided substantiating evidence for the fact that when a man’s testosterone levels are restored there are positive effects on mood. Bayer denied that the tagline was misleading.

Code Committee decision
In a unanimous decision no breach of Section 1.3 or 1.7 of the Code was found

Consideration of the complaint
The Committee considered the concerns expressed by the Monitoring Committee about the two advertisements for Testogel and Reandron 1000 in which the statement ‘When testosterone is restored the Gimmicks can go’ is associated with visual images of fishing/hunting trophies being removed and a motorbike up for sale.

The Committee considered that the advertisements were acceptably clear in their message – that restoration of a man’s testosterone levels can restore his confidence and reduce the need for ‘gimmicks’ symbolic of male virility. Members did not consider that a prescriber would interpret the advertisements other than was intended. In a unanimous decision the Committee found that the tagline in the advertisements was not
misleading and was not in breach of Section 1.3 of the Code.

The Committee considered whether the tagline was an actual or implied comparison with other treatments. The Committee did not agree with the Monitoring Committee that the tagline was a comparative claim. The Committee agreed with Bayer Healthcare that the tagline was not making a claim about Testogel and Reandron 1000 beyond the fact that both products can restore testosterone levels. The Committee accepted that the tagline was intended to mean that when testosterone was restored the need for symbols of male virility can be reduced and that the advertised products can restore testosterone. There was no suggestion from the tagline, in the Code of Conduct Committee’s view, that Testogel or Reandron 1000 were superior to other testosterone replacement therapies. In a unanimous decision no breach of Section 1.7 of the Code was found.

Sanction
The Committee determined by unanimous decision that there was no breach of Sections 1.3 and 1.7, therefore no sanction was imposed.

Beat HepC Advertisement – 1069

Subject Company: Roche Products

Complainant: Health care Professional

Product: N/A

Complaint
Dr Bruce Short submitted a letter of complaint to the Therapeutic Goods Administration (TGA) in relation to an advertisement placed by Roche Products in the Sunday Telegraph’s Body+Soul magazine, with the tagline “I beat Hep C for my family”. The complaint was forwarded by the TGA to Medicines Australia for adjudication. The complainant alleged that the advertisement is overly emotive, misleading and confusing. Additionally, he alleges that Roche mislead the public by not acknowledging that they are suppliers of hepatitis C antivirals. Dr Short believes the advertisement to be distorted, incorrect and providing distorted and confusing information.

Sections of the Code
Materials alleged to be in breach of the following Sections of Edition 16 of the Code:
- 1.1: Nature and availability of information and claims
- 1.3: False or misleading claims
- 12.6: Educational information to the general public
- 12.7: Disease education activities in any media
- 12.7.7: Disease education activities in any media: Presence of pharmaceutical company name/logo in activity
- 12.8: Use of the internet
- 18: Discredit to an reduction of confidence in the industry

Response
Roche denied that the advertisement and associated website were in breach of the Code. Roche considers that the advertisement is a mechanism of a disease awareness campaign that points readers to the website. They contend that the website is balanced, informative and promotes awareness of all aspects of the disease and its management. Roche further note that a successful cure from hepatitis C is possible – the disease can be completely overcome and this effect can be sustained. This is supported by publicly-available material using the word ‘cure’ in the same context. Additionally, the emotive tone of the piece is not overt and is in line with disease awareness campaigns running in the community.

Roche supported its response to the complaint with advice from Hepatitis Australia that the use of the advertisement and website were entirely appropriate and that the
contents are fair, accurate, balanced and are not misleading and provides appropriate hepatitis C disease education information.

**Code Committee decision**
- In a majority decision no breach of Sections 1.1, 1.3, 12.6, 12.8 and 18 of the Code was found.
- In a unanimous decision no breach of Sections 12.7 and 12.7.7

**Consideration of the complaint**
The Committee was advised that this complaint was forwarded to Medicines Australia by the Therapeutic Goods Administration (TGA). Medicines Australia Secretariat staff used Dr Short’s complaint to the TGA to select the areas of the Code of Conduct to be answered in the complaint. The Committee acknowledged the Sections under consideration were broad. The Committee suggested to the Medicines Australia Secretariat that they consider offering the facilities of an independent facilitator to all complainants where a complaint is referred by the TGA.

The Committee discussed whether this advertisement was overly emotional in tone. The Committee considered the language used in the advertisement was in context and was used as common practice by the consumer groups representing the effected community. One member of the Committee felt that the use of the term “beat” was of main concern as it may be offensive to patients in the target audience who have failed treatment and giving the impression that by not beating the disease through treatment they are to be considered failures. The Committee felt that the target audience of this advertisement are those who have not yet received treatment, and is to encourage them to seek treatment.

The Committee noted that the messages in the campaign are to raise awareness of the disease and focusing on increasing the number of people seeking treatment for the disease. The majority of the Committee agreed that the messages were balanced and were in line with Government Health Policy on Hepatitis C.

The Committee agreed that taken in isolation the individual statements could be construed as overly emotive and unbalanced. However when taken in context as a whole campaign, the tone of the messages was in line with the Code of Conduct requirements. The Committee suggests that Roche consider adding a qualifier to the statement “I beat HepC for my family” to provide context and clarity to the reader.

The Committee considered the complaint relating to the statement “Ask your doctor for a referral for Hepatitis C” and noted that it is not technically incorrect, as patients receive a referral from a General Practitioner for a specialist clinician or clinic. The Committee acknowledged that the treatment of Hepatitis C can only be conducted through a Liver Clinic or in consultation with a Liver Specialist and that a referral for these services need to be provided after an initial consultation with a general practitioner. Therefore, the Committee agreed that there is no breach of the Code in this instance, but suggests that Roche could clarify the statement to read “Ask your doctor for a referral for a Liver Specialist or Liver Clinic”.

**Decision**
The Committee determined in a majority decision that the Beat Hep C advertisements were not in breach of Sections 1.1, 1.3, 12.6, 12.8 and 18 of the Code. Further, the Committee determined in a unanimous decision that there was no breach of Sections 12.7 and 12.7.7.
Subject Company: Merck Serono

Complainant: A member of the General Public

Product: Movectro

Complaint
The Complainant submitted a complaint to the Therapeutic Goods Administration (TGA) on 3 February 2011 that alleges that a piece aired on the Channel 7 nightly news program on 22 October 2010 was promoting the product directly to the General Public. The piece can also be found on www.youtube.com, and linked on the CCSVI Facebook Page (www.facebook.com/ccsviaustralia) and therefore accessible by members of the general public at any time. The complaint was forwarded by the TGA to Medicines Australia for adjudication.

Additionally, the Complainant alleges the piece to be misleading and unbalanced as it only highlighted the positive attributes of the product without providing any negative aspects or potential side effects.

Sections of the Code
Advertisements alleged to be in breach of the following Sections of Edition 16 of the Code:
- 12.1 General principles
- 12.3 Promotion to the general public
- 12.4 Product specific media releases
- 12.5 General media articles
- 12.6 Educational information to the general public
- 12.7 Disease education activities in any media
- 18 Discredit to an reduction of confidence in the industry

Response
Merck Serono outline that they had engaged a PR Agency (the Agency) to undertake a media campaign for health professionals in relation to this product. They advise that the news item was prepared by Channel 7 independently of Merck Serono, and that any information provided to the Agency to prepare the health professional media campaign did not contain any promotional statements, claims or comparisons.

Code Committee decision
In a unanimous decision the Committee found the advertisement to be in breach of Sections 12.1, 12.3, 12.5, 12.6 and 12.7 of the Code. Additionally, the Committee found by unanimous decision that there was no breach of Section 12.4 and by majority decision no breach of Section 18.

Sanction
- Pay a fine of $75,000

Consideration of the complaint
The Committee reviewed the clip in question as available through Youtube and Facebook. The Committee noted in their response, Merck Serono outlined that they had become aware of the potential news story on 15 October 2010, with the story being aired on 22 October 2010. The Committee acknowledges that other than obtaining a legal injunction, which would be difficult in 7 days, it is near impossible to prevent a news story from airing. However, the Committee was not given information to show whether Merck Serono had made any attempts to contact Channel 7 to correct or alter the segment prior to its airing.

The Committee advises that Merck Serono is responsible for the actions of agencies they employ to undertake activities on their behalf. The Committee agreed that ultimately Merck Serono had a responsibility to ensure that any materials stemming from those activities were fair and balanced. The Committee agreed that Merck Serono had ample opportunity to make enquiries and engage with the parties involved. The Committee agreed that without documented evidence of Merck Serono attempting to resolve the issue in the 7 days between becoming aware of the segment and its actual airing on Channel 7, they have no option to believe that Merck Serono made no attempt to prevent this activity occurring.
Further, the Committee noted that this segment is now available on a publically accessible websites (Facebook and Youtube) which widens the audience significantly, without the possibility of removal.

The Committee agreed that it was naïve of the Agency representative to speak with a medical journalist with no thought of potential consequence. One Committee member noted that Merck Serono’s brief provided to the Agency is fair and balanced. The Committee agreed this to be the case, however the lack of information of how the brief was distributed and Merck Serono’s actions to prevent or alter this story led the Committee to determining that this activity was a breach of the Code of Conduct.

The Committee considered the activity to be a mild to moderate breach of the Code of Conduct. While patient safety and prescribing habits were potentially not impacted by the activity, the Committee believed the resulting television segment and Facebook clip have the potential to greatly impact a small population of sufferers of the disease.

**Decision**
In a unanimous decision the Committee found the advertisement to be in breach of Sections 12.1, 12.3, 12.5, 12.6 and 12.7 of the Code. Additionally, the Committee found by unanimous decision that there was no breach of Section 12.4 and by majority decision no breach of Section 18.

**Sanction**
- Pay a fine of $75,000

**Appeal**
Merck Serono lodged an appeal against the Code Committee’s decisions in relation to its finding breaches of Sections 12.1, 12.3, 12.5, 12.6 and 12.7 of the Code.

Merck Serono stated in its written appeal that there was no promotion of a prescription product to the general public by Merck Serono or its Agent. It did not initiate any general media article concerning Movectro and did not attempt to encourage any publication or general media with the aim of promoting the product. Merck Serono’s Agent directed Channel 7 journalist to contact MS Research Australia. Merck Serono had no knowledge of the content of the news item before it went to air and was only notified of the possibility of a news story one day before it went to air. The company had no editorial rights over the information broadcast by Channel 7.

**Response to the Appeal**
The Complainant declined to make a written response to Merck Serono’s appeal or appear in person at the Appeal meeting. However the Complainant asked that the Committee note that the Complainant was not responsible for posting the news item on the CCSVI Australia website.

**Consideration of the Appeal**
The Chairman advised the committee that the Complainant had elected not to appear before the Committee to respond to the appeal and had provided no written response. The following summarises Merck Serono’s appeal presentation:

Merck Serono has been associated with the multiple sclerosis (MS) community for 10 years and is committed to compliance and working within the Code of Conduct. Merck Serono acknowledged that they hadn’t provided the Code Committee with sufficient information to adequately adjudicate the complaint and therefore took the opportunity to appeal in order to bring that information to the Appeals Committee’s attention.

Merck Serono, like other companies, will not be informed by media editors or journalists about information they have obtained from a range of sources and the company has no editorial control over a news broadcast. The material provided by Merck Serono to its Agent, was fair and balanced and this had been acknowledged by the Code Committee as recorded in the minutes.
Merck Serono contended that the Code Committee was misinformed with respect to the timeline of events leading up to the news item broadcast. Merck Serono had become aware of the possibility of a story being aired by Channel 7 only 1 day prior to it being aired. Merck Serono provided a timeline of events leading up to the story being aired:

- **15 October 2010**: Journalist’s initial enquiry to a representative of Merck Serono’s PR Agency at a social function.
- **15 – 20 October 2010**: PR Agency contacted the journalist to ascertain if Channel 7 were planning a news item. Channel 7 advised the Agency that they are unable to confirm.
- **21 October 2010**: Journalist/Channel 7 confirmed to the Agency that a news item is planned. Channel 7 did not indicate potential dates for screening. At this point, the journalist requested to speak with an expert in MS, and the Agency referred them to MS Research Australia (MSRA).
- **22 October 2010**: Channel 7 interviewed MSRA experts, and the news item was edited and aired during that evening’s news bulletin.

Merck Serono advised the Appeals Committee that it was informed through its Agent of interest from a journalist, but the Agency had not been given any confirmation that a news story would be aired, nor did they know its contents before it was aired. Merck Serono asserted that Channel 7 had sourced their story independently.

Merck Serono noted the Code Committee’s comments pertaining to the company’s failure to try to prevent the news item from being broadcast or change its content. Merck Serono challenged this view, because it would not have been possible to prevent the story from being aired, as it was sourced independently by a Channel 7 journalist.

Merck Serono argued that, through its Agent, they had taken appropriate steps to ensure the information provided to Channel 7 was balanced and accurate. The company has been advised by its lawyers that it had no legal grounds to demand that a media organisation provide it with any proposed news item prior to it being aired, and particularly when the company had no knowledge of the content of the media segment or any grounds to say that it was not accurate or balanced. Merck Serono considered that it was unreasonable for the Code Committee to conclude that it was in a position to alter the news story prior to it being broadcast.

Merck Serono reiterated to the Appeals Committee that it had taken no steps to post the segment on websites, and only became aware of its posting after MSRA brought it to its attention. Merck Serono contended that it cannot be held responsible for the actions of the Complainant or others in re-broadcasting the media segment on the public CCSVI Australia Facebook page. The segment does not appear to have been published on YouTube.

Merck Serono responded to each of the findings of breach by the Code Committee:

- **12.1 General principles** – there was no promotion of a prescription product to the general public by Merck Serono or its Agent. Nor did it engage in any activity that would bring discredit to the industry.
- **12.3 Promotion to the general public** – information about the product that was provided by Merck Serono to its Agent was educational, accurate and balanced. Merck Serono did not engage in any activity directed at the general public which encouraged a patient to seek a prescription.
- **12.5 General Media articles** – Merck Serono did not initiate any general media article concerning the product. Neither the company nor its Agent attempted to publish a general media article. The Agent had directed the journalist to independent sources for further information.
- **12.6 Educational information to the general public** – the Code Committee had acknowledged that the written information provided to its Agent was...
presented in a fair and balanced manner. The information provided by its Agent to the journalist was not in any way promotional.

- 12.7 Disease education activities in any media – any alleged disease education in the news item was provided by MSRA representatives. Merck Serono was not informed of the content of the news item or who may be interviewed.

Merck Serono responded to a number of statements in the original complaint:

- The complainant referred to the item as an advertisement – Response: The item was a news story, which was initiated by Channel 7; it was not an advertisement and no inducement was provided to Channel 7 to broadcast the story.
- The complainant referred to ‘the drug being spruiked’ by individuals representing MSRA and MS Australia – Response: The interviewees were a professor who is a leading authority on MS, and who did not refer to any particular medication. The individual from MS Australia was identified by Channel 7 independently through contact with MS Australia.
- The Complainant had commented that there are side effects from the medicine which were not mentioned in the news item – Response: The Therapeutic Goods Administration (TGA) had reviewed all data prior to approving Movectro in Australia. There has been no causal relationship established between Movectro and malignancy, but the Product Information recommends monitoring patients closely due to the mode of action of the medicine.
- The Complainant stated that Movectro has been refused marketing approval in North America and Europe. Response: Decisions by the US FDA and EU advisory committee were issued three to five months after the news item was aired. Merck Serono cannot be responsible for information about events which have not yet occurred.
- The Complainant stated that Merck Serono’s financial support for MSRA was not mentioned in the news item. Response: Merck Serono has provided some limited financial support to MSRA, including for work that was co-sponsored by three other industry partners. MSRA remains an independent organisation and is under no obligation to recommend any product.

- The Complainant argued that the reporting of Movectro by Channel 7 was biased and only mentioned the advantages of the product and therefore must be an advertisement. Response: Merck Serono reiterated that this was an independently sourced news item; it was not initiated by Merck Serono and it had no opportunity to view the item prior to broadcast.

Merck Serono concluded their presentation stating:

- It had no opportunity to review the news item prior to it being broadcast. It was informed that a story was planned one day prior to the broadcast but had received no indication of the date or time of broadcast.
- Merck Serono’s Agent was briefed to only use the material that had been provided by the company, which has been found by the Code Committee to be fair and balanced, and to refer any other queries to independent sources such as the TGA or MSRA.
- Neither the company nor its Agent took any steps to post the news item on Facebook or YouTube (and the item cannot be found on YouTube). The Code Committee appeared to have taken the availability of the item in the social media into account when making its decisions and determining the sanction. Merck Serono should not be held responsible for the actions by the Complainant or others in re-publishing the news item. The Code Committee had made its decisions based on unintentionally incomplete information originally provided by Merck Serono in its response to the complaint.

The Appeals Committee questioned Merck Serono on the TGA approval date for...
Movectro. Merck Serono advised the Committee that it was first approved by the TGA for MS on 2 September 2010.

The Appeals Committee asked what further information was provided to its Agent with the briefing document that was included in the agenda papers. Merck Serono advised that the briefing document was created by the company and its Agent through a series of meetings. The only other document that the Agent was approved to distribute was the Product Information. The briefing document was intended for the purpose of developing a media release for healthcare professional media only, and not for communication with the general media. Merck Serono advised that it did not create a similar document for the general media, as it was not their intention to engage the general media on this product. In answer to a question from the Committee about the lack of any information in the briefing document about the product’s side effects, Merck Serono responded that this was included in the PI, which would have been provided with the briefing document.

The Appeals Committee noted that the Channel 7 news item focussed on the availability of the ‘first ever tablet’ for MS, which appears in the briefing document given to Merck Serono’s Agent. Merck Serono assured the Appeals Committee that it was not their intention to use this document with general media, and that information regarding the availability of an oral treatment for MS would be available in many publicly available documents. The MS community had been aware for some time that an oral treatment would soon be available, and MS Australia and MSRA would be aware of this.

Merck Serono advised the Committee that it had not produced any briefing materials for the general media because it understood that if it had done so it would be at risk of being accused of promoting the product to the general public. The Agency is well informed about the Code requirements. The Agent had been instructed to refer any enquiries from the general media to independent sources such as the TGA and MSRA. The Committee noted the statements in the letter from the Agent to the Secretary of the Code Committee that the Agency had contacted the Channel 7 journalist, provided information about the registration and PBS listing status and had followed up with the journalist after that conversation to ask if a news story was planned. The Agent had referred the journalist to MSRA and other MS experts. The Chairman noted that an alternative approach would have been for Merck Serono’s Agent not to have contacted the journalist or not to have made any comment.

The Chairman thanked the Merck Serono representatives for their presentation. The Merck Serono representatives then left the meeting to allow the Appeals Committee to consider its decision.

The Appeals Committee discussed the briefing document provided to the Agent by Merck Serono and how it had been used during interactions with the Channel 7 journalist. The Appeals Committee agreed it was likely that the use of this document went beyond its original purpose of being solely for use with the professional media. The Appeals Committee did not agree with the Code Committee that this briefing document was fair and balanced. It included statements about the positive attributes of Movectro, but did not include any balancing information about precautions, interactions or side effects. Whilst not subject to any complaint in this instance, the Appeals Committee did not consider that the briefing document would meet the requirements of the Code in relation to media statements for the health professional media (Section 2.8). The Appeals Committee cautioned Merck Serono that any future briefing documents should contain balanced information about a product’s precautions and side effects.

The clinical expert advised other Committee members that the MS community is active and well informed. Movectro had been approved one month prior to the news item and there was considerable interest in the availability of an oral treatment at that time. The Committee agreed that community...
interest does not mean that it is acceptable for a company or its agent to provide promotional information about a prescription medicine to the general media.

The Appeals Committee discussed at length what role Merck Serono and its Agent had in the resulting news story. The Appeals Committee considered that the story was clearly promotional about Movectro. Both Merck Serono and its Agent, in its letter to Medicines Australia, acknowledged that the Agent had contacted Channel 7 following the initial enquiry from the journalist at a social event. There was no firm evidence provided by Merck Serono or the Agent of precisely what was said to the Channel 7 journalist or what written information was provided.

The Appeals Committee agreed with the Code Committee that it was inappropriate for the Agency representative to have pursued communication with the Channel 7 journalist. By its own admission, Merck Serono did not expect to be able to stop the story going to air or to edit its content. The Committee questioned Merck Serono’s Agent’s intent of contacting the journalist on more than one occasion following the initial inquiry at a social event. It was noted that Merck Serono stated that it had instructed its Agent not to engage with the general media.

The briefing document on Movectro apparently formed the basis for the discussion between the Agency and the Channel 7 journalist. The Appeals Committee acknowledged that Channel 7 may have obtained information for the story independent of Merck Serono’s Agent, but the primary topic of the news item was the availability of a new oral MS treatment, which is the same thrust as the briefing document.

The Appeals Committee reviewed a letter from the Executive Director of MS Research Australia to the Code of Conduct Secretary, dated 16 May 2011. MSRA advised that it was approached by Merck Serono’s Agent and asked to assist with proposed interviews with Channel 7. Merck Serono’s Agent evidently was involved in liaising between Channel 7 and MSRA. The Appeals Committee did not question the independence of the opinions expressed by the MSRA and MS Australia in their interviews, but it appeared from the MSRA letter that the Agency had a greater role than simply referring the journalist to MSRA.

The Appeals Committee disagreed with Merck Serono’s statements that it could not develop appropriate information for the general public when a new product becomes available. Whilst the focus should appropriately be on the professional media, there is always the potential for interest from general media in these activities. An appropriate, non-promotional document could be developed to respond to enquiries from the general media.

The Appeals Committee discussed the posting of the news item on CCSVI Australia’s Facebook page and the allegedly negative commentary about Merck Serono on that site. The Appeals Committee did not review the commentary and determined that it would not be considered as part of the decision making process.

The Appeals Committee acknowledged that there remained a degree of uncertainty about the involvement of Merck Serono’s Agent in this activity. However, based on the information provided by the company, the Agency and MSRA, on balance the Appeals Committee concluded that Merck Serono had some responsibility for the broadcast of the news item that promoted the benefits of Movectro. While accepting that Merck Serono could not prevent the publication of the segment by Channel 7, Merck Serono’s Agent’s communication to Channel 7, on more than one occasion, and its suspected use of the briefing document intended for a health professional audience was not consistent with the requirements of Section 12.5 of the Code, General media articles, and resulted in Merck Serono having a degree of responsibility for the outcome. The Appeals Committee unanimously upheld the decision of the Code Committee in finding a breach of Section 12.5 of the Code.
The Appeals Committee considered the other breaches found by the Code Committee. The Appeals Committee agreed that Merck Serono should have more fully responded to the complaint to the Code Committee.

In relation to Sections 12.6 and 12.7, the Appeals Committee concluded that Merck Serono had not published any educational information for the general public and had not engaged in a disease education activity. The Appeals Committee did not consider that these provisions were relevant to the conduct in question and unanimously found no breach of the Code, reversing the decision of the Code Committee.

In relation to Sections 12.1 and 12.3 of the Code, a majority of members did not consider that Merck Serono had engaged in an activity that directly promoted their product to the general product. The Appeals Committee considered that the activity complained of was most appropriately covered by Section 12.5 of the Code. In a majority decision, the Committee reversed the decision of the Code Committee and found no breach of Sections 12.1 and 12.3 of the Code.

Sanction
The Appeals Committee considered the sanction imposed by the Code Committee. Having reversed some of the decisions of the Code Committee the Appeals Committee determined to reduce the fine to $20,000.

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**Somatuline Autogel – 1071**

**Subject Company:** Ipsen

**Complainant:** Monitoring Committee

**Product:** Somatuline Autogel

**Complaint**
As part of its regular review cycle, the Medicines Australia Monitoring Committee reviewed advertisements published between April-June 2010 in the Endocrine and Metabolic Disorders therapeutic class. The Committee’s original review took place in August 2010, and the Committee made subsequent requests for further clarification in September 2010 and March 2011. Following its consideration of Ipsen’s responses, the Monitoring Committee considered that several claims in the advertisement for Somatuline were potentially misleading and unable to be substantiated and referred the complaint to the Medicines Australia Code of Conduct Committee.

**Sections of the Code**
Materials were alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.2 Substantiating Data
- 1.2.2 Level of substantiating data
- 1.3 False or misleading claims

**Response**
Ipsen stated in its response that the data used to substantiate the claims in the Somatuline advertisements had been evaluated by both the TGA and the PBAC. The TGA and PBAC had considered that the referenced study was adequate to support the indication for Somatuline to treat the rare condition carcinoid syndrome. Ipsen contended that the claim and qualifying statements accurately reflected the referenced study, including definitions included therein. Ipsen denied any breach of the Code.

**Code Committee decision**
In majority decisions no breaches of Sections 1.2, 1.2.2 and 1.3 of the Code were found.

**Consideration of the complaint**
The Committee noted that the complaint related to two advertisements for Somatuline, however as the claim referred to in the complaint was identical in both advertisements, only one of the advertisements was included in the agenda papers.

The Committee reviewed the study by Ruszniewski et al used to support the claim “Rapid and sustained improvement in the
symptoms of carcinoid syndrome” and the qualifying statement “significant improvement observed within the first week post-treatment and still observed after 6 months of treatment”. The Committee discussed the limited number of subjects included in the study. It accepted that carcinoid syndrome is an orphan disease with a small number of patients, making it difficult to conduct trials in a larger population. The Committee agreed that the sample size should not discount the validity of the study. The Committee considered that the Ruszniewski paper provided limited information for readers to be able to fully understand the statistical analysis, however it accepted that the paper had been published in a peer reviewed publication and was most likely the best available data in the field of carcinoid syndrome. The results reported in the study were statistically significant and were adequate to substantiate the claims for Somatuline. In a majority decision no breach of Section 1.2 or 1.2.2 was found.

The Committee discussed the results reported in the Ruszniewski et al study, which showed that Somatuline (Lanreotide) was effective in reducing the symptoms of diarrhoea or flushing. The Committee noted that the study showed that Lanreotide had greater efficacy in reducing the frequency of flushing than of diarrhoea (65% of patients with flushing as the target symptom and 18% of diarrhoea target patients achieved greater than 50% reduction from baseline). The Committee discussed whether the claim “Rapid and sustained improvement in the symptoms of carcinoid syndrome (diarrhoea or flushing)” implied that Somatuline was effective in improving both symptoms equally and therefore could be considered to be misleading. A majority of the Committee considered that the claim did not imply that the symptoms were both equally improved by lanreotide. It was also noted that the number of clinicians treating patients with Carcinoid Syndrome is very small and it is a highly specialised area of medicine. Further, Somatuline is only available under Section 100 (highly specialised drugs) of the PBS. The Committee made the assumption that the audience for this advertisement would therefore be aware that diarrhoea is less responsive to this type of treatment than flushing. One Member noted that the claim was directly quoted from the study and that it is supported by the evidence within the study. A minority of the Committee considered that the claim was a broad statement that did imply that Somatuline was equally effective in improving both symptoms and should have been better qualified. In a majority decision the Committee determined that the claim was not misleading and was not in breach of Section 1.3 of the Code.

The Committee discussed the qualifying statement “significant improvement observed within the first week post-treatment and still observed after 6 months of treatment”. It was noted that in Figure 1 in the Ruszniewski study showed that the improvement was demonstrated at the end of the first week, rather than ‘within’ the first week, but accepted that this was a pedantic, semantic interpretation of the qualifying statement. The Committee suggested that the qualifying statement could be amended to more accurately reflect the results of the study. In a majority decision the Committee found no breach of Section 1.3 of the Code.

The Chairman raised with the Committee the procedures followed by the Monitoring Committees in reviewing the materials provided by Ipsen and the company’s responses to the Committee’s requests for further information and explanation. It appeared to the Code Committee that the Monitoring Committee had not made the issues about which it had concerns about sufficiently clear to Ipsen before referring the matter to the Code Committee. The matter of the validity of the Ruszniewski study as substantiating data had arisen following Ipsen’s response. The Code Committee considered that Ipsen should have been given an opportunity to respond to the issue of the validity of the study before the complaint was forwarded to the Code Committee.
One Committee Member noted that the Ipsen’s response to the complaint included a Clinical Expert Statement which supported the company’s response. The member noted that this expert opinion would have been paid for by Ipsen and would only have been submitted to the Code Committee if it supported the company’s position. The Committee considered that it has the appropriate membership to form an opinion on the evidence presented in a complaint and response. It does not assist the Committee in its deliberations to receive an expert opinion prepared at the request of a Complainant or Subject Company.

**Decision**

The Committee determined by majority decision that the claim and qualifying statements in the advertisements were not in breach of Sections 1.2, 1.2.2 and 1.3 of the Code of Conduct.

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**Exforge and Exforge HCT – 1072**

**Subject Company:** Novartis  
**Complainant:** Merck Sharp & Dohme (MSD)  
**Product:** Exforge and Exforge HCT

**Complaint**

The Complainant alleged that the promotional claim “POWER* of the X Factor” in an advertising campaign for Exforge and Exforge HCT was misleading because it created a perception of superiority which could not be substantiated. MSD alleged that the use of the term “X Factor” was not unlike a unique superlative and was inherently comparative, and is not supported by the PI or the body of literature.

MSD had sought to resolve these matters via intercompany dialogue, where Novartis had agreed to reference the Blood Pressure lowering qualifier for the claim. However MSD’s main issue concerning this promotional claim had not been resolved.

**Sections of the Code**

Materials alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.1 Responsibility  
- 1.3 False and misleading claims  
- 1.5 Unqualified superlatives  
- 1.7 Comparative statements

**Response**

Novartis denied that its advertisements were in breach of the Code. Novartis argued that the heading “X Factor” is a stylised play on the “X” icon in the Exforge product name, and denied that it implied superiority, or is a comparative claim. Novartis stated that the heading is not a product claim and is not comparative and does not suggest that Exforge and Exforge HCT have special or unique qualities.

**Code Committee decision**

- In unanimous decisions breaches of Sections 1.1, 1.3 and 1.5 of the Code were found.  
- In a majority decision no breach of Section 1.7 was found

**Sanction**

The Code Committee had determined that Novartis should

- Cease using the claim found in breach of the Code and the advertisements in their current format and not use the claim in any future promotional materials or advertisements  
- Pay a fine of $50,000

**Consideration of the complaint**

The Committee first discussed Novartis’ assertion that the “X Factor” heading is merely a stylised play on the ‘X’ in the product logo and is merely a branding device and not a product claim. The Committee disagreed with Novartis’ assertion; members unanimously agreed that the statement “the power of the X Factor” was a product claim that related to the products Exforge and Exforge HCT. The claim clearly relates to the products, which are a combination of two or three
antihypertensive agents, and it is qualified by the words ‘BP lowering’.

The Committee considered the meaning of the phrase “the X Factor” as it appeared in the advertisement in combination with the graphic imagery used of a stylised sword or arrow pointing downwards. The Committee considered that “the X Factor” was intended to represent a special quality of the product (in each advertisement) and that it inferred that the product was superior or there were synergistic effects from the two/three active ingredients in the medicine, and that this could be substantiated.

The Committee did not agree with Novartis argument that the term “X Factor” had no accepted meaning or that healthcare professionals would not infer some meaning from it. The Committee considered that the phrase has a commonly understood meaning in society, including health professionals, which is of a quality or phenomenon that cannot be fully described or identified but which confers something beneficial or superior to the person or object. In the advertisements subject to the complaint, the term would be interpreted as giving ‘power’ to the advertised products. The claim “the power of the X Factor” infers that there is something special or different about the products and this was the intention of Novartis when using it in the advertisements. The Committee noted that there is no evidence that the combination antihypertensive products Exforge and Exforge HCT have any special or unique characteristics beyond the accepted efficacy of the individual active ingredients. The claim was therefore misleading and unable to be substantiated. The Committee unanimously determined that the claim “the power of the X Factor” was in breach of Sections 1.1, 1.3 and 1.5 of the Code.

The Committee discussed whether the claim was a hanging comparative or implied superiority to other antihypertensive medicines. Some members of the Committee considered that the claim implied that Exforge and Exforge HCT were better or more powerful than other products in the class or other combination antihypertensive products. Other members of the Committee considered that the claim implied superiority of the combination products but not in a directly or indirectly comparative manner. In a majority decision the Committee concluded that the claim was not a hanging comparative and therefore was not in breach of Section 1.7 of the Code.

The Committee agreed that the advertisements had the potential to influence prescribing habits of doctors but did not have any safety implications for patients and therefore considered this to be a moderate breach of the Code.

**Decision**
The Committee determined by unanimous decisions that the claim was in breach of Sections 1.1, 1.3 and 1.5 of the Code of Conduct. The Committee determined by majority decision that the claim did not breach Section 1.7 of the Code.

**Sanction**
The Committee discussed whether corrective advertising or a corrective letter should be required, as proposed by MSD. The Committee noted that a corrective letter and a corrective statement had previously been issued by Novartis in relation to other claims for Exforge and Exforge HCT that had been questioned by MSD. Members who were not in favour of a corrective advertisement were concerned that it should not provide another opportunity for Novartis to state the misleading claim, or to create confusion in the minds of readers. Also, the Committee had agreed that there was no risk of patient harm. The Committee concluded by a majority decision that a corrective advertisement or corrective statement should not be imposed by the Committee.
The Committee determined that Novartis should:

- Cease using the claim found in breach of the Code and the advertisements in their current format and not use the claim in any future promotional materials or advertisements
- Pay a fine of $50,000

**Appeal**

Novartis lodged an appeal against the findings of the Code Committee on the grounds that the Committee had erred in its reasoning in finding breaches of the Code and had incorrectly found that the expression “X Factor” carried a meaning of superiority either generally or to other drugs in its class.

Novartis asserted that the term “X Factor” is not a product claim, which is reinforced by the graphical similarity between the stylised ‘X’ used in the headline and in the product name. Novartis maintained that the expression “X Factor” is intended to raise the profile of the drug’s name in the eyes of the intended audience, but did not convey any claim about its efficacy or superiority.

**Response to the Appeal**

MSD maintained its original assertion that the overarching perception created by the Exforge marketing materials is that the product has, and is, the “X Factor” and thus is extraordinary. MSD asserted that the use of the term “X Factor” in association with Exforge and Exforge HCT attributed special merit to the products and implied superiority that cannot be substantiated in every respect.

**Consideration of the Appeal**

The Chairman invited the Appellant to present the appeal to the Committee. The following is a summary of that presentation:

Novartis takes its responsibilities under the Code of Conduct seriously and considered that the decision by the Code Committee warranted the lodgement of an appeal. This is the first time Novartis has made an appeal under the Code of Conduct, indicating the seriousness with which it takes the matter.

Novartis asserted that the Code Committee made an error in its findings. Novartis reiterated its original argument that the term “POWER* of the X Factor” is a play on words and denied that the term conveys any special qualities or superiority of the products.

Novartis contended that the term is not a promotional claim. It does not convey medical attributes of quality, efficacy or safety of the products. Novartis argued that it is purely a question of law in misleading conduct. The term is purely a play on words intended to raise awareness of the brands Exforge and Exforge HCT.

Novartis described how it had coined the term “X Factor”. It had engaged an external marketing agency to develop brand awareness initiatives for the Exforge group of products. The external agency had conducted market research with general practitioners which showed that the GPs found it difficult to remember the brand name. Novartis acknowledged that its products Exforge and Exforge HCT were late entering the market - there were already a number of brands on the market in the same category. Novartis’ intention with the promotional campaign was to raise the awareness of the product with prescribers. Novartis believe that the activities it undertook were in line with general marketing principles of brand awareness.

Novartis introduced three examples of promotional material for the Committee’s review. The Chairman identified these items as Exhibit 1 – Obama ’08; Exhibit 2 – Kellogg’s; and Exhibit 3 – Target. Novartis noted that in each example the key symbol in each of the advertisements was synonymous with the brand and leveraged off a letter or logo for brand recognition. It was Novartis’ intention to link the stylised ‘X’ in Exforge with the brand, in much the same way the ‘K’ in Kellogg’s Special K and the target icon in Target was synonymous with those brands, thereby identifying the brand in the eye of the target audience and leveraging the logo to represent the particular product.

Novartis further contended that the term ‘X Factor’ is not comparative. The letter ‘X’ in ‘X Factor’ is the same as the stylised ‘X’ in the product name trademark. The large stylised
‘X’ points to the brand name in the bottom right corner of the advertisement. The advertisement contains only one drug name (Exforge) and it does not mention a relevant comparator or class of drugs with which a comparison could be made. The word “Power*” is linked by the superscript asterisk to “blood pressure lowering” and was not making a comparison to another drug.

Novartis identified a number of areas where it considered that the Code Committee had erred. Firstly, the interpretation of the term “misleading”, which Novartis argued should be interpreted in the same manner as Australian consumer law. Novartis argued that it is necessary to identify the particular class of persons who are likely to be misled, and to identify who would fall in that relevant class. In support of this argument, Novartis cited Taco Co of Australia Inc V Taco Bell Pty Ltd (1982) ALR 177. Novartis stated that the advertisements were only directed to healthcare professionals who are the relevant class of persons when considering whether the advertisements were misleading. Novartis argued that healthcare professionals are not ordinary members of the public; they receive rigorous and ongoing training, understand clinical pharmacology and are aware of the competitive nature of the therapeutic class. Therefore, Novartis argued that healthcare professionals would not be misled by the term ‘X Factor’ and would only construe the words as a play on words or marketing puffery.

Novartis then addressed the substantive arguments why the advertisements were not in breach of the Code. In relation to whether the term ‘X Factor’ conveyed uniqueness and superiority, Novartis had conducted a Google search of the term ‘X Factor’ and was presented with 1.43 million references to the term; many of these referred to a particular reality television show. Novartis considers it inappropriate to compare prescription pharmaceutical products to a reality television show. Further, Novartis considered that MSD had selectively chosen references in its complaint that conveyed a meaning of superiority and only these were highlighted to the Code Committee. As part of its research, Novartis had also found responses that defined “X Factor” as “hard to describe” and “a coagulation”. On that basis Novartis argued that the term has no singular meaning and therefore cannot be construed as conveying one particular meaning of superiority.

Novartis argued that a second error made by the Code Committee was that it considered that the term ‘X Factor’ was intended to convey superiority. Novartis argued that the Code Committee should not have considered intent as part of its reasoning because intent is not relevant to whether conduct is misleading. Also, if intent was to be taken into account, Novartis should have been given the opportunity to respond to this proposition to the Code Committee. Novartis asserted that this alone should be sufficient for the Appeals Committee to set aside the Code Committee’s decision.

In responding to the Code Committee’s reasoning that the term inferred that there were synergistic effects from the combination of actives, Novartis contended that this was not a meaning that could be construed from the advertisements and this argument could be substantiated. Novartis stated that it is required by the Code to state the active ingredients of the products and the visual representation of the combination of actives does not convey a synergistic effect or infer superiority.

Novartis argued that it was not open to the Committee to find that the statement claimed uniqueness or superiority because no comparator product or therapeutic class is mentioned in the advertisement. Furthermore, Novartis argued that this reinforces that the term ‘X Factor’ is a play on words, or marketing puffery. The Code Committee had found no breach of Section 1.7 of the Code, which relates to comparative statements and hanging comparatives. It therefore should also have found no breach of Section 1.3 because the term does not imply or infer comparative superiority or uniqueness.
Novartis responded to aspects of MSD’s written response to the appeal. Novartis noted that MSD had stated that the advertising campaign had “ramped up” and that new material supported this fact. Novartis advised the Appeals Committee that the campaign was launched in February 2011. The advertisement referred to in the MSD appeal response – ‘Write the Factor’ – was part of the original campaign. There had been no escalation in the campaign. Novartis argued that this material actually demonstrates that the advertisements were just drawing attention to the product name.

In concluding its appeal presentation Novartis asserted that even if the Appeal Committee agrees with the decision of the Code Committee, the Code Committee had erred in the level of sanction imposed by not considering Novartis’ previous good conduct; nor did the Code Committee apparently review previous conduct and decisions under Section 1.5 and associated sanctions.

Novartis reiterated that it considered that the Code Committee had made fundamental errors that were not consistent with established law on misleading and deceptive conduct. The Committee had made errors in its reasoning for finding that the term ‘the X Factor’ was misleading and claimed superiority or uniqueness. Novartis requested that the Appeals Committee set aside the Code committee’s decision and review the matter afresh and on the basis of the information supplied by Novartis, the Appeals Committee should set aside the original decision. If the Appeals Committee decides that the Code Committee’s decisions were correct in finding breaches of the Code, Novartis maintained that the sanctions imposed were wrong and unreasonable compared with similar conduct found in breach of the Code.

The Chairman invited the MSD representative to provide its response to the Appeal:

MSD noted that Exforge is one product in a therapeutic class where there are a number of competitors, both single and combination therapies. The products in this class all have similar tolerability, safety and efficacy profiles. MSD consider that the advertisements that include the term ‘X Factor’ convey that Exforge is superior amongst its peers in the therapeutic class.

MSD believe that Australians (including healthcare professionals) are aware of the reality television program The X-Factor. Competitors on that show display qualities of uniqueness and superiority. Australians (including healthcare professionals) would also be familiar with the X Men films which depict people with unique qualities which make them superior. MSD asserted that an Australian healthcare professional would link the term ‘X Factor’ with a meaning of superiority and unique qualities.

MSD also conducted an internet search on the term “X Factor” and also identified some1.43 million references. While there were a number of meanings for the term, the most common meanings conveyed superiority and uniqueness.

MSD argued that the Exforge/Exforge HCT campaign had escalated over time. MSD tabled two exhibits – the first included an A5 image of an Exforge advertisement and a copy of an Exforge sales aid, each containing claims relating to using Exforge in uncontrolled hypertensive patients. The Chairman identified this document as Exhibit 4. The second document tabled by MSD contained four images of Exforge advertisements. The Chairman identified this document as Exhibit 5. The top right image in Exhibit 5 was an advertisement that contained the X-sword image forming “Xtraordinary Power”. MSD stated that this advertisement was subject to complaint by MSD about a number of claims and statements that were resolved between MSD and Novartis through intercompany dialogue. This resulted in Novartis sending a corrective letter to healthcare professionals who had seen the advertisement. Exhibit 5 included three other images – the
advertisement that is subject to this complaint, and two other items stating ‘Write the X Factor’ and ‘Experience the X Factor’. MSD stated that these demonstrate that the advertising campaign has changed over time and is not just marketing puffery or a play on words. The advertisements leave the impression that the product is special, unique or extraordinary, which is misleading and in breach of the Code.

MSD reaffirmed its agreement with the Code Committee’s decisions and asked that the Appeal Committee upholds those decisions.

Following this presentation, Novartis made its closing statement:

Novartis consider that it was inappropriate for MSD to bring to the attention of the Appeals Committee matters that have been through intercompany dialogue. Novartis reiterated that these materials in Exhibit 5 were part of the original campaign released in February 2011. Novartis advised that the corrective letter sought to qualify the extent of blood pressure lowering by Exforge, and was not directly related to the claims at the centre of the complaint before the Committee. Exhibit 4 advertisements show that Novartis had included “BP lowering” as a qualifier for “Power” as a result of a complaint from MSD. Novartis reiterated to the Appeals Committee that this matter was fundamentally a legal issue as to the interpretation of the term ‘X Factor’.

The Chairman thanked the Novartis and MSD representatives for their presentations and asked them to leave the meeting to allow the Committee to consider its decision.

The Appeals Committee discussed Novartis’ argument that the Code Committee had erred in attributing an interpretation of Novartis’ intent in using the term ‘X Factor’. The Appeals Committee agreed that intention is not relevant to whether something is misleading. It is not relevant what Novartis’ intent was in using the term ‘X Factor’ in its advertising materials; it is the result or outcome of the conduct that is relevant in determining any misleading conduct.

The Appeal Committee discussed Novartis’ argument that the interpretation of Section 1.3 concerning false and misleading claims should be the same as that in Australian Consumer Law. As noted above, although it is guided by those legal precedents, it is not prescriptively bound by them. The Appeals Committee acknowledged the Taco v Taco Bell principle and agreed that the class of persons who may be affected by the advertisements would be healthcare professionals. The Appeals Committee considered that the Code of Conduct Committee would have understood that the relevant audience for the advertisements were health professionals. The Appeals Committee noted that both Novartis and MSD agreed that healthcare professionals were the correct class of persons to whom the materials were directed. Novartis had argued that healthcare professionals would only regard the claim ‘Power of the X Factor’ as a play on words or puffery. The Appeals Committee then considered argument for what a reasonable healthcare professional
would interpret from this claim in the Exforge advertisements.

The Appeals Committee determined that although other advertisements for Exforge had been tabled in evidence before the Committee, its task was solely to consider the advertisements subject to the complaint. The advertisements in Exhibits 4 and 5 were disregarded except for the single included advertisement which was subject to complaint.

The Appeals Committee noted that there are a number of antihypertensive products in the therapeutic class; some companies use the word “power” in their advertising for these products. Whilst much of Novartis’ argument was directed solely at the words ‘the X Factor’, the words appeared in the advertisements as ‘Power of the X Factor’, with ‘Power’ linked to a qualifier ‘BP lowering’. The Committee considered that the combination of the word ‘power’ with ‘the X Factor’ in the claim ‘Power of the X Factor’ does imply that there is something unique or special about the product. The imagery in the advertisement combined with the claim would convey to a reasonable health professional reader that this product has unique or special qualities, which could not be substantiated. The Appeals Committee agreed that the claim “Power of the X Factor” gave the impression that Exforge or Exforge HCT offered something stronger or more powerful as an antihypertensive, which was false and misleading and implied a special merit that could not be substantiated. The Appeals Committee agreed that however well educated and informed the audience might be, they are still able to be misled. The Appeals Committee unanimously agreed with the Code Committee’s decision that the claim “Power of the X Factor” was in breach of Sections 1.1, 1.3 and 1.5 of the Code.

The Appeals Committee considered Novartis arguments that the Code Committee had erred because it had failed to identify any comparator product against which the claim of superiority or special merit should be assessed. The Appeals Committee noted that the claim was qualified as being related to ‘BP lowering’, which therefore led to a comparison with other products in the class. However, the Appeals Committee also noted that the Code Committee’s finding of a breach of Section 1.3 had evidently flowed from the implication of a unique quality or special merit in terms of Section 1.5 of the Code, which does not require a specific comparator to be identified. The Appeals Committee considered that the Code Committee’s reasoning was correct on this point. The Appeal Committee noted that no breach was found of Section 1.7 of the Code.

The Appeal Committee considered Novartis’ written appeal in sub-point 5.4 and the argument that the Code Committee had chosen an interpretation of the term not alleged in the complaint. The Appeals Committee considered that the Code Committee had all the materials and argument presented by both Novartis and MSD in the complaint and response and could have taken any or all of the meanings attributed to the term as the basis for its decisions.

The Appeals Committee discussed Novartis’ arguments that the sanctions imposed by the Code Committee were unreasonable and excessive. The Appeals Committee noted that the Code Committee had determined the breaches to be moderate and it was open to the Committee to impose a fine from zero to $150,000. The fine of $50,000 was not at the upper end of this scale and was below the middle range. The Appeals Committee unanimously agreed that the sanctions
imposed by the Code Committee were appropriate.

The Appeal Committee unanimously agreed to uphold the decisions of the Code Committee. The Appeals Committee also unanimously agreed to uphold the sanctions imposed by the Code Committee and reinforced to Novartis that this includes the prohibition of using the term “X Factor” and the broader claim as identified in the complaint as “Power of the X Factor”.

Sanction
The Appeals Committee considered the sanction imposed by the Code Committee. Having upheld all decisions of the Code Committee, the Appeals Committee determined to maintain the Sanctions imposed by the Code Committee and reaffirmed that a fine of $50,000 should be imposed. Furthermore, the Appeals Committee confirmed that Novartis must cease using the claim found in breach of the Code and the advertisements for Exforge and Exforge HCT in which this claim appears in their current format and not use the claim in any future promotional materials or advertisements.
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 2010-2011.

**Educational Event Reports**

In accordance with Section 28.2.2 of Edition 16 of the Code of Conduct, the Monitoring Committee commenced its annual review of educational event reports. The Chairman randomly selected three months from the preceding 12 month review period, and in May 2011 the Monitoring Committee commenced this review with a subsequent meeting held in June 2011. The Monitoring Committee reviewed reports from the months July 2010, November 2010 and March 2011 which included over 9,000 events for review, from 38 companies. At the time of this report, the Monitoring Committee has sought further information from 25 companies regarding events held during the reviewed months. The Monitoring Committee anticipates the completion of this review at the end of August 2011, with any events which may be in breach of the Code of Conduct referred to the September 2011 Code of Conduct Committee meeting for its decision.
<table>
<thead>
<tr>
<th>Table 10</th>
<th>Summary of materials and activities reviewed by the Monitoring Committee 2005-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alimentary System</td>
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<tr>
<td>Cardiovascular System</td>
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<tr>
<td>Central Nervous System</td>
<td></td>
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<tr>
<td>Analgesia</td>
<td></td>
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<tr>
<td>Musculoskeletal System</td>
<td></td>
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<tr>
<td>Endocrine &amp; Metabolic Disorders</td>
<td></td>
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<tr>
<td>Genitourinary System</td>
<td></td>
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<tr>
<td>Infections &amp; Infestations</td>
<td></td>
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<tr>
<td>Neoplastic Disorders</td>
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<tr>
<td>Immunology</td>
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<tr>
<td>Respiratory System</td>
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<tr>
<td>Allergic Disorders</td>
<td></td>
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<tr>
<td>Ear, Nose &amp; Oropharynx</td>
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<tr>
<td>Eye</td>
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<tr>
<td>Skin</td>
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<td>Surgical Preparations</td>
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<tr>
<td>Contraceptive Agents</td>
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<tr>
<td>Reviews across all therapeutic classes</td>
<td>Invitations to educational meetings</td>
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<tr>
<td></td>
<td>Websites</td>
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<tr>
<td></td>
<td>Patient education</td>
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<td>Websites</td>
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</tbody>
</table>

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### Table 11
Summary of materials and activities reviewed by the Monitoring Committee in 2010-2011

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Types of material or activity subject to review</th>
<th>Number of companies</th>
<th>Number of items</th>
<th>Number of meetings to undertake review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocrine and Metabolic Disorders</td>
<td>Advertisements</td>
<td>11</td>
<td>110</td>
<td>1</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>Competitions</td>
<td>5</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Skin</td>
<td>Printed Advertisements</td>
<td>2</td>
<td>4</td>
<td>0.5</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>General Company Websites</td>
<td>29</td>
<td>29</td>
<td>1.5</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Market Research with healthcare professionals</td>
<td>26</td>
<td>150</td>
<td>2</td>
</tr>
<tr>
<td>Analgesia</td>
<td>Printed promotional material</td>
<td>8</td>
<td>30</td>
<td>1</td>
</tr>
<tr>
<td>Neoplastic</td>
<td>Advertisements</td>
<td>9</td>
<td>25</td>
<td>1</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Prescribing Software</td>
<td>5</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Contraceptive Agents</td>
<td>Printed Promotional Material</td>
<td>3</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>Nose and Oropharynx &amp; Eye</td>
<td>Printed Promotional Material</td>
<td>6</td>
<td>31</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>402</strong></td>
<td><strong>11</strong></td>
<td><strong>11</strong></td>
</tr>
</tbody>
</table>

**Referrals to the Code of Conduct Committee**

The Monitoring Committee may refer any material or activity to the Code of Conduct Committee for review if it considers there is a potential breach of the Code of Conduct. From its reviews in 2010-2011 the Monitoring Committee referred promotional material and an advertisement from Ipsen and Bayer pertaining to the Endocrine and Metabolic Disorders Review to the Code of Conduct Committee for determination. The outcomes of these complaints can be found on page 93 and 83 of this report respectively.
Outcomes of the Monitoring Committee review of materials and activities 2010-2011

Endocrine and Metabolic Disorders

The Committee reviewed 110 advertisements from member companies with products in this therapeutic area.

Items were provided by the following companies:

- Bayer
- Eli Lilly Australia
- GSK
- Ipsen
- Janssen
- MSD
- Novartis
- Novo Nordisk
- Roche
- Sanofi-aventis
- Servier

The Monitoring Committee did not identify any general issues across the advertisements. The Committee sought feedback in relation to items from Bayer, Ipsen and MSD. Following the review of company responses, the Committee determined that promotional material and an advertisement submitted by Ipsen and Bayer should be forwarded to the Code of Conduct Committee for a determination on a potential breaches of the Code. The outcomes of these complaints can be found on page 90 and 81 of this report respectively.

Musculoskeletal System

The Monitoring Committee reviewed 18 competitions in the musculoskeletal system therapeutic class.

Submissions were received from the following companies:

- Abbott
- Boehringer Ingelheim
- Ipsen
- MSD
- Pfizer

The Monitoring Committee did not identify any general issues across the competitions. The Committee sought feedback from Abbott relating to educational content and prize value. Following the review of company responses, the Committee determined that no competitions should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Skin

The Monitoring Committee reviewed 4 advertisements.

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

- CSL
- Sanofi-aventis

The Monitoring Committee did not identify any general issues across the advertisements. The Committee sought feedback from CSL regarding two items submitted. Following the review of CSL’s response, 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.
Corporate Websites

The Monitoring Committee reviewed 29 corporate websites from the following companies:

- Abbott Australasia
- Abbott Products (Solvay)
- Alcon
- Allergan
- Amgen
- AstraZeneca
- Baxter
- Bayer
- Biogen Idec
- BMS
- Celgene
- CSL
- Eli Lilly
- GlaxoSmithKline Australia
- MSD
- Novartis
- Pfizer
- Roche
- Sanofi-aventis
- Invida
- Ipsen
- Janssen
- Lundbeck
- Merck Serono
- Norgine
- Novo Nordisk
- Nycomed
- Shire
- Smith & Nephew
- UCB

The Monitoring Committee did not identify any general issues across the promotional material. The Committee sought feedback in relation to 15 websites. The Committee noted the considerable improvement in corporate websites when compared to those reviewed in 2008-2009.

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

Market Research with Healthcare Professionals

The Monitoring Committee reviewed 150 items of market research from the following companies:

- Abbott Australasia
- Abbott Products
- Allergan
- Amgen
- AstraZeneca
- Baxter
- Bayer
- Biogen Idec
- BMS
- Boehringer Ingelheim
- Celgene
- CSL
- Eli Lilly
- Gilead
- GSK
- iNova
- Janssen
- Merck Serono
- MSD
- Mundipharma
- Nycomed
- Pfizer
- Roche
- Sanofi-aventis
- Servier
- Shire
- UCB

The Monitoring Committee sought feedback from Abbott Products, AstraZeneca, and Roche. Following the review of company responses, the Committee determined that no items of market research should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.
Analgesia

The Monitoring Committee reviewed 30 items of printed promotional material from the following companies:

- AstraZeneca
- BMS
- CSL
- Janssen
- iNova
- Mundipharma
- Pfizer
- Sanofi-aventis

The Monitoring Committee sought feedback on from BMS, CSL, iNova and Janssen. Following the review of company responses, the Committee determined that none of the printed promotional material should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Neoplastic

The Monitoring Committee reviewed 25 advertisements from the following companies:

- AstraZeneca
- Celgene
- GSK
- Ipsen
- Janssen
- Novartis
- Pfizer
- Sanofi-aventis
- Shire

The Monitoring Committee sought feedback from AstraZeneca, Celgene, Ipsen, Novartis, Pfizer, Sanofi-aventis and Shire.

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.

Prescribing Software

The Monitoring Committee reviewed 5 pop-up communications published in prescribing software from the following companies:

- Alphapharm
- Eli Lilly
- MSD
- Pfizer
- Sanofi-aventis

The Monitoring Committee did not identify any general issues with the pop-ups in the prescribing software. During the course of this review, the Monitoring Committee also viewed a pop-up reminder from Alphapharm. As Alphapharm is not a member of Medicines Australia, the Committee referred comments regarding the material to the Generic Medicines Industry Association for their consideration.

The Committee determined that no pop-up communication should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.
Contraceptive Agents

The Committee reviewed 20 items of printed promotional material from the following companies:
- Bayer
- MSD
- Pfizer

The Committee sought clarification from all three companies. Responses to these requests are due to be reviewed at the July 2011 Monitoring Committee meeting.

Eye, Ear, Nose and Oropharynx

The Committee reviewed 31 items of printed promotional material from the following companies:
- Alcon
- Allergan
- AstraZeneca
- Bayer
- Boehringer Ingelheim
- GSK
- iNova
- MSD
- Norgine
- Novartis
- Pfizer
- Sanofi-aventis

The Committee sought clarification from Alcon, Allergan, GSK and Pfizer. Responses to these requests are due to be reviewed at the August 2011 Monitoring Committee meeting.