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As the Chairman and the Chief Executive Officer of Medicines Australia we congratulate Member companies and the Secretariat on their achievements this year. The 2014-2015 Code of Conduct Annual Report provides an overview of these achievements.

This year, consistent with global standards for the innovative medicines industry, Medicines Australia’s Members demonstrated very high standards of ethical conduct when they engaged with healthcare professionals, consumers and other stakeholders. Member companies have maintained their very high level of Code compliance.

Through implementing Code Edition 18 and the new transparency model, the innovative Australian medicines industry is putting patients first by demonstrating the value of industry partnerships and taking the lead to boost transparency. The new Code builds on 55 years of successful, responsible, ethical industry self-regulation.

Code of Conduct Authorisation

On 24 April 2015, the Australian Competition and Consumer Commission (ACCC) published its final determination, granting 5 years’ authorisation for Code of Conduct Edition 18. This was the culmination of almost 10 months’ discussion and negotiation between Medicines Australia, the ACCC and interested stakeholders. Although the authorisation included several conditions relating to the details of the transparency model in the Code, we are very pleased to have achieved this important, positive outcome for Medicines Australia’s Members.

In its media release announcing the authorisation, ACCC Commissioner Dr Jill Walker commended Medicines Australia for introducing transparency about payments provided to individual doctors.

Following authorisation, Code Edition 18 came into effect on 16 May 2015 and the new transparency requirements will commence on 1 October 2015.

Medicines Australia moved swiftly following authorisation of the Code to implement the required changes to the Code relating to the transparency model. At a General Meeting of Members on 11 June 2015, Members agreed to adopt the amended Code.

Having achieved the Code’s authorisation, Medicines Australia has initiated a broad healthcare professional communications campaign. The campaign reinforces that a strong working relationship and ongoing knowledge exchange between the companies that make medicines and healthcare professionals are critical to better patient outcomes. Our communications through a range of media seek to ensure that all relevant Australian healthcare professionals are aware of the new Code and the transparency requirements for Member companies and are confident that the transparency requirements will be implemented professionally and in accordance with Australia’s privacy laws.

Continuing Education Program

The Medicines Australia Continuing Education Program (CEP) provides education for company medical representatives to a recognised industry standard. It also educates other company personnel about the Medicines Australia Code of Conduct. In calendar year 2014 just over 1100 students enrolled in one or more Programs offered under the CEP. This demonstrates the real value of the CEP to our Members and others. In Semester 1 2015, 533 students undertook the updated Refresher Module for Code Edition 18. This shows the high level of interest by Members in ensuring that their personnel and the external agencies they engage are well informed about the new Code requirements.

We wish to thank Professor Peterson and his team at the University of Tasmania who delivered the CEP in 2014-2015 for our Members.
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 are very grateful for their ongoing commitment to assisting Medicines Australia to ensure that industry self-regulation through a world class industry Code of Conduct remains strong and effective.

In addition to the above Committees, Medicines Australia is fortunate to have the support of a number of working groups who help the Code Secretariat on specific projects. We acknowledge the work of the Guidelines Working Group who assisted in the development of the Code of Conduct Guidelines that sit alongside Edition 18 of the Code, and who continue to provide advice for the ongoing implementation of Edition 18. Additionally we acknowledge the work of the Central Database Working Group, which has been tasked with investigating the feasibility and desirability of a centralised database for the reporting of transfers of value.

On behalf of the Board and all Member companies, we also particularly acknowledge Deborah Monk, Sophie Hibburd and Karen Patten, the Ethical Conduct team, who implement and oversee the Code of Conduct and Continuing Education Program. These are essential elements of Medicines Australia’s activities. It was sometimes challenging to firstly achieve Member company consensus on the Code requirements and then to negotiate the ACCC’s authorisation of the Code. However, Deborah, Sophie and Karen continue to demonstrate great professionalism, are always doing their utmost to assist Members wherever they can through the year and form a strong and cohesive team. We acknowledge their work on behalf of the industry.
It’s been another busy year for the Code Secretariat, with the team’s focus on achieving authorisation of Code Edition 18. As the Chairman and CEO have highlighted in their report, the Australian Competition and Consumer Commission (ACCC) granted 5 years’ authorisation for the new Code. Although the authorisation included several conditions relating to the details of the transparency model in Code Edition 18, we are very pleased to have achieved this important, positive outcome for Medicines Australia’s Members.

Following authorisation, Code Edition 18 came into effect on 16 May 2015 and the new transparency requirements will commence on 1 October 2015.

The new Code requires member companies to report for individual healthcare professionals the cost of all flights, accommodation and registration fees provided to healthcare professionals and any honoraria, sitting or consulting fees. During the first twelve months of implementation, reporting will only occur with each healthcare professional’s consent to publish the information. From 1 October 2016, reporting will become mandatory. That is, companies may not make a payment or provide an airfare, accommodation or registration fee unless a healthcare professional is notified of the disclosure obligation and therefore expects the information to be disclosed.

The Ethical Conduct team is now focused on our healthcare professional communications campaign to reinforce that a strong working relationship between companies and healthcare professionals and ongoing knowledge exchange are critical to better patient outcomes. Through a range of media, we are seeking to ensure that all relevant Australian healthcare professionals are aware of the new Code and its requirements.

I wish to echo the Chairman and CEO in acknowledging the considerable contributions by many Member companies to assist us in achieving the Code’s authorisation. Members’ submissions and participation in our discussions with the ACCC were invaluable. I am also very grateful to the members of the Code Guidelines Working Group for their engagement and participation in this important process.

Transparency Reports under Code Edition 17

Whilst transitioning between Code Edition 17 and 18, member companies have continued to report all educational meetings and symposia that they organise or sponsor, as required by Code Edition 17. Medicines Australia publishes these reports every six months on its website. Under the Code of Conduct Edition 17, new transparency reports were introduced in which member companies report on their consultancies involving healthcare professionals and meetings of their Advisory Boards. The Advisory Board reports are published every six months, coinciding with the educational event reports. The Healthcare Professional Consultancies report is an annual report covering a calendar year, published in June each year.

In 2014-2015 member companies consistently demonstrated a high level of compliance with the Code and their ongoing commitment to improved transparency of interactions with healthcare professionals, to deliver and support valuable education about the treatments available to Australians, and to support health consumer organisations in their important services to Australian consumers.

Educational Event Reports

In December 2014 and June 2015 Medicines Australia published educational event reports for the periods April to September 2014 and October 2014 to March 2015. These were the fifteenth and sixteenth six monthly reports published since reporting commenced in 2007. There were 15,962 events reported for the period April to September 2014 and 12,278 events reported for October 2014 to March 2015. The number of events reported for each period in 2014-2015 is consistent with previous years and reflects that fewer events are held during the Christmas and New Year period.

Advisory Board Reports

In December 2014 and June 2015, Medicines Australia published member companies’ Advisory Board reports. These reports covered the periods April to September 2014 and October 2014 to March 2015. There were 211 Advisory Board meetings held by 35 member companies during the 12 month period.
Healthcare Professional Consultants Reports

The second member companies’ Healthcare Professional Consultancies reports were published in June 2015. These reports covered consultancies commenced during the 2014 calendar year. A review of these reports showed that 34 of our member companies engaged 973 healthcare professional consultants across 741 projects during the year, with the total value of consultancies of $2,577,525.

Health Consumer Organisation Support Reports

In June 2015 Medicines Australia also published the second annual reports of member companies’ financial support for Health Consumer Organisations (HCO), a new requirement under Edition 17. Previously member companies published these reports on their websites and did not include the financial information. Member companies supported 260 different HCOs across Australia in the calendar year of 2014, ranging from national consumer organisations to small local groups, relating to 376 different projects or events to the total value of $10,025,160.

How we performed

Complaints handling

In 2014-2015, Medicines Australia received 15 new complaints. This is an increase over 2013-2014, when 10 new complaints were received, but a decrease when compared with 2012-2013, when 18 new complaints were received.

A third of the new complaints received this year were submitted by Member Companies (five complaints), another third submitted by the Monitoring Committee (five complaints), with the balance submitted by healthcare professionals (four complaints) and a member of the general public (1 complaint).

Of the 15 new complaints received and finalised in 2014-15, six were found not in breach of the Code and nine complaints were found to be in breach of some or all aspects of the alleged breaches.

There were four appeals against the Code of Conduct Committee’s decisions during the year. One appeal was upheld and three appeals were not upheld.

Details of the complaints considered and finalised in 2014-2015 and the outcomes are reported in this Code of Conduct Annual Report, published on the Medicines Australia website.

Monitoring of Member company activities

The Monitoring Committee continued its schedule of monitoring reviews during 2014-2015. The Committee undertook five reviews of materials associated with particular therapeutic areas:

- disease education material in the respiratory system therapeutic area
- printed advertisements in the immunology therapeutic area
- printed promotional materials in the skin therapeutic area
- non-promotional apps in all therapeutic classes (reviewed over two meetings)
- media releases to the general public media in all therapeutic classes

The Monitoring Committee also undertook a review of Member companies’ Health Consumer Organisation Support reports and Healthcare Professional Consultancies reports. These reviews of HCO support reports, HCP Consultant Reports and Company materials as listed above are in addition to the Monitoring Committee’s annual review of one quarter of all educational event reports submitted by Member Companies during the preceding 12 months.

The Monitoring Committee reviewed 7969 educational events held between 1 April 2013 and 31 March 2014 reported by 39 companies. Of these events, two were referred to the Code of Conduct Committee for its consideration of whether the events had breached the Code. One event was found to have breached the Code; the other did not breach the Code.

The Monitoring Committee has commenced its review of educational event reports submitted between 1 April 2014 and 31 March 2015. The outcomes of this review will be reported in the 2015-2016 Annual Report.
Improved Communication Channels

In 2014-2015 the Code Secretariat continued to improve ways of communicating with member companies and other stakeholders. The Code Help Desk drop box (codehelpdesk@medicinesaustralia.com.au) continues to be a successful portal to facilitate submission of code related queries, and enables the Secretariat to promptly respond to these queries. This has proved very popular with members, non-members and companies providing services to pharmaceutical companies, such as advertising agencies. All communications to the Code Help Desk are kept commercially in confidence.

In addition, the Secretariat has continued to hold regular monthly Code related training webinars. These webinars can be an overview of the Code for newcomers to the industry, or can be about a specific topic of interest proposed by members. Many of the webinars in 2014/2015 have focused on the anticipated implementation of Edition 18, specifically the key changes being implemented in the new edition as well as the increased transparency measures that it requires. The training webinars continue to be popular as they provide a forum for members to discuss and debate issues that impact their business decisions.

Our People

Successful implementation of the ethical conduct program cannot be achieved without committed and professional staff. I wish to add my appreciation to the comments from the Chairman and Chief Executive Officer. Code of Conduct Manager, Mrs Sophie Hibburd returned to work after maternity leave in late 2014 and quickly picked up the reins, managing the Code of Conduct, Appeals and Monitoring Committees. Sophie continues to ensure that the Committees’ work is conducted efficiently and effectively. Sophie and Deborah work closely together to provide advice and assistance to Members, other companies and service organisations, to assist them when applying the Code day to day within their businesses. Sophie is also pivotal in ensuring the CEP is delivered to a high standard and that Medicines Australia’s interactions with the University of Tasmania are maintained in a professional and effective way.

During Sophie’s maternity leave Mrs Karen Patten, our Code Administration Officer, assumed higher duties to ensure that the impact of Sophie’s leave was minimal on the effective management of the ethical conduct program, which was very much appreciated. Karen continues to be an excellent administrator of our activities and ensures that all materials required by the three Committees are delivered on time to enable the Committee to function effectively.

The Year Ahead

As Code Edition 18 is now the effective Code, the Secretariat and our Members are fully engaged in preparing to implement the transparency requirements of the new Code, which commence on 1 October 2015. We have much to do to inform and educate healthcare professionals about the new Code requirements. We are grateful to the numerous healthcare professional organisations that have assisted Medicines Australia by informing their health professional members about the new Code requirements.

Implementation of the transparency requirements is a very significant change, which will deliver much greater openness for Australians about how pharmaceutical companies interact with healthcare professionals. Medicines Australia is very pleased to be spearheading transparency in our sector in Australia.
Complaints received by Medicines Australia are considered by the Code of Conduct Committee and, when required, by the Appeals Committee.

The Medicines Australia Board and the Secretariat staff do not 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](#).

**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 unless there are no complaints received. A schedule of meeting dates is available from the Medicines Australia website.

<table>
<thead>
<tr>
<th>Table 1: Code of Conduct Committee Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisation</td>
</tr>
<tr>
<td><strong>Full Members (Voting rights)</strong></td>
</tr>
<tr>
<td>Chairman</td>
</tr>
<tr>
<td>(One independent Lawyer selected from a panel of up to five trade practices lawyers)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Australian General Practice Network (AGPN)</td>
</tr>
<tr>
<td>Australian Medical Association (AMA)</td>
</tr>
<tr>
<td>Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)</td>
</tr>
<tr>
<td>(One ASCEPT member selected from the panel of four members)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Consumers Health Forum of Australia (CHF)</td>
</tr>
<tr>
<td>(Two CHF representatives to participate in complaints where the activity is directed at the general public or patients)</td>
</tr>
<tr>
<td>Royal Australasian College of Physicians (RACP)</td>
</tr>
<tr>
<td>(One RACP member selected from the panel of three members)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Royal Australian College of General Practitioners (RACGP)</td>
</tr>
<tr>
<td>Medicines Australia Association Representatives (maximum of 3)</td>
</tr>
<tr>
<td>(Maximum two Medicines Australia Member company Senior Executives and maximum one Medicines Australia Member company Marketing Director)</td>
</tr>
<tr>
<td>Medicines Australia Member company Medical/Scientific Directors (Maximum of 2)</td>
</tr>
<tr>
<td>Where a complaint relates to an activity or material directed to the practice of Pharmacy, one pharmacist representative nominated by the Pharmacy Guild of Australia (PGA), The Pharmaceutical Society of Australia (PSA) or the Society of Hospital Pharmacists (SHPA)</td>
</tr>
<tr>
<td><strong>Observers (No voting rights)</strong></td>
</tr>
<tr>
<td>Therapeutic Goods Administration (TGA)</td>
</tr>
<tr>
<td>(one TGA representative attends)</td>
</tr>
<tr>
<td>Medicines Australia Member Companies’ employees (Maximum of 2)</td>
</tr>
<tr>
<td>Observer nominated by Medicines Australia (Maximum of 1)</td>
</tr>
<tr>
<td><strong>Medicines Australia Advisors (No voting rights)</strong></td>
</tr>
<tr>
<td>Secretary, Code of Conduct Committee</td>
</tr>
<tr>
<td>Medicines Australia Chief Executive Officer or delegate</td>
</tr>
<tr>
<td>Medicines Australia Officer responsible for Ethical Conduct</td>
</tr>
</tbody>
</table>
Meeting Attendance

The Code Committee held 8 meetings to consider 15 complaints received in 2014-2015. Two CHF representatives were in attendance at the November 2014 and June 2015 Code Committee meetings because there were complaints allegedly relating to activities directed at the general public. A quorum was achieved at all meetings with apologies from RACP at the July 2014 and January 2015 meetings, and RACGP and AMA at the September 2014 meeting.

Appeals Committee

Appeals Committee meetings are organised on an ‘as needs’ basis, when an appeal is lodged. No member of the Appeals Committee may have been a member of the Code Committee which adjudicated on the original complaint.

<table>
<thead>
<tr>
<th>Table 2: Appeals Committee Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisation</td>
</tr>
<tr>
<td>Full Members (Voting rights)</td>
</tr>
<tr>
<td>Chairman</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>One representative from:</td>
</tr>
<tr>
<td>Australian Medicare Local Alliance (AML Alliance), or</td>
</tr>
<tr>
<td>Australian Medical Association (AMA), or</td>
</tr>
<tr>
<td>Royal Australian College of General Practitioners (RACGP)</td>
</tr>
<tr>
<td>Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)</td>
</tr>
<tr>
<td>(One ASCEPT member selected from the panel of four members)</td>
</tr>
<tr>
<td>Consumers Health Forum (CHF)</td>
</tr>
<tr>
<td>(Two CHF representatives to participate in complaints where the activity is directed at the general public or patients)</td>
</tr>
<tr>
<td>The College and/or Society associated with the therapeutic class of the product subject to appeal</td>
</tr>
<tr>
<td>Medicines Australia Association Representatives (Maximum of 2)</td>
</tr>
<tr>
<td>(Maximum 1 Medicines Australia Member company Senior Executive and maximum 1 Medicines Australia Member company Marketing Director)</td>
</tr>
<tr>
<td>Medicines Australia Member company Medical/Scientific Directors (Maximum of 1)</td>
</tr>
<tr>
<td>Where a complaint relates to an activity or material directed to the practice of Pharmacy, one pharmacist representative nominated by the Pharmacy Guild of Australia (PGA), The Pharmaceutical Society of Australia (PSA) or the Society of Hospital Pharmacists (SHPA)</td>
</tr>
<tr>
<td>Medicines Australia Advisors (No voting rights)</td>
</tr>
<tr>
<td>Secretary, Code of Conduct Committee</td>
</tr>
<tr>
<td>Medicines Australia Chief Executive or delegate</td>
</tr>
<tr>
<td>Medicines Australia Officer responsible for Ethical Conduct</td>
</tr>
</tbody>
</table>

Meeting Attendance

The Appeals Committee held 3 meetings in 2014-2015 to consider 4 appeals. 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 schedule of meeting dates is available from the Medicines Australia website.

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Nominee/s</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full Members (Voting rights)</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Chairman | Mr Russell Edwards  
(Selected from a panel of three consultants with industry experience in marketing and knowledge of the Code of Conduct) Ms Helen Maxwell-Wright  
Mr Wayne Strong |
| Australian Medical Association (AMA) | Dr Robyn Napier |
| Royal Australian College of General Practitioners (RACGP) | Dr Sue Whicker |
| Consumers Health Forum | Mr Barry Cahill to Dec 2014  
(Two CHF representatives participate in reviews where activities are directed at the general public or patients) Ms Alison Marcus from Jan 2015  
Ms Helena Lake (Alternate)  
Ms Rigoula Roussakis (Alternate) |
| The College and/or Society associated with the therapeutic class of the product(s) subject to review | Various, depending on the materials or conduct being reviewed |
| Medicines Australia Member company Medical/Scientific Director | Various, depending on the materials or conduct being reviewed |
| Medicines Australia Member company Marketing Director | Various, depending on the materials or conduct being reviewed |
| **Medicines Australia Advisors (No voting rights)** | |
| Secretary, Code of Conduct Committee | Mrs Sophie Hibburd |
| Medicines Australia Officer responsible for Ethical Conduct | Ms Deborah Monk |

The Committee held 10 meetings in 2014-2015. All permanent members of the Monitoring Committee attended the scheduled meetings except for the AMA who was an apology for the August 2014 meeting. Two consumer representatives participated in 7 of the Committee’s reviews as activities were 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; and
- applying for authorisation of the Code by the ACCC when required.
Code Secretariat Staff

- Ms Deborah Monk, Director Compliance
- Mrs Sophie Hibburd, Manager Code of Conduct
- Mrs Karen Patten, Code of Conduct Officer
- Ms Darinka Zubovic, Code Administration Officer (May-Sept 2014)

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 and educational seminars for

- 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.

Within the Australian environment, Ms Monk and Mrs Hibburd responded to many requests for guidance and advice on code provisions and interpretations. In 2014-2015 Code Secretariat staff conducted or participated in 45 events pertaining to communication about the Code, with a combined audience of 1,405. See Table 4 for details on these events.

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>No. of Events</th>
<th>No. of Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conferences - sessions on the code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
<td>4</td>
<td>230</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>Presentations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
<td>12</td>
<td>385</td>
</tr>
<tr>
<td>Businesses working with industry</td>
<td>12</td>
<td>115</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>Workshops and meetings on the Code, including review updates, changes and/or amendments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member &amp; non-member companies, businesses working with industry, Stakeholders</td>
<td>14</td>
<td>626</td>
</tr>
<tr>
<td>TOTAL</td>
<td>45</td>
<td>1405</td>
</tr>
</tbody>
</table>
Medicines Australia’s Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard.

The 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 18 of the Code).

In addition to medical representatives, the Medicines Australia Code of Conduct (Section 6.5 of Edition 18) 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 as an online course through the University of Tasmania's Unit for Medication Outcomes, Research and Education (UMORE), which is backed by the resources of the University's School of Pharmacy. The course is tailored for adult learning and designed to provide flexibility for participants in full-time employment.

**CEP Programs available through the University of Tasmania**

**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: Human Anatomy and Physiology**
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 4, 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).

**Program 4: An Introduction to Pharmacology**
Pharmacokinetics and pharmacodynamics, how drugs are administered, transported through the body and absorbed.

**Program 5: 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 6: 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.

**Code Refresher**
This 2-hour long 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.
CEP Enrolments in 2014-2015

Table 5 shows the number of enrolments in Semester 2, 2014 and Semester 1, 2015. 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</th>
<th>Semester 2, 2014</th>
<th>Semester 1, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program 1</td>
<td>305</td>
<td>277</td>
</tr>
<tr>
<td>Program 2</td>
<td>116</td>
<td>148</td>
</tr>
<tr>
<td>Program 3</td>
<td>74</td>
<td>71</td>
</tr>
<tr>
<td>Program 4</td>
<td>73</td>
<td>77</td>
</tr>
<tr>
<td>Program 5</td>
<td>106</td>
<td>74</td>
</tr>
<tr>
<td>Program 6</td>
<td>102</td>
<td>59</td>
</tr>
<tr>
<td>Total for Core Programs</td>
<td>776</td>
<td>706</td>
</tr>
<tr>
<td>Code Update</td>
<td>89</td>
<td>533</td>
</tr>
<tr>
<td>TOTAL</td>
<td>865</td>
<td>1239</td>
</tr>
</tbody>
</table>

CEP Continuous Improvement

The University of Tasmania continued its focus on the continuous improvement of the CEP during 2014-2015. As part of this process, Program 1, the Code of Conduct Module was fully revised and updated in line with newly authorised Edition 18 of the Code. Other programs to be reviewed were: Program 2, The Pharmaceutical Industry; Program 5, Understanding Product Information; and Program 6, Understanding Clinical Trials and Scientific Literature. This continuous improvement process ensures that the CEP stays current, is appropriate and that modern teaching methods are incorporated.

People

We wish to thank the team at the University of Tasmania who delivered the CEP in 2014-2015 for our Members. The CEP Program team is led by Professor Greg Peterson, Professor of Pharmacy and Dr Corinna Dwan, Projects Manager & Academic Lead (Medicines Australia CEP). Professor Peterson and Dr Dwan are ably assisted by Mr Alex Smith, Project Officer. Mr Smith took over the role from Ms Kelli Lloyd who left the University of Tasmania at the end of 2014.

CEP Awards

Medicines Australia hosts an annual awards ceremony to celebrate the achievements of students in the Continuing Education Program. The CEP awards are presented annually to sales representatives who achieve the highest marks in the course. Additionally, the University of Tasmania offered a prize to students based on the level of engagement and quality of participation in the course.

The CEP Awards for 2014 were presented at an Awards Lunch in March 2015. Guest Speaker Dr Brian Morton, Chairman, AMA Council of General Practice, 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.

The Medicines Australia Continuing Education Program has been in existence for over forty years. Commencing 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, before moving to Deakin University and the University of Queensland. In 2012 the University of Tasmania was awarded the contract to deliver and develop the CEP following a competitive tender process.

At the CEP Awards Lunch event, Medicines Australia Chief Executive Mr Tim James congratulated all students who completed the course, and in particular the recipients of the awards. The fact that so many students had been recognised for their high achievement in this program shows pride in the industry, a passion to deliver quality education to healthcare professionals with the purpose of ensuring patients get the best use out of medicines that are available today.
UTAS Prize for Excellence

The two UTAS Prizes for Excellence were presented to:

CEP Course Facilitators at the University of Tasmania nominate one finalist for each semester from their program based on the level and quality of participation in group discussions and personal reflections in the online tutorials. The winners are selected by a panel from the University.

Ms Jacqui Bardellini from Sanofi (left) for Semester 1 and Ms Olivia Di Sisto from iNova Pharmaceuticals for Semester 2 (right) (pictured receiving the award from Professor Gregory Peterson, Head of UMORE and Associate Dean (Research), Faculty of Health, University of Tasmania)

Code of Conduct Award

Finalists for the Code of Conduct Award include all students who achieve the highest mark for Program 1, excluding anyone who has achieved final mark via resubmission or supplementary assessment.

Among finalists, the winner is determined through review of learning log book and online participation by a panel from the University of Tasmania which is made up of Program facilitators and program administration staff, with Medicines Australia to make final decision if it is difficult to identify a clear winner.

The Code of Conduct Award was presented to Sean Newman from AstraZeneca (pictured receiving the award from Dr Brian Morton)

CEP Achievement Award

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). Program 3 Human Anatomy and Physiology is not included in the aggregate calculation, as not all students are required to undertake this program.

The award evaluation excludes anyone who has achieved his or her marks via resubmission or supplementary assessment.

CEP Achievement Award recipients pictured below:

- Eilise D’Arcy – Alcon
- Irma Brink – Bristol-Myers Squibb
- Sean Newman – AstraZeneca
- Catherine Solomonson – AstraZeneca
- Ben Warner – Pfizer
- Louise Thomas – iNova Pharmaceuticals
- Alex Roytman – Mundipharma
- Edward Punshon – Alphapharm

CEP Achievement Award recipients not present at the awards event:

- Lawrence Currion – Novartis
- Catriona Truscott – Independent Student

*Award recipients’ companies were current at the time of completion of CEP. Some award recipients may have moved to other companies or roles outside the industry.*
Medicines Australia is pleased to report the continued high level of compliance with the Code with respect to educational 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 31.2.2 in Edition 18) 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 might have occurred. If so, the Committee will refer the educational event to the Code of Conduct Committee for a determination. Table 6 provides a summary of the number of educational meetings reported in each of the 16 reporting periods to date and the number of events found to be in breach of the Code by the Code of Conduct Committee following a 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>Report 2: January – June 2008</td>
<td>15,836</td>
<td></td>
</tr>
<tr>
<td>Report 4: January – June 2009</td>
<td>16,020</td>
<td></td>
</tr>
<tr>
<td>Report 6: January – March 2010</td>
<td>5,857 Note: 3 month report only</td>
<td></td>
</tr>
<tr>
<td>Report 7: April – September 2010</td>
<td>16,880</td>
<td>April 2010 – March 2011 Review of 3 random months data 0</td>
</tr>
<tr>
<td>Report 8: October 2010 – March 2011</td>
<td>13,873</td>
<td></td>
</tr>
<tr>
<td>Report 9: April – September 2011</td>
<td>18,175</td>
<td>April 2011 – March 2012 Review of 3 random months data 0</td>
</tr>
<tr>
<td>Report 10: October 2011 – March 2012</td>
<td>13,611</td>
<td></td>
</tr>
<tr>
<td>Report 11: April – September 2012</td>
<td>18,205</td>
<td>April 2012 – March 2013 Review of 3 random months data 0</td>
</tr>
<tr>
<td>Report 12: October 2012 – March 2013</td>
<td>13,290</td>
<td></td>
</tr>
<tr>
<td>Report 16: October 2014 – March 2015</td>
<td>12,278</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>239,381</strong></td>
<td><strong>37</strong></td>
</tr>
</tbody>
</table>

Member company educational event reports can be found on the Medicines Australia website.
Rights

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

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

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:

Phone: 02 6122 8500; or Email: secretarycodecommittee@medicinesaustralia.com.au

The following documents are available on the Medicines Australia website:

- Code of Conduct Edition 18
- Code of Conduct Guidelines (to be read in conjunction with Edition 18)
- Lodging a complaint (non-industry complainant)
- Complaints Submission Form for Non-Industry Complainants
- Responding to and lodging a complaint (pharmaceutical company)
Source of Complaints

In 2014-2015, 15 new complaints were received by Medicines Australia. As shown in Table 7, the majority of complaints were submitted by member companies (5 complaints) and the Monitoring Committee (5 complaints) with the balance submitted by healthcare professionals (4 complaints), and a member of the general public (1 complaint). Table 7 provides details on the source of all new complaints received in 2014-2015.

<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>0</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>1</td>
</tr>
<tr>
<td>Academic</td>
<td></td>
</tr>
<tr>
<td>Monitoring Committee</td>
<td>5</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td></td>
</tr>
<tr>
<td>Member company</td>
<td>5</td>
</tr>
<tr>
<td>Non- Member company</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>15</strong></td>
</tr>
</tbody>
</table>
Complaints received in 2014-2015

Of the 15 new complaints received in 2014-2015, all complaints were considered and finalised by the end of the financial year. As shown in Figure 1, of the 15 complaints finalised in 2014-2015, 6 were found not in breach of the Code and 9 complaints were found to be in breach of some or all aspects of the alleged breaches. The link to the reasons for the decision with respect to these complaints can be found in Table 8.

Appeals

In 2014-2015, 4 of the 15 new complaints considered and finalised by the Code Committee were subject to an appeal. Figure 2 shows the outcomes of the 4 appeals held in 2014-2015.
Sanctions
Sanctions may be imposed on a company where breaches of the Code have been established. All complaints were considered under the provisions of Edition 17; 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.

Monetary fines
Figure 3 shows the financial penalties imposed on companies found in breach of the Code. There were seven fines imposed that were less than $75,000, and two fines in the $75,000 - $100,000 range.

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 (in working days). Medicines Australia publishes on its 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, which extends the timeframe for resolution as the complaint will be referred to the next meeting.

The average time to resolve a complaint finalised in 2014-2015 was 42 working days. This time was reduced to 23 working days where the complaint was not subject to appeal. The shortest time to resolve a complaint was 21 working days.

Code provisions subject to complaint
There was a total of 80 alleged breaches of the Code with the majority of alleged breaches falling under Sections 1 (55 alleged) and 9 (15 alleged) of the Code. The actual breaches were 21 and 2 respectively for complaints received and finalised in 2014-2015.
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 2014-2015.

Table 8 provides a summary of each finalised complaint. Complaints received and finalised in 2014-2015 were all considered under Edition 17 of the Code.

<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>1113</td>
<td>bioCSL Limited</td>
<td>Invitation to receive hospitality</td>
<td>n/a</td>
<td>Healthcare Professional</td>
<td>No breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1114</td>
<td>Shire Australia Pty Ltd</td>
<td>Promotional Material</td>
<td>Mezavant</td>
<td>Healthcare Professional</td>
<td>Breach of Sections 1.1 and 1.3</td>
<td>Fine of $20,000 Material to be withdrawn from use</td>
</tr>
<tr>
<td>1115</td>
<td>GlaxoSmithKline Australia Pty Ltd</td>
<td>Advertisement</td>
<td>Votrient</td>
<td>Pfizer Australia Pty Ltd</td>
<td>Breach of Sections 1.1, 1.2.2, 1.3, 1.8</td>
<td>Fine of $20,000 Advertisement withdrawn from use</td>
</tr>
<tr>
<td>1116</td>
<td>Pfizer Australia Pty Ltd &amp; Bristol-Myers Squibb Australia Pty Ltd</td>
<td>Promotional Material</td>
<td>Eliquis</td>
<td>Bayer Australia Limited</td>
<td>No breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1117</td>
<td>Novartis Pharmaceuticals Pty Ltd</td>
<td>Conduct</td>
<td>n/a</td>
<td>Healthcare Professional</td>
<td>No Breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1118</td>
<td>GlaxoSmithKline Australia Pty Ltd</td>
<td>Promotional Material</td>
<td>Seretide</td>
<td>Mundipharma Pty Ltd</td>
<td>Breach of Sections 1.2 and 1.3</td>
<td>Fine of $40,000 Material to be withdrawn from use</td>
</tr>
<tr>
<td>1119</td>
<td>Janssen Pty Ltd</td>
<td>Promotional Material</td>
<td>Velcade</td>
<td>Monitoring Committee</td>
<td>No breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1120</td>
<td>Bayer Australia Limited</td>
<td>Detail Aid</td>
<td>Nexavar</td>
<td>Monitoring Committee</td>
<td>Breach of Sections 1.1 and 1.3</td>
<td>Fine of $10,000 Material to be withdrawn from use</td>
</tr>
<tr>
<td>1121</td>
<td>Novartis Pharmaceuticals Pty Ltd</td>
<td>Educational Event</td>
<td>Lucentis</td>
<td>Monitoring Committee</td>
<td>Breach of Sections 9.1 and 9.3</td>
<td>Fine of $90,000 Do not hold further meetings in same form</td>
</tr>
<tr>
<td>1122</td>
<td>Amgen Australia</td>
<td>Educational Event</td>
<td>Aranesp</td>
<td>Monitoring Committee</td>
<td>No Breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1123</td>
<td>Bayer, Merck Sharp &amp; Dohme, Novartis Pharmaceuticals</td>
<td>Advertising</td>
<td>Eylea, Saflutan, Lucentis</td>
<td>Member of the General Public</td>
<td>No Breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1124</td>
<td>Bayer Australia</td>
<td>Promotional Material</td>
<td>Xarelto</td>
<td>Pfizer/Bristol-Myers Squibb</td>
<td>Breach of Sections 1.1, 1.2 and 1.3</td>
<td>Fine of $30,000 Cease use of claim found in breach</td>
</tr>
</tbody>
</table>
Table 8: Complaints finalised in 2014-2015

<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>1125</td>
<td>iNova Pharmaceuticals</td>
<td>Presentation</td>
<td>Duromine</td>
<td>Healthcare Professional</td>
<td>Breach of Section 1.1</td>
<td>Fine of $100,000 Corrective letter to attendees</td>
</tr>
<tr>
<td>1126</td>
<td>Bristol-Myers Squibb Australia</td>
<td>Promotional Material</td>
<td>Sprycel</td>
<td>Novartis Pharmaceuticals</td>
<td>Breach of Sections 1.2 and 1.3</td>
<td>Fine of $45,000 Material to be withdrawn from use</td>
</tr>
<tr>
<td>1127</td>
<td>Novartis Pharmaceuticals</td>
<td>Media Release</td>
<td>Ultibro Breezhaler</td>
<td>Monitoring Committee</td>
<td>Breach of Section 13.4.1</td>
<td>Fine of $30,000 Do not use statement again in activities for the general public</td>
</tr>
</tbody>
</table>

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 18 of the Code of Conduct.

**Advertisement** in relation to therapeutic goods as defined in the Therapeutic Goods Act 1989 includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

**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.

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

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

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

**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, dispense, recommend supply or administer a Product.

**Indications** mean the registered therapeutic use of a medicine as approved by the Therapeutic Goods Administration (TGA).

**Member** means an entity registered as a Member of Medicines Australia Ltd.

**Minor breach** is a breach of the code that has no safety implications to the patient’s wellbeing 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.

**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.

**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 either the current Australian Approved Product Information or in the case of a product whose registration pre-dates the current regulatory review (‘Grandfathered Product’) the document registered is known as the ‘Full Product Information’. This Product Information must comply with the format specified in the TGA Australian Regulatory Guidelines for Prescription Medicines. Product Information may also be presented as a Minimum Product Information.

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.

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.

Therapeutic Goods Administration (TGA) is the Division of the Commonwealth Department of Health and Ageing (as the Department was formerly named) that is responsible for the regulation of therapeutic goods in Australia.
Dr Woodruff lodged a complaint in relation to an invitation from bioCSL to attend a “casual meal” during the 2014 ARA conference in Hobart. Dr Woodruff was concerned that the invitation had been faxed to one of his work locations and was not addressed to him personally. Dr Woodruff argued that this was a serious breach of the Code of Conduct as there is no mention of any educational content. Dr Woodruff alleged that the hospitality was the primary purpose of the event.

Sections of the Code
The promotional activities are alleged to be in breach of the following Sections of Edition 17 of the Code:

- 5.9 Roles and Ethical Conduct
- 9.1 General Principles
- 9.3 Educational Events
- 9.4.1 Educational Content
- 9.4.3 Meals and Beverages

Response
bioCSL disagreed that the invitation was in breach of the Code. The purpose of the invitation was to invite delegates who were attending the 55th annual Australian Rheumatology Association (ARA) Scientific Meeting to a dinner organised by bioCSL, in association with the meeting.

bioCSL stated that the invitation was not faxed to Dr Woodruff. The invitation was personally delivered by a bioCSL representative, who was unable to speak with Dr Woodruff at his Brighton consulting rooms. The receptionist at these rooms confirmed to the bioCSL representative that Dr Woodruff would be attending the ARA Scientific meeting and the invitation was left with her to hand deliver to Dr Woodruff. The invitations were not personalised because of the requirement for the bioCSL representative to check first whether the healthcare professional would be attending the ARA meeting prior to issuing the invitation.

bioCSL argued that the hospitality offered at the event was secondary to the educational meeting at the ARA conference, and otherwise was wholly consistent with the Code. However, the dinner had been cancelled by bioCSL and did not take place.

Code of Conduct Committee Decision

The Code of Conduct Committee determined:
- By unanimous decision, no breach of Section 9.1
- By unanimous decision, no breach of Section 9.3
- By majority decision, no breach of Section 9.4.1
- By majority decision, no breach Section 9.4.3
- By unanimous decision, no breach of Section 5.9

Sanction
As the Committee did not find a breach of the Code of Conduct, no sanction was imposed.

Consideration of the Complaint
The Committee noted that the invitation to the evening hospitality stated that the invitation was to “colleagues who are attending the 2014 ARA (Australian Rheumatology Association) conference in Hobart”. The conference started at 10 am on Saturday 17 May and concluded at lunchtime on Tuesday 20 May. The Committee accepted that there was substantial education provided over the three and a half day conference. The program included speakers who are international and Australian leading experts in rheumatology.

On Sunday 18 May, the night on which bioCSL offered to provide hospitality to certain attending healthcare professionals, there had been no evening function scheduled in the conference program. There were evening functions scheduled for Saturday and Monday nights. The bioCSL function was not identified as part of the conference program.

Dr Woodruff noted in his complaint that main courses at the restaurant selected by bioCSL start at $38, whereas bioCSL stated in its response to the complaint that a three course function menu had been planned at a cost of $65 per person. However, bioCSL had cancelled the dinner. The Committee did not consider that the cost of the meal was extravagant.

The Committee discussed the distribution of the invitation. Dr Woodruff alleged that the invitation had been faxed to one of his work locations and was not addressed to him personally. bioCSL responded that the invitations had been hand delivered by the bioCSL representative to rheumatologists to ensure that the clinician was actually attending the ARA conference. bioCSL stated that the invitation had been left with Dr Woodruff’s receptionist after the company representative had confirmed that Dr Woodruff was attending the conference. The Committee accepted that the invitation referred to hospitality being offered to healthcare professionals who are attending the ARA conference; the hospitality was therefore intended to be in association with an educational meeting.

The Committee noted that Code Edition 17 and the Code Guidelines permit companies to offer...
hospitality to delegates attending a conference that has been organised by an independent organisation. There is no requirement for an evening function offered by a company to include an educational component; such evening functions rely on there being educational content delivered at the associated conference during the day. The Committee referred to the Code of Conduct Guidelines, Table 5 “Guidance recommending appropriate conduct for educational events”. It noted that the section “Company organised activities: Company organised hospitality provided in association with third party educational conferences” refers to a company organised dinner “in association with third party conferences/congresses”. The Committee considered that the phrase “in association with” third party conferences did not adequately convey the principle that hospitality must always be secondary to the primary purpose of education.

Some members of the Committee considered that there should be a clear nexus between a third party conference and any hospitality offered by a pharmaceutical company to delegates attending the conference, such as by inclusion of the evening function on the conference program. For example, a company sponsored dinner function is identified in the conference program, or hospitality is only provided to healthcare professionals whom the company has sponsored to attend the conference. Alternatively, the evening event could include an educational component, such as an overview of the day's conference proceedings.

The Committee expressed the view that it should not be acceptable for a company to provide hospitality to healthcare professionals who are attending a conference where that company is not involved with the conference and is merely using the opportunity to provide hospitality to healthcare professionals. The fundamental premise is that companies should not provide hospitality merely for the opportunity to provide a benefit to healthcare professionals; the primary purpose of the interaction must be education. The Committee further recommended that the statement in the Guidelines (Table 5) “it is not a requirement for education to be provided at the function because the delegates will have attended the conference/congress during the day” should be reviewed in order to make the link between the hospitality and conference explicit. Ms Monk undertook to refer the Committee’s views to the Code Guidelines Working Group that will be developing updated Guidelines for Edition 18 of the Code.

The Committee considered the sections of the Code under which the complaint was made. A majority of the Committee concluded that the invitation to receive hospitality on one evening during the ARA conference in Hobart was consistent with the Code of Conduct and found no breach of any section of the Code. A minority of the Committee were concerned that the offer of “a casual meal” to healthcare professionals did not convey the impression that the primary purpose of the interaction was the provision of education. Therefore, the Committee’s decisions to find no breach of sections 9.4.1 and 9.4.3 of the Code were by the majority of members. The decisions to find no breach of sections 9.1, 9.3 and 5.9 of the Code were unanimous. Whilst finding no breach of the Code, the Committee directed that its comments that the nexus between the provision of hospitality and the educational purpose of interactions with healthcare professionals should be made more explicit in the Code Guidelines should be referred to the Working Group.

Sanction
As the Committee did not find a breach of the Code of Conduct, no sanction was imposed.

MEZAVANT PROMOTIONAL MATERIAL – 1114
Subject Company: Shire Australia Pty Ltd
Complainant: Healthcare Professional
Product: Mezavant
Complaint
A Healthcare Professional lodged a complaint against Shire in relation to promotional material for Mezavant in the form of testimonial case studies. The complainant alleged that the materials contain promotion that is unbalanced and outside of the approved product information. The complainant alleged that these promotional pieces are not clearly labelled as promotion and do not improve the quality use of medicines and therefore are in breach of the Code.

The complainant also alleged that the materials contain no disclosure that the information has been paid for by Shire. However, there is “a covert mention” on the last page of the brochure that the case study was funded by Shire.

Sections of the Code
The promotional material is alleged to be in breach of the following Sections of Edition 17 of the Code:

- 1.1 Responsibility
- 1.3 False and misleading claims
- 2 Promotional material directed at HCPs
- 2.1.1.4 Company commissioned articles
- 4.1 Medical Education material
- 9.1 General Principles
Response

Shire rejected that the case studies do not conform to the requirements of the Code of Conduct for printed promotional material and argue that the materials are clearly identified as promotional material. Shire also rejected the allegations that the materials do not improve the quality use of medicines, contain false or misleading claims, are unbalanced and make claims that are not supported by the Product Information.

Shire did not accept that the pieces should be classified as Company Commissioned Articles or Medical Education material and believed that Sections 2.1.1.4 and 4.1 are not applicable to the materials. Shire rejected the allegations that the promotional materials were in breach of any section of the Code.

Consideration of the Complaint

The Committee noted that there were several aspects to this complaint. The alleged breaches of the Code were, in summary:

- that Shire was promoting Mezavant outside of the approved Product Information and in an unbalanced manner because, in relation to the case study about 'Amy':
  - The Complainant interpreted the case study as indicating that Amy had severe ulcerative colitis whereas Mezavant is only approved for mild to moderate disease.
  - The case study begins when Amy is 17 years old. Whilst she was not prescribed the product until she is over 30, Mezavant is not approved for children less than 18 years of age. The Complainant alleged that the case study could be misconstrued that Mezavant may be prescribed for a 17 year old.
  - The approved dose of Mesasal, which Amy was initially prescribed, is 1.5 grams a day according to that Product Information, whereas she was prescribed up to 3 grams a day.
  - When Mezavant was commenced, Amy was prescribed 4.8 grams a day to induce remission. The Product Information states that when using this highest dose, the effect of the treatment should be reassessed after 8 weeks. However, in the case study Amy continued at the higher dose for 5 months, after which she was reduced to 2.4 grams a day.
  - The case study lacks balance because it fails to acknowledge that Amy's disease improvement may have been explained by the natural history of ulcerative colitis, which is relapsing and remitting.
  - The Complainant interpreted the case study as indicating that Amy had severe ulcerative colitis whereas Mezavant is only approved for mild to moderate disease.

- that the materials were not clearly labelled as promotional materials or Company commissioned articles and therefore were in breach of Sections 2.1.1.4 and 4.1 of the Code.

- that the materials did not support the quality use of medicines and therefore were in breach of Sections 4.1 and 9.1.

- that there is a financial obligation for the healthcare professionals to produce the case studies which may have been conditional upon an obligation to recommend, prescribe dispense or administer the product, which is contrary to Section 9.1.

The Committee discussed each of the alleged breaches of the Code.

The Committee considered that it was unclear in the brochure whether the ‘Amy’ case study represented severe ulcerative colitis. Mezavant is indicated for mild to moderate active ulcerative colitis, but the Product Information does not provide a definition of mild, moderate or severe disease. The Second European evidence-based consensus on the diagnosis and management of ulcerative colitis (Dignass et al (2012)) provides a definition of severe disease, which requires hospital admission amongst other parameters, and mild to moderately active disease which can be managed as an outpatient.

The Committee noted that at the time that Amy was prescribed Mezavant Amy had not required a recent hospital admission. However, the case study described someone with long-standing, relapsing remitting disease, which would be typical of the condition. The Committee considered that the Amy case study gave the overall impression that she was someone with severe disease who had been hospitalised in the past. It was not clearly stated in the case study that Amy had mild to moderate disease at the time she was prescribed Mezavant, which is consistent with the approved indications, and did not have severe disease. A majority of the Committee considered that the omission of a clear statement of Amy’s disease severity made the case study unbalanced and potentially misleading and therefore in breach of Sections 1.1 and 1.3 of the Code in relation to this point.

The Committee noted that the case study started when Amy was aged 17 but Mezavant was not prescribed until she was 29 or 30 years old. The Committee did not agree with the Complainant that the case study implied or suggested that Mezavant may be prescribed for people under 18 years. In unanimous decisions, no breach of Sections 1.1 or 1.3 was found in relation to this point.

The Committee discussed the dosing of Mesasal in the case study. Mesasal contains the same active ingredient as Mezavant, mesasalazine, but has a different formulation and a different pharmacokinetic profile. It noted that Mesasal is not Shire’s product.
In the case study, Amy had been prescribed Mesasal between 1999 and 2007, some years before being prescribed Mezavant. The Committee accepted that according to the case study Amy had been prescribed a higher dose of Mesasal than the maximum daily dose stated in the Product Information. However, the Committee did not consider that Shire was promoting Mesasal outside of its approved use in the Mezavant promotional brochure. No breach of Sections 1.1 or 1.3 was found in relation to this point.

The Committee discussed the duration of treatment with Mezavant at the highest dose of 4.8 grams a day in the case study. It noted that the Product Information recommends that patients should be evaluated after 8 weeks at this dose, but does not state that treatment should not continue at the high dose. The high dose should be used to induce remission, and then the dose reduced to maintain remission. The case study stated that Amy had achieved remission after 4 weeks, but had remained at the highest dose for 5 months. In its response to the complaint, Shire had explained that Amy had continued at the highest dose to allow her concurrent treatment with oral and topical corticosteroids to be reduced and withdrawn. However, this explanation was not provided in the case study. A minority of the Committee considered that the case study was not promoting the product outside of its approved dose. These members considered that this was an actual case study about a person with long-standing disease. The audience for the material was gastroenterologists who would be familiar with such management challenges. A majority of the Committee considered that the case study was evidently a person with long-standing disease who had been very difficult to manage. The audience for the material was gastroenterologists who would be familiar with such management challenges. A majority of the Committee were not concerned about lack of balance. A minority of the Committee were not concerned about lack of balance in the case study. These members considered that this was a case study about a real patient who had been very difficult to manage. Whilst further explanations could have been included in the case study, their omission did not result in an unbalanced representation of the case.

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prescribe Mezavant. In unanimous decisions, the Committee found no breach of Sections 9.1 or 4.1.

Sanction
As the Committee had found that the Mezavant case study relating to Amy was in breach of Sections 1.1 and 1.3 of the Code the Committee considered what sanction should be imposed. The Committee determined that this was a minor breach of the Code because it would not have any implications for patients’ safety and would have no major effect on the way that healthcare professionals prescribe the product. The Committee determined in a majority decision to impose the following sanctions:

- the case study promotional material should be withdrawn from use and not used again in the same or similar form.
- pay a fine of $20,000.

The Committee determined that no corrective action was required.

Response
GlaxoSmithKline rejected the allegations that the advertisements and the claim were in breach of the Code. GlaxoSmithKline argued that the claim is fully supported by the COMPARZ study, which is the only head to head, randomised controlled study that compares Votrient and sunitinib as first line therapy in metastatic renal cell carcinoma. GSK asserted that the claim is an accurate reflection of the quality of life indicators reported in the COMPARZ study. The COMPARZ study was published in a peer reviewed journal and has been included in the Votrient Product Information following TGA evaluation.

GSK strongly disagreed that the advertisements had the potential to mislead healthcare professionals or to negatively impact patient care.

During intercompany dialogue GlaxoSmithKline had proposed to modify future versions of the advertisements to include the non-inferiority design of the primary endpoint and the statistical significance of the quality of life indicators. These changes have been implemented.

Code of Conduct Committee Decision
The Code of Conduct Committee determined by majority decisions that the Votrient advertisements subject to complaint were in breach of the following Sections of the Code of Conduct:

Issue 1: Overarching superiority claim
1.1 Responsibility
1.3 False or Misleading Claims
1.8 Comparative statements

The Committee agreed by unanimous decision that the Votrient advertisements subject to complaint were not in breach of the following Sections of the Code of Conduct:

Issue 2: Lack of substantiation
1.2 Substantiating data
1.8 Comparative statements

Sanction
Having found that the advertisements were in breach of Sections 1.1, 1.3 and 1.8 of the Code, the Committee determined that the advertisements should be withdrawn from use and not used again in the same or similar form. In addition, the Code Committee imposed a fine of $20,000.

Consideration of the Complaint
The complaint concerned an advertisement with claims comparing two tyrosine kinase inhibitors, which block the growth of renal cell carcinoma in people who have advanced and/or metastatic renal cell carcinoma – sunitinib (Sutent), Pfizer’s product,
and GSK’s pazopanib (Votrient). A randomised, open label, Phase III trial comparing the two drugs was completed and is included in the Votrient Product Information, following evaluation by the Therapeutic Goods Administration (TGA). This study, known as the COMPARZ study, included 1110 patients and was powered to show the non-inferiority of pazopanib versus sunitinib for progression-free survival. The study was conducted by a lead investigator who is highly respected in the field and who has conducted clinical trials for both GSK and Pfizer. The study was published in the New England Journal of Medicine, a well-respected, peer-review journal, in August 2013.

Study secondary endpoints included health-related quality of life assessments which were measured using several different instruments, some of which had been validated, but one of which was not validated in the usual manner. The results of these quality of life assessments favoured Votrient over sunitinib in 11 of the 14 indicators, with a p-value of <0.05, which was statistically significant.

Pfizer’s complaint alleged that the Votrient advertisement was in breach of the Code on three grounds:

Issue 1 – The advertisement conveys an overarching superior survival claim for Votrient over sunitinib that is false and misleading

Issue 2 – The quality of life claim cannot be substantiated by the referenced study, COMPARZ

Issue 3 – the advertisement has the potential to adversely impact patient care and is therefore a serious breach of the Code.

Issue 2 - The quality of life claim cannot be substantiated by the referenced study, COMPARZ

The Committee discussed the claim “The majority (11/14) of QoL indicators significantly favoured VOTRIENT over Sunitinib in a head-to-head study in first-line mRCC” which was referenced to the COMPARZ study. This claim appeared in prominent red text immediately below a kidney-shaped hourglass image with the heading “Every day counts”. The Committee noted that the claim relating to quality of life (QoL) indicators was closely similar to wording included in the Votrient Product Information and the COMPARZ study, which each described these as “health-related QoL” assessments.

The Committee considered the arguments presented by Pfizer relating to the timing of administration of the quality of life measures during the study and whether the QoL indicators had been validated. The Committee noted that the quality of life assessments were pre-specified secondary or tertiary endpoints in the study; their analysis was not retrospective or post hoc. Whilst the study reported significant differences for 11 of 14 comparisons of health-related quality of life assessments, seven of these had a small to medium effect size, one had a medium to large effect size and the rest had a small effect size. The Committee noted that the results of the QoL indicator assessments were consistent with the side effect profile for Votrient, as was noted in the Product Information and the COMPARZ study.

The Committee did not agree that the quality of life claim was false or misleading or that this claim by itself implied an overall superiority claim for survival for Votrient. In the Committee’s view the claim specifically related to the quality of life assessments and did not imply an overall survival advantage for Votrient. The claim accurately reflected the results of the COMPARZ study and the representation of these results in the Product Information. In unanimous decisions, the Committee found no breach of sections 1.2 or 1.8 in relation to the quality of life claim.

Issue 1 – The advertisement conveys an overarching superior survival claim for Votrient over sunitinib that is false and misleading

The Committee discussed the heading claim “Every day counts” and the associated imagery of a kidney-shaped hourglass with a bright white curved line wrapped around the neck of the hourglass, seemingly stopping the flow of sand, symbolising time, in the hourglass. The Committee considered that the claim in association with the imagery and the claim relating to quality of life indicators would suggest to readers that Votrient is able to slow or stop the progression of time running out for patients and therefore suggested a survival advantage for Votrient. The Committee noted that the COMPARZ study showed non-inferiority for progression-free survival with Votrient compared to sunitinib, not superiority.

The Committee considered that the claim “Every day counts” was intentionally ambiguous. It could be interpreted that Votrient gives patients more days in their life if they are treated with Votrient rather than sunitinib, or it could be interpreted that the daily quality of life for patients during their treatment with Votrient was better than if they were treated with Sunitinib. This ambiguity contributed to the Committee’s view that the claim was misleading and falsely implied a survival advantage for Votrient over Sutent which was not consistent with the COMPARZ study.

The Committee determined by majority decisions that the claim “Every day counts” as it appears in the advertisement was a misleading and unfair comparison with sunitinib because it implied that there is a survival advantage for Votrient which is not correct or consistent with the evidence. In majority decisions the Committee found that the
overarching superiority claim “Every day counts” as it appeared in the advertisement was in breach of sections 1.1, 1.3 and 1.8 of the Code.

**Issue 3 – The advertisement has the potential to adversely impact patient care and is therefore a serious breach of the Code**

Issue 3 related to the quality of life claim in the advertisement. Having found that the quality of life claim was not in breach of the Code and was consistent with both the COMPARZ study and the Votrient Product Information, the Committee did not accept Pfizer’s argument that the advertisement may adversely affect patient care. It was noted that Votrient is a specialised treatment prescribed by oncologists who would be closely familiar with the use of these products and the data supporting their safety and efficacy. Oncologists are encouraged to consider quality of life as well as efficacy of treatments. The Committee considered that a specialist oncologist would assess each patient for their quality of life and side effects during treatment. If a patient experienced quality of life problems the oncologist would consider whether this required a change in therapy. The allegation that the claim was a serious breach of the Code was unanimously dismissed.

**Sanction**

Having found that the advertisements were in breach of Sections 1.1, 1.3 and 1.8 of the Code, the Committee discussed an appropriate sanction. The Committee considered that this was a minor breach based on how the claim “Every day counts” would be interpreted. The Committee determined that advertisements containing the claim “Every day counts” should be withdrawn from use and not used again in the same or similar form. In addition, the Code Committee imposed a fine of $20,000.

**Appeal**

Pfizer Australia, the Complainant, lodged an appeal concerning the Code Committee’s decision that the claim “The majority (11/14) QoL indicators significantly favoured Votrient over sunitinib in a head-to-head study in first-line mRCC” was not in breach of Sections 1.8, 1.2.2 and 1.3 of the Code.

Pfizer asserted that the Code Committee failed to fully consider all aspects of Pfizer's complaint and made a number of errors of interpretation. Pfizer argued that the Committee did not fully consider whether the claim subject to complaint met the Code requirement that care should be taken to distinguish between mathematically determined statistical significance on the one hand and clinical significance on the other. In addition, Pfizer argued that the Code Committee erred in determining that the claim for superiority of Votrient could be adequately substantiated by the COMPARZ study.

**Appeal Response**

GSK responded that Pfizer’s assertions were addressed in full in GSK’s original response and had been fully evaluated by the Code Committee. GSK argued that Pfizer had not provided any relevant additional information or evidence to support its arguments that the Committee ‘made a number of errors of interpretation’ in reaching its determination.

**Appeals Committee decision**

The Appeals Committee agreed by unanimous decisions that the claim “The majority (11/14) of QoL indicators significantly favoured VOTRIENT over sunitinib in a head-to-head study in first-line mRCC” was in breach of the following Sections of the Code of Conduct:

1.3 False or Misleading Claims
1.2.2 Level of Substantiating Data
1.8 Comparative statements

**Sanction**

Having found that the claim was in breach of Sections 1.3, 1.2.2 and 1.8 of the Code, the Committee determined that any advertisement containing the claim should be withdrawn from use and not used again in the same or similar form. Noting that the Code Committee had imposed a fine of $20,000 in relation to its finding that the overarching claim ‘Every Day Counts’ in the advertisement was in breach of the Code, the Appeals Committee did not impose any further monetary sanction or impose any other sanction.

**Consideration of the Appeal**

The Pfizer representative stated that Pfizer fully agreed with the Code Committee’s summary of the COMPARZ study in its Reasons for Decision. It also agreed with the Code Committee’s reasoning in finding that the hourglass imagery in association with the headline claim ‘Every Day Counts’ was ambiguous, misleading and falsely implied a survival advantage for Votrient over sunitinib that could not be substantiated from the COMPARZ study.

Pfizer considers that the Code Committee’s decision to find that the claim “The majority (11/14) QoL indicators significantly favoured Votrient over sunitinib in a head-to-head study in first-line mRCC” (“The QoL claim”) was not in breach of the Code was in error. Pfizer stated that the Code Committee had failed to consider that the Code requires a company to distinguish between mathematical significance and clinical significance when making a comparative claim. In addition, Pfizer contends that the Code Committee had failed to fully consider that the Quality of Life (QoL) measures in the COMPARZ study were inadequate to substantiate a claim of clinical superiority for Votrient over sunitinib on the basis of these measures.
Pfizer explained that QoL measures commonly utilise a sliding scale to record patient reported outcomes. QoL measures are validated following internationally accepted criteria to determine the Minimally Important Difference (MID) for each measure, which indicates whether a statistical difference in result is clinically meaningful. The effect size is an estimate of the strength of a result. However, there is no direct relationship between effect size and clinical significance.

Pfizer noted that Section 1.8 of the Code requires that care should be taken to distinguish between mathematically determined statistical significance and clinical significance when making comparative statements. Pfizer highlighted that the COMPARZ study protocol stated that MID would be used to interpret the QoL results. Expert opinion about the QoL results has stated that there was no difference shown on one QoL measure (FACIT-F) and although there were differences with two other QoL measures (FKSI-19 and CTSQ), the level of MID was not reached. Therefore, no reliable conclusions can be made about the difference between Votrient and sunitinib. In addition, the Votrient Product Information (PI) does not state that 11 of the 14 QoL measures were clinically meaningful. The PI states that differences in fatigue, mouth/throat and hand/foot soreness, feelings about side effects and satisfaction with therapy were likely to be important because the effect size was above the accepted threshold of 0.2, but this does not mean that these measures were clinically significant.

Pfizer argued that given the lack of clinical significance for the QoL measures, when the QoL claim referencing the COMPARZ study is used MIDs must be provided, which would allow healthcare professionals to evaluate whether the QoL measures are clinically meaningful. Pfizer noted that a 14 page Votrient promotional brochure from the UK includes a table with the MIDs for each QoL measure (where these had been established).

Pfizer then argued that the QoL evidence from the COMPARZ study was not adequate to support the QoL claim. The QoL measures were a secondary outcome measure. However, the secondary outcome was not clinically significant, was not the pre-specified method to interpret results, was weakened by bias due to the timing of when the QoL measurement was taken, was weakened by the open-label design of the study which introduces subjectivity and was not related to the primary outcome of progression-free survival. Pfizer then explained these points.

Pfizer presented its analysis of the claim that 11 of the 14 QoL measures significantly favoured Votrient over sunitinib. Pfizer argued that the 14 measures were derived from 4 questionnaires. Two questionnaires (containing 6 QoL measures) were validated, but the differences in score were below the MID. One, the Cancer Therapy Satisfaction Questionnaire (CTSQ), containing 3 measures, was not a QoL instrument and the differences were below the MID. The Supplemental QoL Questionnaire (SQLQ) containing 5 measures had not been validated and no MID had been established. Therefore, Pfizer argued, the QoL claim could not be adequately substantiated from the COMPARZ study.

Pfizer argued that the Code Committee may have erred in its evaluation of the clinical significance of the QoL measures by forming the opinion that the difference in side effect profile between the Votrient and sunitinib meant that Votrient was better tolerated. However, whilst the two medicines do have different side effect profiles, which is important in treating cancer, their overall tolerability is similar. The COMPARZ study showed that rates of more serious adverse effects were similar, as were discontinuation rates due to toxicity.

Pfizer also argued that the Code Committee made an error of interpretation when it found that the QoL measurements were pre-specified secondary or tertiary endpoints in COMPARZ. Pfizer noted that the study protocol had stated that MIDs will be used to interpret results of statistical treatment comparisons, but there was no pre-specified method to interpret QoL scores other than MIDs.

Pfizer stated that the QoL measures had been weakened by the timing of QoL measurements in the treatment cycle. Sunitinib is administered daily for four weeks followed by 2 weeks without treatment, during which adverse effects would improve. Votrient is a daily dose continuously. The QoL measures were assessed on day 28 of the first 9 treatment cycles and on day 42 of subsequent cycles. The COMPARZ authors had acknowledged that this timing of assessments could be interpreted as being biased towards Votrient because it did not capture sunitinib patients’ recovery after two weeks without treatment.

Finally, Pfizer argued that the QoL measures were weakened because COMPARZ was an open label study. Biases by physicians and patients can be introduced when taking QoL measurements in an open label study. In addition, there is no direct positive correlation between the primary outcome measure – progression-free survival – and Quality of Life, which is an independent secondary outcome. An Appeals Committee member asked what is the relevance of the primary and secondary outcomes not being related to each other with respect to the QoL claim for Votrient. Pfizer responded that secondary endpoints tend to be stronger if they are related to the primary endpoint.

An Appeals Committee member asked about the relationship between effect size and clinical significance of the QoL measures. Pfizer explained...
that due to the variability in results from QoL measures, the measures are evaluated to determine the Minimally Important Difference – MID – and then whether it is clinically significant. The COMPARZ study stated that it followed the established convention that an effect size of less than 0.2 is unlikely to be important. Eight of the 14 QoL measures had an effect size greater than 0.2.

An Appeals Committee member asked whether Pfizer rejects the overall indication from the COMPARZ study data that the measures were all trending to favour Votrient over Sutent (sunitinib). Pfizer responded that they would agree with respect to the primary outcome measure, but for the QoL measures the Code requires that if the MID (which is the relevant indicator of clinical significance) was not reached this needs to be clear to a reader. Whilst there has been a diversity of opinions expressed by experts about the COMPARZ QoL measures, the question at hand relates to a promotional claim subject to the Code.

An Appeals Committee member noted that whilst the tolerability profiles for Votrient and Sutent are similar, the QoL measures are concordant with the toxicity data which shows there are lower toxicity rates for pazopanib versus sunitinib. Pfizer reiterated that the question relates to a promotional claim – whether it was clinically significant and whether it can be substantiated by the COMPARZ study. A number of the QoL measures did not meet MIDs and, as previously described, the measures were biased towards Votrient.

An Appeals Committee member asked whether Pfizer had suggested to GSK that it include the MID table from the UK promotional material in the Australian advertisement. Pfizer advised that the UK material had not been discussed in inter-company dialogue. However, the table would give healthcare professionals the opportunity to evaluate the QoL data. The Appeals Committee noted that the UK piece was a 14 page detail aid, whereas the advertisement subject to complaint contains a single claim.

The Chairman invited the GSK representatives to give their response to the appeal.

The GSK representative provided a short history of the complaint. GSK noted that, although GSK considered that the advertisement fully complied with the Code, during intercompany dialogue it had offered to amend the advertisement to include the non-inferiority design of the primary endpoint and to include the statistical significance of the QoL indicators. However, a resolution was not achieved and Pfizer submitted its complaint.

GSK summarised the evidence supporting the QoL claim, pointing to the consistency between the relevant statements about the QoL measures in the COMPARZ study publication, the Votrient PI and the QoL claim subject to complaint. The Code Committee had agreed that the claim accurately reflected the COMPARZ study and the PI and unanimously found that the QoL claim was not in breach of the Code.

In response to the alleged breach of Section 1.2.2, GSK argued that the COMPARZ study has been published in the New England Journal of Medicine (NEJM), a highly respected peer-review journal; has been evaluated by the TGA and included in the Votrient PI; and has been evaluated and included in independent treatment guidelines. The claim in the advertisement is solely related to the extent that side effects impact on Quality of Life. The claim can be fully substantiated by the COMPARZ study.

In response to the alleged breach of Section 1.8, GSK argued that the claim is an accurate reflection of the QoL endpoint, which was a pre-specified secondary endpoint in the COMPARZ study. The claim is entirely consistent with the conclusions of the COMPARZ study and further supported by the inclusion of the COMPARZ study in the Votrient PI. GSK have now modified the QoL claim to clarify that this endpoint was “statistically” significant. This change was implemented in Votrient advertisements following the intercompany dialogue.

GSK explained that the COMPARZ authors considered that effect size and not MID was important. This is reflected in the statement in the TGA approved Votrient PI “The differences in fatigue, mouth/throat and hand/foot soreness and their limitations, feelings about side effects and satisfaction with therapy were considered likely to be important (effect size >0.2)”. MIDs were not discussed by the authors in the COMPARZ study primary publication or supplementary publication; only effect size was mentioned. GSK noted that the Code Committee had recognised the consistency between the COMPARZ study, and the PI.

GSK noted in relation to the clinical significance of the QoL evidence in the COMPARZ study, Table 2 in the study publication provides the P value for the statistical comparisons for the 14 QoL measures between pazopanib and sunitinib. Eleven of the measures favoured pazopanib and for the other 3 none favoured sunitinib. GSK argued that the totality of the evidence needs to be considered as it is likely that benefits, even modest ones in multiple QoL domains, are likely to be of benefit to a patient. GSK referred to a statement by one of the COMPARZ study investigators, D. Cella, that “A clear trend across domains (and HRQoL tools) favouring a particular treatment in terms of HRQoL should be considered as an important signal of benefit”. GSK argued, therefore, that oncologists should be made aware of QoL data to help them care for their patients, which was the purpose of the Votrient advertisement. The advertisement had only been published in specialist journals.
In summary, GSK concluded that it had presented the QoL evidence in a manner that was consistent with the way the data was presented in the COMPARZ study publication and in the Votrient PI. Therefore, GSK considers that the advertisement was not in breach of Section 1.8. The COMPARZ study is a high quality study, consistent with the body of evidence and supports the claim. Therefore, the advertisement is not in breach of Section 1.2.2 of the Code. Finally the claim is not misleading, but is accurate and balanced and not in breach of Section 1.3 of the Code. GSK argued that Pfizer’s appeal should be rejected.

The Chairman noted that Section 1.8 of the Code requires companies to distinguish between mathematical significance and clinical significance. He asked GSK to state whether it considered that the QoL measures are clinically significant. GSK responded that the company believes that the QoL measure differences are important clinically. The Chairman noted that, whilst not binding, GSK had agreed in the intercompany dialogue to amend the Votrient advertisement to state that the QoL measures were statistically significant.

An Appeals Committee member noted that a placebo controlled study of pazopanib (Sternberg et al, 2010, Journal of Clinical Oncology), found that patients treated with pazopanib did not have a clinically important difference relative to the MID for QoL measures. GSK responded that in the COMPARZ study publication, published in the NEJM, the authors did not mention MIDs for the QoL measures. This study has been peer reviewed for publication and was included in the Votrient PI at the TGA’s request. The primary publication and the PI are the most important sources according to the Code, and neither mention MID but refer to the pattern observed in the side effect profile.

GSK added that the claim was virtually verbatim from the published study and the PI. A Committee member noted that taking one or two lines out of another source and communicating it can change the meaning and context. Another Committee member noted that the claim omits the word “statistically” (significant) as compared with the statement in the PI. GSK responded that it considered it was implicit that the differences were statistically significant but has made this explicit in the revised QoL claim.

A Committee member questioned the timing of the QoL measures, noting that the measure is a ‘snapshot’ on a particular day. In the COMPARZ study the timing of the QoL measures was recognised by the investigators as favouring pazopanib (Votrient). This introduced a bias that undermined the reliability of the QoL indicators. GSK responded that the QoL questionnaires did ask about the preceding two weeks, but different tools looked at different effects. An Appeals Committee member noted that with respect to anaemia, this becomes worse after treatment with sunitinib for four weeks and declines to day 42 in the cycle before it rebounds. This would impact the QoL measure.

A Pfizer representative contributed that in theory a change in haemoglobin would affect the peak score (for QoL). In Pfizer’s complaint, it had highlighted that the QoL measures were consistently worse at the end of 4 weeks treatment compared with at 6 weeks. This highlights that 11 of 14 QoL measures favouring Votrient were only on a statistical measure. Pfizer reiterated its argument that only 8 of the 14 measures had an effect size greater than 0.2. However, Pfizer has argued about the clinical significance (MID) of the QoL measures. Pfizer asserts that none of the QoL measures reached its MID. GSK has included the MIDs in UK promotional materials.

Pfizer responded to GSK’s reference to the quotation from Dr Cella. Pfizer noted that this statement referred to a ‘trend’ favouring pazopanib, but a ‘trend’ is not the standard of evidence required by the Code for making a comparative claim. Pfizer reiterated that a company should only claim clinical relevance if the MID was reached for QoL measures. This needs to be clear to healthcare professionals. Pfizer argued that there was inadequate information provided in the advertisement to enable healthcare professionals to correctly interpret the QoL data. In conclusion, Pfizer argued that there is no statistical measure (P value) for the claim that 11 of 14 QoL measures favoured Votrient. This is merely an observation from the COMPARZ study.

GSK re-joined that the Votrient advertisement was a ‘reminder’ style of advertisement, following earlier communications by GSK about the COMPARZ study outcomes. The full study report is freely available. The Code requires that communications to healthcare professionals are consistent with peer-reviewed literature, the PI and the Code.

The Chairman thanked the GSK and Pfizer representatives for their presentations and excused them from the meeting to allow the Committee to deliberate on the appeal.

Appeals Committee Consideration

An Appeals Committee member explained the grading of adverse effects in oncology and how these relate to QoL measures. Grades 1 and 2 adverse effects represent how the patient is feeling – the level of nausea, for example. Grade 3 adverse effects require some intervention by the treating physician. Grade 4 adverse effects are life threatening. QoL measures relate to Grade 1 and 2 adverse effects. Interpretation of QoL measures is inherently controversial. The effect size is arbitrarily determined. QoL measures are ‘summary’ indicators that do not necessarily reflect an individual patient’s
experience. A clinician would interpret the QoL measure’s MID according to guidance from experts and compare an individual patient with what is reported in clinical studies. When treating an individual patient, a clinician has a range of drugs available to choose. For a particular patient, a clinician will base their choice of therapy on toxicity and tolerability, as well as considering the extent of the disease and other clinical factors.

The Appeals Committee discussed whether the claim could be adequately supported by the COMPARZ study. Whilst the study was published in the NEJM, there are flaws in the study, as acknowledged by the authors, such as the timing of the QoL questionnaires favouring pazopanib. Further, the SQLQ, which included 5 QoL measures had not been validated and the MID had not been established. COMPARZ was an open label study, which introduces potential bias for patients and clinicians administering the QoL measures. However, the QoL measures are repeated during the course of the study, which possibly mitigates the potential for bias. The Appeals Committee noted that the MID had not been reported for 8 of the 14 QoL measures in the COMPARZ study. Overall, the Committee considered that the QoL measures were robust, but are subject to considerable interpretation. The Committee concluded that the study data were not adequate to support a claim that Votrient had demonstrated clinical superiority to sunitinib for the QoL measures. The Appeals Committee further determined that, as the study was not adequate to support the claim, it was misleading.

The Committee discussed the question of mathematical or statistical significance versus clinical significance. The Appeals Committee agreed that the QoL claim implied clinical superiority of Votrient over sunitinib by omission of the word “statistically”. The Committee considered that the omission of the word “statistically” from the claim failed to meet the requirement in Section 1.8 of the Code to distinguish between statistical and clinical significance.

Appeals Committee decision
The Appeals Committee unanimously determined that the QoL claim in the Votrient advertisement was in breach of Sections 1.2.2, 1.3 and 1.8 of edition 17 of the Code.

The Appeals Committee agreed by unanimous decision that the Pfizer appeal against the decisions of the Code Committee was upheld.

Sanction
Having found that the claim was in breach of Sections 1.3, 1.2.2 and 1.8 of the Code, the Appeals Committee determined that GSK must cease using the QoL claim in its present form in any advertisement and the claim must not be used again in the same or similar form.

The Appeals Committee considered whether an additional fine should be imposed. It noted that the Code Committee had imposed a fine of $20,000. The Appeals Committee concluded that no further fine was required on this occasion.

Bond
As the appeal was upheld, the Appeals Committee determined that the appeal bond of $20,000 should be returned to Pfizer Australia.

ELIQUIS PROMOTIONAL MATERIAL – 1116

Subject Company: Pfizer Australia Pty Ltd and Bristol-Myers Squibb Australia
Complainant: Bayer Australia Limited
Product: ELIQUIS

Complaint
Bayer Australia alleged that a claim for Eliquis (apixaban) which appeared in various promotional materials and advertisements was in breach of the Code of Conduct. Specifically, Bayer alleged that these materials make claims for Eliquis based on the secondary objectives of the ARISTOTLE study, which claim superiority of Eliquis compared with warfarin, and fail to state the primary objective of this study, which was to determine if Eliquis is non-inferior to warfarin. Bayer alleged that the materials may mislead or deceive healthcare professionals by failing to state that the primary objective was non-inferiority.

Sections of the Code
The promotional activities are alleged to be in breach of the following sections of Edition 17 of the Code:
1.2.2 Level of substantiating Data
1.3 False or misleading Claims
1.8 Comparative Statements
4.2 Medical Literature and Reprints

Response
Pfizer and Bristol-Myers Squibb denied that the promotional materials and advertisements were in breach of the Code. Pfizer and Bristol-Myers Squibb argued that the claims for Eliquis were appropriately qualified and directly reflected the findings of the pivotal registration study, ARISTOTLE. The statistical design of this study included a pre-specified hierarchical sequential testing. The study first tested for non-inferiority for the primary outcome
and then superiority for the primary outcome once non-inferiority was achieved. Pfizer and Bristol-Myers Squibb argued that the materials subject to complaint accurately reflect the findings of the study and were fully compliant with the Code.

**Code of Conduct Committee Decision**

**Issue 1 – ‘Superiority’ Claims**

The Committee agreed by unanimous decisions that the promotional materials and advertisements subject to complaint were not in breach of Sections 1.2.2, 1.3 or 1.8 of the Code of Conduct.

**Issue 2 – ‘Less Bleeding’ claims**

The Committee agreed by unanimous decisions that the promotional materials and advertisements subject to complaint were not in breach of Sections 1.2.2, 1.3, 1.8 or 4.2 of the Code of Conduct.

**Sanction**

Having found that the advertisements and promotional materials were not in breach of any Section of the Code, no sanction was imposed.

**Consideration of the Complaint**

**Issue 1 – ‘Superiority’ Claims**

The Committee noted that the primary issue related to claims that Eliquis was superior to warfarin in preventing strokes in patients with non-valvular atrial fibrillation based on the ARISTOTLE study. The Committee referred to the study by Granger et al (2011) which was published in the New England Journal of Medicine. It noted that the study was designed with a hierarchical, sequential statistical plan for analysis. If non-inferiority was demonstrated for the primary endpoint of prevention of stroke and systemic embolism, then superiority for this endpoint would be tested. Further endpoints would be tested if superiority was demonstrated for the primary endpoint. This is a legitimate statistical approach. The Committee considered that the claims for Eliquis versus warfarin based on this study were therefore adequately substantiated and were not false or misleading. Further, that the design of the study was such that the omission from the promotional materials of any reference to the primary end point was not misleading.

The Committee unanimously dismissed the allegations that the claims for superiority of Eliquis versus warfarin were in breach of the Code and found no breach of Sections 1.3, 1.8 or 1.2.2. The Committee discussed whether the qualifying statement “Findings from the ARISTOTLE clinical trial: ELIQUIS vs warfarin” had been located directly below or adjacent to the claims to which it related. The Committee referred to Section 1.3 of the Code and the associated text in the Code Guidelines. The Committee noted that the Code Guidelines allow a qualifying statement relating to one or more points in a list of dot points to be located immediately below or adjacent to the dot point list. The Committee debated whether the statement “Eliquis, an oral anticoagulant that delivers E ALL OF THE ABOVE” was part of the preceding points a, b, c and d or a separate statement and claim. The Committee noted that the intention of the Code requirements relating to qualifying statements was to ensure that claims are not false or misleading by requiring such statements to be clearly visible to a reader. In the particular instance of the Eliquis promotional claims, the Committee accepted that the qualifying statement was in a prominent position and located immediately below the dot points it qualified. It was clearly visible to a reader of the advertisements. The Committee unanimously agreed that the location of the qualifying statement was not in breach of Section 1.3 of the Code.

**Issue 2 – ‘Less Bleeding’ claims**

The Committee discussed whether the claim for “less bleeding” for Eliquis versus warfarin could be substantiated. It reviewed Table 3 from the ARISTOTLE study (Granger et al, 2011) and noted that for all bleeding outcomes except GI bleeding Eliquis had a statistically significant lower number of bleeding events compared with warfarin. GI bleeding was approximately equivalent between the two drugs. The number of GI bleeding events was numerically lower for Eliquis compared with warfarin, but this was not statistically significant. The overall incidence of any bleeding event was lower for Eliquis and this was statistically significant. The Committee concluded that the “less bleeding” claim was fully supported by the ARISTOTLE study.

The Committee determined in unanimous decisions that the “less bleeding” claims were not in breach of Sections 1.2.2, 1.3, 1.8 or 4.2 of the Code of Conduct.

**Sanction**

Having found that the advertisements and promotional materials were not in breach of any Section of the Code, no sanction was imposed.

**NOVARTIS PHARMACEUTICALS’ CONDUCT – 1117**

**Subject Company:** Novartis Pharmaceuticals

**Complainant:** Healthcare Professional

**Product:** n/a

**Complaint**

A healthcare professional (a General Practitioner) lodged a complaint in relation to alleged unethical behaviour by Novartis Pharmaceuticals’ representatives that contravenes the Code. The
Complainant alleged that this was a serious breach of the Code of Conduct. The Complainant stated that the Novartis representatives no longer make appointments to see her or provide her with samples (starter packs). Further, the Complainant stated that they no longer receive invitations to attend Novartis’ educational events and feels that they have been unfairly discriminated against on the basis of her prescribing behaviour. The Complainant also alleged misconduct in relation to Novartis’ use of IMS data and that this use contravened Australia’s privacy laws.

Sections of the Code
The conduct was alleged to be in breach of the following Sections of Edition 17 of the Code:

5.2 Roles and Ethical Conduct
9.1 General Principles
9.3 Educational Events
9.14 Discredit to and Reduction of Confidence in the Industry
20 Discredit to and Reduction of Confidence in the Industry

Response
Novartis Pharmaceuticals rejected all allegations that Novartis was in breach of the Code. Novartis stated that its interactions with the Complainant have at all times been professional and have upheld the principles that would meet both public and professional scrutiny.

Novartis argued that Novartis’s policies specifically preclude interacting with healthcare professionals and government officials on the basis of prescribing behaviours either past, present or future. Novartis confirmed that its representatives do not currently make appointments with the Complainant as they have found interactions in the past not to be conducive to a professional dialogue. The representatives had offered to provide the Complainant with starter packs, which were refused on every occasion.

Novartis argued that companies are not obliged to invite all healthcare professionals to educational meetings and it would not be practical to do so. Novartis stated that it reserves the right to choose whom it invites to an educational event that it conducts and stated that the Complainant had invited herself to Novartis events, but on a number of occasions, the Complainant had disrupted the meeting such that it was not in the interest of other attendees for the Complainant to attend.

Novartis denied that the Complainant’s privacy had been compromised in relation to her prescribing practice. Novartis, like many companies, uses IMS’ data analysis of the prescription market but this is fully compliant with the Privacy Act. Novartis denied that any conversation regarding IMS data ever took place between the Complainant and a Novartis company representative.

Code of Conduct Committee decision
The Committee agreed by unanimous decisions that there was no breach of Sections 9.1, 9.3, 5.2, 9.14 or 20 of Edition 17 of the Code of Conduct.

Sanction
As no breach was found, no sanction was imposed by the Code of Conduct Committee.

Consideration of the complaint
The Committee noted that the Code does not require companies to invite all healthcare professionals to its educational meetings, require companies to make sales calls on all healthcare professionals or to provide starter packs to all healthcare professionals. The Committee noted that the Complainant had not provided any evidence to support their allegation that Novartis had ceased interacting with her on the basis of her prescribing behaviour. Novartis had confirmed that it did not interact with the Complainant, but stated that this was due to previous interactions not being professionally valuable.

Industry representatives attending the meeting advised that individual GP prescribing data is not available to companies from IMS or any other source. IMS does gather market data such as the number of prescriptions dispensed by pharmacies within a certain area, but not the number of prescriptions by individual healthcare professionals. The Committee also noted that the Complainant may contact Novartis’ Privacy Officer and request to be informed of any personal information held by the company.

The Committee regretted that the Complainant evidently felt very aggrieved by the circumstances described in her complaint but did not agree that the material before the Committee established that Novartis had breached the Code. On this basis, the Committee agreed unanimously that there was no breach of Sections 9.1, 9.3 or 5.2, 9.14 or 20 of Edition 17 of the Code.

Sanction
As no breach was found, no sanctions were imposed by the Committee.

Appeal
The Complainant appealed the Code Committee’s decision, arguing that the information Novartis had provided to the Code Committee was false and therefore the Committee had made an error in its decision.

The Complainant strongly rejected the allegations that Novartis has made against them in relation to their attendance at educational meetings and their...
attempts to discredit their version of events and professional ability as a healthcare professional.

**Appeal Response**

Novartis responded that it accepted that the Complainant felt aggrieved by the outcome of the Code Committee decision. However, it argued that the Code Committee made a correct determination.

Novartis stood by their right to choose with whom the company interacts. It had chosen not to call on the Complainant as a result of a history of interactions over the past few years.

**Outcome of Appeals Committee – 12 November 2014**

At the request of the Appeals Committee, Novartis was asked to investigate new allegations raised by the Complainant during the Appeals Committee meeting on 12 November 2014. The Committee asked Novartis to provide supplementary information for its further consideration.

**Supplementary Information – Novartis**

Novartis provided further advice to the Appeals Committee that continued to reject the allegations contained in the complaint and the new allegations of fraudulent activities alleged by the Complainant.

**Response to Supplementary Information – The Complainant**

The Complainant maintained their position and insisted that Novartis’ conduct in this matter did not meet any professional or industry standard in dealing with healthcare professionals.

**Appeals Committee decision**

The Appeals Committee unanimously agreed to confirm the Code of Conduct Committee decisions that there had been no breach of Sections 5.2, 9.1, 9.3, 9.14 or 20 of Edition 17 of the Code of Conduct.

**Sanction**

As the Appeals Committee confirmed the decisions of the Code of Conduct Committee that there had been no breach of the Code, no sanction was imposed.

**Consideration of the Appeal**

**12 November 2014 Meeting**

The Chairman explained the process for consideration of an appeal. The Appeals Committee must be persuaded that the findings of the Code Committee involved an error on the basis of which the decisions of the Code of Conduct Committee should be set aside or varied.

The Chairman summarised the complaint: The Complainant has complained that Novartis had ceased to deal with her. The Complainant alleged that the reason for this was that Novartis held confidential information about the Complainant’s prescribing behaviour for Novartis’ products. Novartis has responded confirming that it had decided to cease interacting with the Complainant, but this was not due to their prescribing behaviour but was due to previous interactions not being professionally valuable. The Code of Conduct Committee determined that the basis for the Complainant’s complaint had not been made out.

The Chairman invited the Complainant to give their appeal presentation to the Committee, and particularly to elaborate on the allegations as to the reasons that Novartis Pharmaceuticals’ representatives had given the Complainant for not visiting them or inviting them to educational meetings. The following summarises that presentation and discussion with the Appeals Committee.

The Complainant stated that they had been told by a Novartis sales representative that the company has a ‘target list’ of doctors who the representatives will visit and that the Complainant is not on that target list. The Complainant had not received any visits from Novartis representatives over the last 18 months to two years. Whilst other doctors in the same practice are targeted – they receive visits from sales representatives, are offered samples and receive invitations to educational meetings – the Complainant has not received similar attendance for approximately two years.

The Complainant advised that in late 2013 (late November or early December) they had wanted to attend two Novartis educational meetings. The Complainant had contacted the medical representative organising the meetings who made excuses and told the Complainant that they could not attend the educational meetings. The Complainant had contacted the Novartis’ Sales Manager for Victoria who also told the Complainant that they could not attend the educational meetings. The Complainant noted that this was corroborated by the exchange of emails between the Novartis Sales Coordinator, a Medical Representative and the Regional Sales Manager. These emails were included in Novartis’ response to the Complainant’s privacy request for personal information held by Novartis, which had been included in the Appeals Committee’s agenda papers.

The Complainant further explained that on 14 August 2014 the Complainant became aware that Novartis was holding another educational meeting. The Complainant had contacted the medical representative organising the meeting who told the Complainant that they could not attend because they were not one of Novartis’ ‘target doctors’. The Complainant also reported a conversation with another Novartis medical representative, at about the same time. The Complainant had asked this medical representative why he did not visit or give samples although other doctors at the GP practice...
did receive samples. The medical representative had told the Complainant that they were not on the company’s target list of doctors, which the company head office gives to medical representatives. When the Complainant had asked why they were not on the target list, the medical representative had responded that it related to IMS data.

The Complainant had looked into IMS data. Her research indicated that the data includes patient demographics, prescription data and that IMS can provide physician identity and specialty. The Complainant stated that Novartis has denied that medical representatives had told them about IMS data. The Complainant had contacted the Novartis’ Victorian Sales Manager, who had responded that Novartis was not the only company using a system of targeting certain doctors and using IMS data.

The Complainant argued that if Novartis was targeting one doctor in a GP practice and not another, the company must have individual prescribing data.

The Complainant stated that they considered that Novartis’ statements in its response to the complaint were false. Novartis had stated that the Complainant had refused the offer of samples, which the Complainant denied – they had never been offered samples. Novartis had denied that the reason for not visiting the Complainant was related to prescribing behaviour from IMS data. The Complainant stated this was false, as two Novartis medical representatives had told the Complainant this.

The Complainant further alleged that Novartis had falsified information provided in response to the privacy information request. This information included data extracted from the company’s Customer Relationship Management (CRM) database. The database stated two dates on which a Novartis representative called on the Complainant at their practice, but the Complainant denied that these visits had occurred.

The Chairman advised the Complainant that the Appeals Committee could only consider conduct that falls within the scope of the provisions of the Code of Conduct. The question for the Committee is whether there has been a breach of the Code.

The Chairman invited the Novartis representatives to give their response to the appeal.

Novartis stated that it had investigated the Complainant’s complaint. Novartis considered that Section 9.1 of the Code allows companies to choose which healthcare professionals to support and interact with. Novartis agreed with the Code Committee that there is no requirement for a company to invite all healthcare professionals to its educational meetings, make sales calls on all healthcare professionals or provide starter packs to all healthcare professionals.

With regard to the allegation that Novartis is not targeting the Complainant on the basis of IMS data, Novartis described the IMS data available to pharmaceutical companies. IMS data provides insight into prescription volumes in a territory, which will encompass multiple doctors. Data for an individual doctor’s prescribing pattern is not available to a pharmaceutical company. The multiple doctors within the territory where the Complainant’s practice is located demographically includes prescribing of Novartis’ products that would categorise the Complainant (and other doctors in the territory) as a tier 1 target for sales representatives.

Novartis further explained that targeting decisions are based only partly on IMS data. Other variables are also included, such as market research of territory demographics, feedback from the field and healthcare professional feedback. Up until December 2013, the Complainant had been categorised as a tier 1 target for a number of Novartis’ products.

Company target lists are reviewed annually, which includes removing any healthcare professionals who have asked not to receive sales representative visits, or who have said they do not have any patients for whom Novartis’ products are appropriate or where sales representatives’ visits have been found not to be conducive to a professional dialogue. There is also an increased focus on compliance within Novartis. In January 2014, Novartis had feedback from the field force that led Novartis to form the view that the Complainant’s interactions were less than professional and her attendance at educational meetings appeared to be more focused on receiving hospitality than the educational purpose. Novartis had received advice and complaints from other doctors that the Complainant had behaved unprofessionally at certain Novartis educational meetings. These doctors had asked that Novartis not invite the Complainant to future educational meetings.

Novartis advised the Committee that it had interviewed all relevant medical representatives and they had consistently confirmed they did not tell the Complainant that they were not targeted because of IMS data. Novartis confirmed that its investigation had included two medical representatives identified by the Complainant and the Victorian Sales Manager. Two other medical representatives identified in the Agora CRM database as having interacted with the Complainant are no longer employed by Novartis and therefore could not be interviewed.

Novartis noted that the Complainant had confirmed that they had attended a Novartis meeting in March 2014 to which they had not been invited, but had received the invitation from another doctor. Novartis accepts that the Complainant conducted herself appropriately at this meeting. However, at previous
Novartis meetings the Complainant’s conduct had not been professional and other doctors have asked Novartis not to invite the Complainant to further meetings. It is Novartis’ understanding that other companies have also decided not to interact with the Complainant. Novartis noted that it does not question the Complainant’s professional capabilities as a doctor.

Novartis concluded that it has chosen not to have any further interactions with the Complainant. Novartis argued that the Code Committee’s decision was correct and should not be set aside or varied by the Appeals Committee.

In response to a question from an Appeals Committee member about IMS data, Novartis explained that prescription data for a territory are based on pharmacy dispensing data. These data would mostly reflect prescriptions from doctors within that territory. However, some prescriptions could relate to doctors from outside the territory and some prescriptions written by doctors within the territory might be dispensed in another territory. A company only gets an overview of the number of doctors and prescriptions dispensed in a territory. The territory that includes the Complainant’s GP practice includes a number of other doctors and practices. An Appeals Committee member noted that, based on IMS data, a tier 1 doctor would be valued by a company. Novartis has decided not to interact with the Complainant, although the IMS data would indicate that they would be a tier 1 doctor. This indicates that other factors have caused Novartis to cease its interaction with her.

The Complainant responded to Novartis’ appeal presentation stating that Novartis’ allegations regarding her conduct were false. The Complainant argued that if Novartis states that its medical representatives did not call on them, why does Novartis also claim that starter packs were offered and refused. The Complainant further stated that they do not receive Novartis’ promotional material via mail. The Complainant repeated the allegation that Novartis had falsified entries in the CRM database indicating that a Novartis medical representative had visited her in August 2013 and March 2014.

The Chairman noted that the Complainant had made a number of further allegations against Novartis that should be investigated before the Committee determines whether the appeal should be upheld. In particular, the Chairman asked Novartis to provide a further response to the Appeals Committee addressing the Complainant’s allegations concerning the alleged refusal of offered starter packs (samples); to explain the entries in the CRM contacts database which the Complainant alleges are false; provide further details about Novartis’ investigations with relevant sales representatives; and provide an explanation of the relevance of the company anti-bribery policy to the substance of this complaint.

15 December 2014 Meeting

The Complainant and Novartis were not present at the Appeals Committee meeting of 15 December 2014.

Novartis Pharmaceuticals had provided a further submission in response to the Complainant’s allegations. It rejected the Complainant’s allegations in her complaint and the new allegations of fraudulent activities.

The Complainant provided a further response to Novartis’ second submission. The Complainant maintained their position and insisted that Novartis’ conduct in this matter did not meet any professional or industry standard in dealing with healthcare professionals.

The Appeals Committee considered the appeal and the further submissions to determine whether the appeal should be upheld.

The Complainant has alleged breaches by Novartis of Sections 5.2, 9.1, 9.3, 9.13, and 20 of the Code, which relevantly govern the conduct of companies in their general dealings with health care professionals. Section 9.3 does not seem to be particularly relevant to the substance of the Complainant’s complaint.

The gist of the Complainant’s complaint was that they were being denied services and starter packs by Novartis because they were not (or was thought not to be) prescribing their product. The Complainant claimed that Novartis was using confidential information about their prescribing behaviour provided by an audit firm.

In their appeal and subsequently, the Complainant has alleged that Novartis has provided false or misleading information to Medicines Australia concerning its dealing with them, causing the Code of Conduct Committee to fall into error in finding no breach by Novartis. The Complainant also alleged that they were being discriminated against, and seemed to suggest that there was some overarching obligation on companies to provide their product and their support services to all healthcare professionals. There is no such obligation in the Code.

A complaint under the Code procedure necessarily bears the onus of establishing the facts which would make out a breach of the Code. Although the standard of proof is not such as would be required in a court of law, the Code Committees can only safely proceed if they are reasonably satisfied that the conduct (if not admitted by the company) has in fact occurred. Medicines Australia is not in a position to conduct its own investigations; it is dependent on the “evidence” provided by the parties before and (in the case of an appeal) at the
In the present case, Novartis did not dispute that it had decided to cease dealing with the Complainant. The issue of fact was its motivation in so doing. Had Novartis’ motivation been to “punish” the Complainant, or to discriminate against them on some basis which involved conduct of the kind described in Sections 5.2, 9.1, 9.14 or 20 of the Code (there being for present purposes some overlap between these provisions), it could have been in breach.

Novartis disputes the Complainant’s characterisation of its motivation and says its motivation was simply that the relationship with the Complainant had broken down and it had elected to have no further dealings with the Complainant. It is clear that a company is not required by any provision of the Code, or otherwise so far as the Committee is aware, to provide product or services to a particular healthcare professional (for example, Section 7.5 in relation to starter packs, which was one of the Complainant’s complaints).

The evidence was that Novartis did not have access to information that would enable it to determine an individual doctor’s prescribing habits or history, due, among other things, to the fact that such information as it received was aggregated and did not relate to individual doctors.

Novartis’ initial response to the complaint did not expressly contradict the Complainant’s attribution of motivation; in particular, it did not deal with the words attributed to one of its medical representatives in speaking to the Complainant. Novartis’ response dealt with the complaint at the level of policy, which was not particularly helpful. Nonetheless, the Code Committee found no breach. The Appeals Committee requested Novartis to deal with this aspect of the complaint and it has since done so. It appears that the medical representative is no longer employed by Novartis and it is therefore impossible to put to him the words attributed to him by the Complainant. However, assuming against Novartis that the words used were as quoted by the Complainant, what interpretation is to be placed on them? The Complainant contends that the words were: “you are no longer on our target list of doctors”, and interprets this as meaning that they were being denied product and services by Novartis due to prescribing habits or history. However, when these words are taken with the fact that Novartis did not have access to the Complainant’s prescribing behaviour or history, they do not convey the meaning the Complainant attributes to them. It is perhaps understandable that the Complainant placed this meaning on them, because they were under the impression that Novartis had information about her prescribing behaviour. The words are, however, perfectly consistent with the explanation of its motivation given by Novartis, since it did not have the prescribing behaviour information and, indeed, it would have been contrary to its commercial interests to decline to supply product to any doctor. It follows that Novartis has decided to cease dealing with the Complainant for other reasons than the ones attributed to it by the Complainant. If this amounts to discrimination, it is not something which is proscribed by the Code.

The evidence concerning the Complainant’s attendance and conduct at educational events conducted by Novartis is of a subjective and disputed nature. It is part of the reasons Novartis gives for its decision not to interact with the Complainant. It is not possible for Medicines Australia to resolve this controversy and it is largely beside the point, given that it is open to a company to invite whomever it wishes to such events, and decide whether or not to deal with a particular healthcare professional, as long as its reasons (whether articulated or not) for doing so are not such as can be characterised as unethical or unprofessional (Section 5.2), would not withstand public scrutiny or be in bad taste (Section 9.1), and therefore are not such as might bring the industry into disrepute or discredit (Sections 9.14 and 20).

The Appeals Committee noted that a company is obliged to provide a safe workplace for its employees. If employees are having difficulties with a healthcare professional, the company must take appropriate action to resolve any situation where the relationship between company employees and a healthcare professional have broken down.

While there may have been exchanges between Novartis’ employees and the Complainant which were intemperate (as alleged by the Complainant), they do not appear to have risen to the serious level of proscribed conduct under the Code. It was for the Complainant to make out this part of her complaint and they have not been able to do so. The parties have unfortunately reached an impasse where any further dealings are likely to be fraught and unproductive. The Complainant has chosen to interpret Novartis’ decision to cease dealing with them as directed at undermining their own professional standing, but there is at least some evidence that their own conduct has at times been provocative, such as attending meetings to which they were not, or not initially, invited. The testimony of others attending these meetings is in conflict and as such it is not possible for the Appeals Committee to resolve the controversy. However, there appears to be at least sufficient basis in this and the Complainant’s other communications with the company for Novartis to make the decision it has.

In these circumstances, and having heard at some length from both parties, the Appeals Committee is
not persuaded that Code Committee was in error in the decision it reached that the complaints had not been made out.

**Appeals Committee decision**
The Appeals Committee unanimously determined that the Code of Conduct Committee’s decisions should be confirmed. The appeal was not upheld.

**Sanction**
As the Appeals Committee confirmed the decisions of the Code of Conduct Committee that there had been no breach of the Code, no sanction was imposed.

**SERETIDE PROMOTIONAL MATERIALS – 1118**

Subject Company: GlaxoSmithKline Australia Pty Ltd
Complainant: Mundipharma Pty Ltd
Product: Seretide

**Complaint**
Mundipharma alleged that certain claims for Seretide (fluticasone propionate / salmeterol xinafoate) which appeared in various print and electronic advertisements and printed promotional materials were in breach of the Code of Conduct. Mundipharma raised concerns with the use of the GOAL study in the promotional materials and questioned the applicability of the study in clinical practice. Mundipharma alleged that insufficient information regarding the study and its design had been provided in the promotional materials that would ensure the study’s proper interpretation. Mundipharma alleged this was false and misleading and in breach of the Code.

Mundipharma alleged that these materials could potentially significantly influence doctors’ treatment choice for an asthmatic requiring an inhaled corticosteroid/long acting beta agonist combination inhaler, which Mundipharma alleged was a severe breach of the Code.

Mundipharma stated that GlaxoSmithKline Australia (GSK) had agreed to amend or withdraw much of the promotional materials subject to complaint, but had declined to undertake corrective action. Mundipharma had proposed that GSK send a letter to all healthcare professionals and a full page advertisement in the same journals as the original advertisements.

**Sections of the Code**
The promotional materials were alleged to be in breach of the following Sections of Edition 17 of the Code:

1.1 Responsibility
1.2 Substantiating data
1.2.2 Level of Substantiating Data
1.3 False or misleading claims
1.4 Unapproved Products and Indications
1.6 Unqualified superlatives
1.8 Comparative statements

**Response**
GlaxoSmithKline Australia (GSK) denied that the promotional materials and advertisements were in breach of any section of the Code. GSK rejected Mundipharma’s assertion that the GOAL study is inappropriate to use in a promotional context. GSK considered that it was unreasonable that Mundipharma would question the applicability of the GOAL study in clinical practice, as it has been incorporated into the Seretide approved Product Information and into independent global asthma guidelines.

GSK asserted that all promotional claims used in the advertisements and promotional materials subject to complaint are fully supported by the GOAL study, a pivotal and landmark asthma study, and the Product Information for Seretide. The GOAL study data had been accurately represented in the printed promotional materials and sufficient details about the study had been provided in order to contextualise the applicability of the results to clinical practice.

GSK stated that any amendments to its materials that were agreed during intercompany dialogue with Mundipharma had been offered in order to achieve resolution of Mundipharma’s concerns, were undertaken in good faith and were not an admission of having breached the Code. GSK asserted that patient care was not compromised as a result of the promotional materials and argued that Mundipharma had not presented any substantiation for this assertion. Therefore GSK did not agree that any corrective action was warranted.

**Code of Conduct Committee decision**

**Issue 1 - “Australia’s Most Prescribed ICS/LABA”**
The Committee agreed by unanimous decision that the promotional materials and advertisements subject to complaint were not in breach of Section 1.8 of the Code of Conduct.

**Issue 2 - Use of Fictitious Patient Quotes**
The Committee agreed by unanimous decisions that the promotional materials and advertisements subject to complaint were in breach of Sections 1.2 and 1.3 of the Code of Conduct.

**Issue 3 – Statistics Quoted from the GOAL Study**
The Committee agreed by unanimous decisions that the promotional materials and advertisements subject to complaint were not in breach of Sections 1.1 and 1.3 of the Code of Conduct.

**Issue 4 – Images and claims:** “Is managing asthma like a marathon or a sprint”, “Choose Seretide: Sustained bronchodilation (24 hour with bd dosing)”

The Committee agreed by unanimous decisions that the promotional materials and advertisements subject to complaint were not in breach of Sections 1.3, 1.6 or 1.8 of the Code of Conduct.

**Issue 5 – “Sustained bronchodilation (24 hour with bd dosing)”**

The Committee agreed by unanimous decisions that the promotional materials and advertisements subject to complaint were not in breach of Sections 1.2.2, 1.3, 1.4 or 1.8 of the Code of Conduct.

**Sanction**

The promotional material found in breach must be withdrawn from use and must not to be used again in the same or similar format. The Committee also agreed by majority decision to impose a fine of $40,000.

**Consideration of the complaint**

The Committee considered the complaint in the order set out in the Mundipharma complaint document.

**Issue 1 – “Australia’s most prescribed ICS/LABA”**

Mundipharma had alleged that the claim “Australia’s most prescribed ICS/LABA” was a hanging comparative and in breach of Section 1.8 of the Code. The Committee considered that this claim was a statement of fact and had been referenced to an appropriate source. The Committee did not agree that the statement was a hanging comparative. It was clearly a comparison with other inhaled corticosteroid/long-acting beta agonist combination inhalers.

The Committee unanimously found no breach of Section 1.8 of the Code.

**Issue 2: Use of Fictitious Patient Quotes**

The Committee noted that promotional item AUS/SFC/0035b included two statements in quotation marks beside an image of a young woman. The Committee agreed that readers would interpret the material to mean that these statements were actual patient quotes, whereas GSK had acknowledged that these were fictitious quotations. GSK had agreed during intercompany dialogue to make clear that the statements were not from real patients. The Committee agreed in unanimous decisions that the failure to make it clear that these statements were fictitious quotes and not from real patients was false and misleading. The claims were not referenced and, as they were created by GSK, could not be substantiated and therefore were in breach of Sections 1.3 and 1.2 of the Code.

**Issue 3 – Statistics Quoted from the GOAL Study**

Mundipharma had argued that the GOAL study was an inappropriate source for promotional claims due to methodological problems with the study design. The Committee did not agree with this assessment of the GOAL study. The Committee noted that the study is a real world study published in a good quality peer-reviewed journal and had been included in the Seretide Product Information, indicating that the study had been evaluated by the TGA and considered appropriate.

The Committee observed that sufficient details of the GOAL study and its design had been included in the promotional material. Further, the promotional material accurately represented the results of the study. The statistics quoted in the promotional material reflected these results. The Committee considered that the study did support the claims made in the promotional material. The Committee agreed in unanimous decisions that the claims in the promotional material that quoted statistics from the GOAL Study were not in breach of Sections 1.1 or 1.3 of the Code.

**Issue 4 – Images and claims:** “Is managing asthma like a marathon or a sprint”, “Choose Seretide: Sustained bronchodilation (24 hour with bd dosing)”

Mundipharma had alleged that the images and claims referring to asthma management as a marathon or a sprint made an implied comparison with other, undefined products. Mundipharma alleged that the comparison was an unqualified superlative and a hanging comparison. The Committee did not agree that there was any implied or explicit comparison between Seretide and another product or other products. It noted that the green and red outfits worn by the runners allegedly representing other products could not be associated with particular products. The Committee agreed in unanimous decisions that the promotional material was not in breach of Sections 1.3, 1.6 or 1.8 of the Code.

**Issue 5 – “Sustained bronchodilation (24 hour with bd dosing)”**

The Committee considered Mundipharma’s allegation that the claim “Sustained bronchodilation (24 hour with bd dosing)” implied a longer duration of action than is stated in the Seretide Product Information. The Committee unanimously disagreed with Mundipharma’s interpretation of the claim. The Committee considered that the claim only would be interpreted to mean that with twice daily dosing, 24 hours of bronchodilation may be achieved, which is
consistent with the approved Product Information. The Committee agreed in unanimous decisions that the promotional material was not in breach of Sections 1.2.2, 1.3, 1.4 or 1.8 of the Code for reasons of this claim.

Alleged abuse of the Code

The Committee noted that GSK had alleged that Mundipharma may be in breach of Section 25 - Abuse of the Code. However, as GSK had been found in breach of the Code in relation to one part of the compliant, the Committee did not consider that Mundipharma should be required to respond to the allegation of having abused the Code process.

Sanction

Having found that one item of promotional material was in breach of the Code due to the use of fictitious patient quotes, the Committee considered an appropriate sanction. The Committee considered that this was a moderate breach of the Code because it may have some influence on how healthcare professionals prescribe this product, but there were no safety implications for patients. The Committee did not agree that any corrective action was required.

The Committee agreed that a monetary sanction should be imposed because the promotional material had the potential to affect prescribing of Seretide. The promotional material found in breach must be withdrawn from use and must not to be used again in the same or similar format. In addition, the Committee agreed by majority decision to impose a fine of $40,000.

LIVE PROGRAM FOR VELCADE – 1119

Subject Company: Janssen Pty Ltd
Complainant: Monitoring Committee
Product: Velcade
Complaint

Following its review of printed promotional material in the Neoplastic Disorders therapeutic class (MIMS Class 9) and subsequent requests for clarification, the Medicines Australia Monitoring Committee considered that the LivE program brochures containing the claim “Leading Excellence in SC and IV therapy” may be in breach of the Code and therefore referred the matter to the Code of Conduct Committee for adjudication.

Sections of the Code

The promotional activities are alleged to be in breach of the following Sections of Edition 17 of the Code:

1.2.2 Level of Substantiating Data
1.3 False or Misleading Claims

Response

Janssen denied that the materials were in breach of the Code of Conduct as the materials were never intended to relate to Velcade, the therapy being administered. The sole purpose of the materials was to educate healthcare professionals about the service. The brochures were only made available to healthcare professionals who had expressed interest in the service. Janssen asserted that the materials were produced by the QUM Department of Janssen, which acts independently from the commercial part of the business. The materials did not form part of sales material.

Janssen also advised that the tagline in question will be removed from all future materials when they are reprinted and all current materials with the tagline will be removed from the QUM service centres and destroyed.

Code of Conduct Committee decision

The Committee agreed by majority decisions that the LivE program brochures, published by Janssen, subject to complaint were not in breach of Sections 1.2.2 and 1.3 of the Code of Conduct.

Sanction

Having found that the promotional materials were not in breach of the Code, no sanction was imposed.

Consideration of the complaint

The Committee noted that the primary issue that concerned the Monitoring Committee was whether the claim “Leading Excellence in SC and IV therapy” was a claim of “excellence” for the product Velcade or for the injection program for administration of the drug. The Committee reviewed the patient and healthcare professional brochures. The majority of the Committee considered that the statement “Leading Excellence in SC and IV therapy”, which appeared with the ‘LivE’ logo and in the brochure text, was not directly associated with qualities of Velcade. These Committee members considered that the brochures’ text did not directly or indirectly make claims for Velcade. A Committee member noted that injection administration programs provide a valuable service to enable patients to receive their treatment efficiently and with no cost to the patient.

A minority of the Committee agreed with the Monitoring Committee that it was ambiguous as to whether the claim related to the administration program or to Velcade. This ambiguity made the claim misleading and unable to be substantiated in these Committee members’ view.

The Committee noted that Janssen had removed the tagline from all future materials and all current
materials will be removed from the service centres and destroyed.

The Committee agreed by majority decisions that the Live program brochures, published by Janssen, subject to complaint were not in breach of Sections 1.2.2 or 1.3 of the Code

Sanction
As the Committee did not find a breach of the Code of Conduct, no sanction was imposed.

NEXAVAR DETAIL AID – 1120

Subject Company: Bayer Australia Limited
Complainant: Monitoring Committee
Product: Nexavar

Complaint
Following its review of printed promotional material in the Neoplastic Disorders therapeutic class (MIMS Class 9) and subsequent requests for clarification, the Medicines Australia Monitoring Committee considered that the Nexavar Detail Aid containing the claim “The only systemic treatment proven to significantly improve overall survival in advanced HCC … Regardless of patient characteristics and extent of disease” may be in breach of the Code and therefore referred the matter to the Code of Conduct Committee for adjudication.

Sections of the Code
The promotional activities are alleged to be in breach of the following Sections of Edition 17 of the Code:
1.1 Responsibility
1.3 False or Misleading Claims

Response
Bayer denied that the claim was in breach of the Code of Conduct or that the detail aid is misleading or unbalanced in any way. Bayer argued that the Monitoring Committee had misconstrued the claim. The two claims in the item were a heading claim: “The only systemic treatment proven to significantly improve overall survival in advanced HCC … Regardless of patient characteristics and extent of disease” may be in breach of the Code and therefore referred the matter to the Code of Conduct Committee for adjudication.

Bayer rejected the allegation that there is potential for patient harm if reliance is placed on the detail aid for information.

Code of Conduct Committee decision
The Committee agreed by majority decisions that the Nexavar Detail Aid subject to complaint was in breach of Sections 1.1 and 1.3 of the Code of Conduct.

Sanction
The Committee determined that materials should be withdrawn from use and not used again in the same or similar form. In addition, in a majority decision, the Code Committee imposed a fine of $10,000.

Consideration of the complaint
The Committee noted that the main issue in this complaint was whether the statement “Regardless of patient characteristics and extent of disease”, which appeared in bold text and in a larger font size than other text on the page, should be read as one statement with “Nexavar demonstrated consistent OS advantage in the SHARP trial”, which appeared immediately below the preceding statement, was not bolded and was in a smaller font size. These claims appeared on the left page of a double page spread which carried the heading claim “The ONLY systemic treatment proven to significantly improve overall survival in advanced HCC”.

Bayer had argued that the two statements (one in bold and the following unbolded statement) should be read together. Bayer argued that the unbolded statement qualified the preceding bolded statement as only relating to patients in the SHARP trial. However, a majority of the Committee members considered that the bolded statement “Regardless of patient characteristics and extent of disease” would be read by healthcare professionals as a separate statement in the context of the heading claim “The ONLY systemic treatment proven to significantly improve overall survival in advanced HCC”. As the two statements in question were in a different font size and one was bolded and the other not, a reader would not read the two statements together as one sentence as argued by Bayer. Rather, a healthcare professional would read the overarching heading statement and the bolded statement together.

The Committee noted that the Nexavar Product Information states, under Precautions, that no data is available on patients with Child-Pugh C (severe) hepatic impairment. The Committee also noted the claim below the graph, on the same page as the statements in question, “Consistent survival advantage with Nexavar” followed on the next line by “across a range of advanced HCC patient populations”. The Committee considered that this claim reinforced the claim “Regardless of patient characteristics and extent of disease”, which was not consistent with the Nexavar Product Information.
The Committee concluded that whilst there was some ambiguity regarding how the statements may be read – whether together or as one statement – there was the potential to mislead healthcare professionals in their interpretation of which patients should be treated with Nexavar.

The Committee determined in majority decisions that the claims were misleading and were not consistent with the approved use of Nexavar. The Committee determined that the promotional material was in breach of Sections 1.1 and 1.3 of the Code. The Committee determined that this was a minor breach of the Code and was unlikely to negatively affect patient care.

Sanction
Having found that the promotional materials were in breach of Sections 1.1 and 1.3 the Code, which was a minor breach of the Code, the Committee determined that materials should be withdrawn from use and not used again in the same or similar form. In addition, in a majority decision, the Code Committee imposed a fine of $10,000.

Novartis argued that improving presentation skills for healthcare professionals forms a key part of medical education and improvement of the quality use of medicines. Medical knowledge is enhanced by educating healthcare professionals in their ability to communicate their knowledge to others.

Novartis considered that the event was fully compliant with and in the spirit of the Code. However it would welcome any further guidance from the Code Committee to inform the design of future educational programs.

Code of Conduct Committee Decision
The Committee agreed by unanimous decisions that educational event subject to complaint was in breach of Sections 9.1 and 9.3 of the Code of Conduct. The Committee agreed by unanimous decision that this was a moderate breach of the Code.

Sanction
Having found that the educational event was in breach of the Code, the Committee imposed the following sanctions:

- By a majority decision, pay a fine of $90,000
- Do not hold any further meetings in the same or similar form

Consideration of the Complaint
The Committee discussed the educational value for healthcare professionals of the one-day presentation skills program delivered by the National Institute of Dramatic Art (NIDA) Corporate Performance. The Committee referred to Sections 9.1 and 9.3 of the Code, which require that the primary purpose of companies’ interactions with healthcare professionals and involvement in educational events must be the enhancement of medical knowledge and the quality use of medicines (QUM). The Committee also reviewed the Code of Conduct Guidelines relating to Section 9.3, which state (inter alia): “provision of training that will enhance the interaction of healthcare professionals with their peers or patients may be justifiable”.

The Committee noted that only three retinal specialist ophthalmologists had attended the event, who were described in the Novartis invitation as “Novartis Retinal Fellows”. The Committee considered that a very select group of healthcare professionals, who had an established relationship with Novartis, had been invited to attend the educational meeting. The Committee therefore questioned whether the primary objective of the meeting was to enhance medical knowledge and QUM or in fact had primarily a commercial objective for the company’s interests. The Committee was concerned that the educational event was targeted at a group of specialist healthcare professionals who were Novartis Retinal Fellows, which gave the appearance that the event was a form of reward to these individuals who prescribed Novartis’ ophthalmological product.
The Committee reviewed the course outline and duration of the event. The program covered four areas: 'The Presenter's Voice', 'Engaging Others', 'Physical Presence' and 'Presentation' over six and three quarter hours excluding meal breaks. There was no evidence provided to demonstrate how these topics, although evidently focused on presentation skills, related to the enhancement of medical knowledge and QUM or to enhance interactions with peers or patients when communicating medical or scientific information. Whilst the Code Guidelines recognise that training that enhances healthcare professionals' interactions with their peers or patients may be justifiable, the Committee did not agree that a full day program for just three doctors in a very narrow therapeutic area at a substantial cost could be justified. The cost of the meeting and its duration was disproportionate to the educational value expected under the Code. The Committee also considered that the educational event could not successfully withstand public or professional scrutiny, as required under Section 9.1 of the Code.

The Committee reviewed the background and rationale provided for the educational event. The Committee considered that the rationale was very brief and did not provide sufficient justification for the event with respect to enhancing medical knowledge and QUM.

The Committee reviewed the testimonial provided by one of the three attendees but was not persuaded that because the healthcare professional had found it useful this justified the event.

The Committee agreed in unanimous decisions that the educational event was in breach of Sections 9.1 and 9.3 of Edition 17 of the Code.

Sanction
Having found that the educational event was in breach of the Code, the Committee discussed appropriate sanctions.

The Committee noted that the event subject to complaint was the first of a series of planned events of the same type. The Committee determined that Novartis should not arrange or support further educational meetings in the same or similar form.

The Committee considered that this was a moderate breach of the Code because the interactions with healthcare professionals relating to this event may influence how they will prescribe Novartis’ ophthalmological product but there would be no safety implications for patients. The Committee determined by majority decision that Novartis should be required to pay a fine of $90,000.
The Committee agreed by unanimous decisions that educational event subject to complaint was in breach of the Sections 9.1, 9.3 and 9.7 of the Code of Conduct.

The Committee agreed by unanimous decision that this was a severe breach of the Code.

**Sanction**

Having found that the educational event was in breach of the Code, the Committee imposed the following sanctions:

- Pay a fine of $200,000.
- Send a copy of the full reasons for the decision to all healthcare professionals who attended the educational event.

**Consideration of the complaint**

The Committee expressed considerable concern that Australian healthcare professionals had been flown to Puerto Rico, from Atlanta, to undertake a plant tour and receive presentations about Amgen’s biologic product Aranesp.

With regard to the rationale for providing a biologic medicine manufacturing plant tour, the Committee did not accept Amgen’s justification that healthcare professionals needed to be assured through first-hand experience of a manufacturing facility that biologic medicines meet appropriate quality standards. The Code Committee agreed with the Monitoring Committee that Australian healthcare professionals are assured of product quality by the Therapeutic Goods Administration’s (TGA) evaluation and approval of a product.

The Committee reviewed the presentations by Amgen’s Director of Global Biosimilars Policy and an Australian healthcare professional that were provided in Amgen’s response to the complaint. The Committee considered that the primary purpose of these presentations and the plant tour were to persuade the attending healthcare professionals to continue to prescribe and recommend Aranesp rather than any biosimilar product. The Committee noted that Amgen had stated in its response that the attending healthcare professionals were “opinion leaders in the nephrology community” who not only prescribed medicines for their patients but also were in influential positions as members of hospital or state formulary committees. Therefore, the Committee was concerned that the plant tour in Puerto Rico may have broader influence on maintaining prescribing of Aranesp than just the individual healthcare professionals who attended.

The Committee referred to Sections 9.1, 9.3 and 9.7 of the Code, which each require that the primary purpose of companies’ interactions with healthcare professionals and involvement in educational events must be the enhancement of medical knowledge and the quality use of medicines (QUM). The Committee considered that whilst the presentations provided clinical information about erythropoietin and the treatment of anaemia associated with chronic kidney disease and biosimilar medicines, it was unnecessary for these presentations to be delivered at an educational meeting at a manufacturing facility in Puerto Rico. These presentations could have been given in Australia or in Atlanta where the healthcare professionals attended the ASN meeting. The Committee noted that the cost of the Puerto Rico meeting was over $46,000 for 14 healthcare professionals and included two nights’ accommodation and two dinners. The Committee further noted that whilst Amgen had stated that it had not sponsored the healthcare professionals to attend the ASN meeting in Atlanta, it was evident from the testimonial letters that some of the healthcare professionals had also received sponsorship for the ASN conference registration and accommodation in Atlanta for the duration of the conference.

The Committee concluded that there was a lack of balance between the educational purpose of the meeting in Puerto Rico and the travel, accommodation and hospitality provided. The Committee was very concerned that the primary purpose of the meeting was to influence individual healthcare professionals to prescribe Aranesp and more broadly to influence key decision makers who are members of hospital formulary committees. The Committee considered that the educational meeting would not withstand public and professional scrutiny as is required under section 9.7.1 of the Code.

The Committee reviewed the testimonial letters from 10 healthcare professionals who had attended the event subject to complaint. The Committee was not persuaded by the letters that the educational purpose of the meeting was to enhance medical knowledge and the quality use of medicines. Most of the letters from healthcare professionals emphasised their interest in the manufacturing process for biologic medicines. The Committee reiterated that it considered that it was unnecessary to fly healthcare professionals to Puerto Rico to assure them of the quality of medicines supplied in Australia.

The Committee determined by unanimous decisions that the educational meeting held in Puerto Rico was in breach of Sections 9.1, 9.3 and 9.7 of the Code. The Committee also agreed by unanimous decision that it considered that this was a severe breach of the Code because the conduct would not withstand public or professional scrutiny.

**Sanction**

Having found the educational event to be in breach of the Code, the Committee considered appropriate sanctions. The Committee determined by majority...
decision that Amgen should be required to pay a fine of $200,000. In relation to taking corrective action, the Committee determined that Amgen should be required to send a copy of the full Code of Conduct Committee reasons for the decision in relation to this complaint to each healthcare professional who had attended the educational event found in breach of the Code.

**Appeal**

Amgen appealed the Code Committee’s decisions as it considered that the Code Committee had based its decisions on a number of errors of fact and assumptions. Amgen argued that a number of irrelevant matters appeared to have influenced the Code Committee’s considerations.

Amgen argued that education for prescribers about biologics is legitimate and is supported by Medicines Australia. Experiential learning is commonly used for adult education and other companies have undertaken similar activities involving a visit to a manufacturing facility, which has not been subject to complaint or adverse public opinion. Amgen argued that the hospitality was reasonable given the location and logistics for the event.

**Appeals Committee decision**

The Appeals Committee agreed by unanimous decision to uphold the appeal and amend the decisions of the Code of Conduct Committee. The Appeals Committee determined that the Amgen educational event was not in breach of the following Sections of the Code of Conduct:

9.1 Relationship with Healthcare professionals – General Principles

9.3 Educational Events

9.7 Sponsorship of Healthcare Professionals to attend educational events

**Sanction**

As the appeal was upheld and the Code of Conduct Committee’s decisions overturned, the sanctions imposed by the Code Committee were removed.

**Consideration of the Appeal**

The Chairman explained the process for consideration of an appeal. The Appeals Committee must be persuaded that the findings of the Code Committee involved an error on the basis of which the decisions of the Code of Conduct Committee should be set aside or varied.

The Chairman invited the Amgen representatives to give their appeal presentation. The following summarises that presentation and discussion with the Appeals Committee.

The Amgen representative noted that a healthcare professional who gave a presentation at the meeting held in Puerto Rico was present to provide a perspective from a participant in the educational event but not to advocate on behalf of Amgen or for its conduct.

Amgen stated that education of healthcare professionals on biologic medicines and biotechnology manufacturing is critical and there is a strong link to quality use of medicines (QUM) outcomes. The TGA is responsible for evaluating products for quality, safety and efficacy but the TGA does not provide education on issues that concern biologics such as substitutability and pharmacovigilance.

The education provided at the Amgen event in Puerto Rico was entirely consistent with existing industry standards and benchmarks. Amgen noted that Medicines Australia’s Policy Considerations for Biologics and Biosimilars recommends educating healthcare professionals on the complexities associated with biologics and biosimilars. Amgen argued that the event was consistent with the Code and with actions of other companies that had held similar plant tours for healthcare professionals in association with educational meetings. Therefore, Amgen considers that the educational event in Puerto Rico would stand up to public and professional scrutiny.

Amgen stated that the Code Committee made errors in its decision making that justify reconsideration of the alleged breach.

In its reasons for decision the Code Committee expressed the view that the primary purpose of the Amgen event was the promotion of Aranesp and gave some weight to that in its decision. However, there is no biosimilar to Aranesp and Amgen has its own biosimilars program. The healthcare professional’s presentation in Puerto Rico had referred to other biologics as well as to Aranesp. Amgen argued that it was incorrect to determine that the purpose of the Amgen event was to promote Aranesp.

The Code Committee had referred to its consideration that some healthcare professionals who attended the meeting had been sponsored to attend the American Society of Nephrology (ASN) meeting in Atlanta prior to the Amgen educational event. Amgen argued that the ASN meeting was a separate event and reference to this event or sponsorship of healthcare professionals to attend it was irrelevant to consideration of the Amgen educational event in Puerto Rico.

The Code Committee had found that the Amgen event was a serious breach of the Code based on the inability to withstand public or professional scrutiny. However, there has been no negative commentary about the event from any professional college or society or the media. A number of the attendees work in Western Australia, where they must have prior approval from senior bureaucrats in
the Department of Health before receiving sponsorship to attend an educational meeting. The agenda and hospitality are scrutinised before approving the sponsorship. The healthcare professionals’ attendance at the Amgen event was approved without question. Further, in its appeal submission Amgen had provided examples of at least five educational events organised by two companies involving similar site visits. Therefore, Amgen considers that the event can withstand public and professional scrutiny and was not in breach of the Code.

Amgen responded to the Code Committee’s reasons regarding the location of the Amgen event in Puerto Rico. Amgen argued that the choice of the venue was appropriate. The event in Puerto Rico minimised the cost and participant time in comparison with the alternative of visiting the Amgen manufacturing plant in Ireland. The hotel chosen for accommodating the delegates was close to the airport and had 24 hour security – security is a particular concern in Puerto Rico. Puerto Rico is not in any way a holiday destination and the educational program occupied all of healthcare professionals’ time in Puerto Rico except for travel to and from the airport. There was no allowance for free time or leisure activities.

Amgen responded to the Code Committee’s opinion that the Amgen meeting did not have medical education and the quality use of medicines as its primary purpose. Amgen stated that experiential learning is a validated approach to delivering effective adult learning that is retained by participants. The complexity of biotech manufacturing requires an experiential approach to learning because the manufacturing steps in producing a biologic are significantly greater than for small molecule medicines; there is a higher need for process controls and trend monitoring.

Amgen described the QUM purpose of the educational event. Amgen argued that the event educated delegates about why it is necessary for healthcare professionals to be clear on which biological they intend to prescribe for a patient and to know which product the patient actually receives. Pharmacovigilance considerations are especially important for biologics and the ability to track the patient and exactly which product was administered is critical. In response to a question from the Committee Amgen explained that these issues were particularly critical for biologics, which are large protein molecules injected into patients. Patients must be monitored for allergic reactions. Minor changes in the manufacturing process can have profound effects on the product, which therefore requires very close controls on manufacturing.

Amgen outlined the cost of the event. The level of hospitality was consistent with the Code, comprising two dinners at less than $100 per person for each and two nights’ accommodation. The majority of the cost for the 14 delegates was airfares to and from Puerto Rico. Delegates arrived late one afternoon, had an early morning pick up for the site visit, which finished at 5.30pm, and at 6.30am the following morning returned to the airport. There was no leisure time.

The healthcare professional gave his perspective on the Amgen educational event at which he spoke. He outlined his academic and industry relationships, which included being an Advisory Board member for both innovator and biosimilar companies. In the past, he had attended factory tours organised by three other companies. The purpose of the Amgen factory tour and presentations was to help healthcare professionals understand the issues with pure red cell aplasia and biosimilars and the safeguards employed in manufacturing biologics and biosimilars.

The audience for the presentations in Puerto Rico were Australian nephrologists and Amgen executives from Puerto Rico. The healthcare professional prepared his own presentation, which described the history of the treatment of anaemia in Australia. It was a balanced presentation, which was about not only Aranesp but also discussed outcomes related to other companies’ products and biosimilars. The presentation included a criticism of an Aranesp trial, which showed that increasing the dosage interval resulted in more of the product being used.

The healthcare professional described the personal imposition on his time and loss of income from attending the Amgen event. However, whilst the benefit was to gain scientific information from Amgen, it also allowed him to provide research and development feedback directly to Amgen staff about their product and delivery system. The dissemination of information about biologics and biosimilars is important. The Amgen educational event took place in a venue that allowed direct interaction between healthcare professionals and R&D staff, enabling questions to be put to Amgen staff whilst the plant tour was conducted.

Amgen summarised their appeal. Amgen argued that the evidence and data do not support the Code of Conduct Committee’s decisions. Amgen considers that education of healthcare professionals on biologics and biotechnology manufacturing is appropriate and has clear QUM outcomes. Prescribers do not receive education from the TGA, nor does the TGA take responsibility for such matters. The education provided would appear to be entirely consistent with existing standards and benchmarks. Amgen believes that the Code Committee made errors in its decision-making. Therefore, the Appeals Committee should uphold the appeal and find that the Amgen educational event had not breached the Code.
An Appeals Committee member asked whether nephrologists have a choice of whether to prescribe Aranesp or an alternative product. Amgen responded that some hospitals provide a choice whereas others do not.

Amgen reiterated the importance of experiential learning and the significant impact on learning of seeing something in real life.

The Chairman thanked the Amgen representatives and the healthcare professional for their presentation and excused them from the meeting to allow the Committee to deliberate on the appeal.

Amgen had argued to the Committee that it was reasonable and appropriate to provide education to healthcare professionals about the challenges of manufacturing of biologics and biosimilars and that this is of educational value to prescribers of these medicines.

The Appeals Committee accepted that the travel and accommodation provided to the delegates was appropriate to the educational content and purpose. There had been no leisure time provided for at Puerto Rico; the entire duration of the event had been taken up by the educational program and travel to and from Puerto Rico. It appeared to the Appeals Committee that the Code Committee had inappropriately conflated their perception that there was no educational value in the event and its being held in a distant location.

The Appeals Committee discussed whether there was sufficient rationale to justify holding the educational meeting at the Puerto Rico biologics plant. A majority of the Committee accepted that biologic medicines are very complex. As biologic medicines are manufactured using living cells, small changes in the process can have significant impact for patients. A majority of the Appeals Committee accepted that it was beneficial for specialist physicians to be educated about these complex molecules and the differences between biologics and small molecule medicines. A majority of the Committee accepted that it was reasonable to hold the educational meeting at the Puerto Rico plant following the ASN meeting in Atlanta, as the delegates were in relatively close proximity.

The Appeals Committee considered that the Amgen meeting did have educational value for the delegates and the costs were reasonable given the necessity for flights.

The Appeals Committee discussed the Code Committee’s opinion expressed in its reasons for decision that the primary purpose of the event was to promote Amgen’s product Aranesp. A majority of the Committee accepted that the healthcare professional’s presentation was fairly balanced. These members accepted that, as the plant tour was held at Amgen’s manufacturing facility, the education about biologic manufacture would have focused on Aranesp. However, this was counterbalanced by the need for education about biologic medicines.

The Appeals Committee noted that Amgen had pointed to several other events held by other companies at their manufacturing facilities outside Australia, which had not been questioned. A minority of the Committee remained concerned that a number of Australian healthcare professionals had been taken to Puerto Rico for a factory tour. Other members of the Committee took into account that the healthcare professionals were already in the US for the ASN meeting.

The Appeals Committee discussed the Code Committee’s reasons for finding the educational event in breach of the Code.

The Appeals Committee considered that the Code Committee had erred in its reasoning by finding that Amgen could not justify the educational purpose because the TGA’s product evaluation provides assurance of product quality. The Appeals Committee accepted that it was appropriate to educate healthcare professionals about the complex manufacturing process for biologic medicines, which would encourage prescribers to be more aware of potential individual patient reactions to the complex protein molecules.

The Appeals Committee also considered that the Code Committee had erred in its reasoning by finding that the primary purpose of the presentations and plant tour was to persuade healthcare professionals to prescribe and recommend Aranesp rather than a biosimilar product. The Appeals Committee considered that this reasoning could not be sustained on review of the information before the Appeals Committee.

The Appeals Committee considered that the Code Committee had erred by taking into its consideration that some healthcare professionals attending the educational event had been sponsored by Amgen to attend the ASN conference in Atlanta. This information was not relevant to the consideration of whether the educational event held in Puerto Rico was consistent with the Code. The Appeals Committee did not agree with the Code Committee’s conclusion that there was a lack of balance between the educational purpose of the meeting and the travel, accommodation and hospitality provided.

The Appeals Committee considered that the Code Committee had erred in its decision that the educational event would not withstand public and professional scrutiny. The Appeals Committee accepted that there was acceptable educational value provided at the educational meeting and, in particular, were persuaded of the value of experiential learning by the healthcare professionals being able to see the manufacturing process first.
hand and to interact with the personnel responsible for R&D and the manufacturing process. This education would ultimately benefit patients.

Appeals Committee decision
The Appeals Committee unanimously determined to uphold the appeal and amend the decisions of the Code of Conduct Committee. The Appeals Committee determined that the Amgen educational event was not in breach of the following Sections of the Code of Conduct:

9.1 Relationship with Healthcare professionals – General Principles
9.3 Educational Events
9.7 Sponsorship of Healthcare Professionals to attend educational events

Sanction
As the appeal was upheld and the Code of Conduct Committee’s decisions overturned, the sanctions imposed by the Code Committee were removed.

Bond
As the appeal was upheld, the Appeals Committee determined that the appeal bond of $20,000 should be returned to Amgen Australia in full.

ADVERTISING IN NON-HCP PUBLICATION – 1123

Subject Companies: Bayer Australia Ltd, Merck Sharp & Dohme (Australia) Novartis Pharmaceuticals

Complainant: A Member of the General Public

Products: Elyea, Saflutan and Lucentis

Complaint
A member of the general public alleged that advertising by three member companies of prescription medicine products in the mivision magazine are in breach of the Code. The Complainant alleged that this magazine is distributed to optical dispensers who are not healthcare professionals, and therefore should be treated as members of the public.

Sections of the Code
The promotional activities were alleged to be in breach of the following Sections of Edition 17 of the Code:

13.3 Promotion to the general public

Response
Each responding company stated that they endeavour to be fully compliant with the Code and do not dispute placing advertisements for prescription medicines in the mivision magazine.

Code of Conduct Committee decision
The Committee agreed by unanimous decision that there had not been a breach of Section 13.3 of the Code of Conduct. As it was determined that no breach had occurred, no sanction was imposed by the Committee.

Consideration of the complaint
The Chairman summarised for the Committee that the complaint had been made by a member of the general public, alleging that all three companies have placed advertisements for prescription products in a publication that is also distributed to non-healthcare professionals. No complaint had been made concerning the content of the advertisements.

The complaint relates to the audience for mivision. The Complainant alleged that mivision is distributed to optical dispensers who are not healthcare professionals. Further, the Complainant argued that advertisements for prescription medicines should not be included in a publication that is distributed to non-healthcare professionals. No complaint had been made concerning the content of the advertisements.

The Chairman noted that the Code definition of a healthcare professional covers healthcare professionals as described in the Therapeutic Goods Act 1989 (the Act), to whom prescription medicines may be promoted. In their responses, the Subject Companies had noted that the definition of healthcare professionals in the Act includes optometrists and that the Act and the Code do not make a distinction between optometrists who have or have not been endorsed by the Optometry Board. All companies acknowledged that optical dispensers are not healthcare professionals, but mivision is not distributed to optical dispensers.

The Committee noted that the publisher of mivision had provided advice to the Subject Companies, which was included in their responses to the complaint, stating that the publication was only available to “…eyecare professionals who work in the Optometry and Ophthalmology professions in Australia and New Zealand. To be eligible to receive a subscription to mivision journal you must be either
an Optometrist, Ophthalmologist, Ophthalmic Nurse, Orthoptist or an academic with a healthcare qualification. [Optical] Dispensers, [and] non-healthcare professionals...are eligible to receive a free subscription to mivision’s e-newsletter...which does not contain any advertising of prescription medication...”.

Some members of Committee queried why some classes of healthcare professionals, such as optometrists, should be permitted to receive advertising of prescription medicines, since they are unable to prescribe the products. The Committee agreed, however, that these individuals are included in the definition of healthcare professional as set out in both the Code and the Act. Therefore, it was acceptable for them to be included in the distribution list for a publication that includes advertisements for prescription medicines.

The Committee had no evidence before them that the publication was being distributed to people other than a healthcare professional audience. The Complainant had not provided any evidence that the publication is being distributed to optical dispensers. The Committee agreed, therefore, that the Subject Companies had undertaken due diligence and, based on the information provided by the publisher, it is appropriate for this publication to include advertisements for prescription products. The Committee unanimously agreed that no breach of Section 13.3 of the Code of Conduct had occurred.

Sanction
Having found that no breach of the Code of Conduct had occurred, no sanction was imposed by the Committee.

Appeal
The Complainant continued to argue that mivision is a consumer magazine that contained prescription medicine advertisements available to the general public. The Complainant stated that mivision is distributed to optical dispensers and orthoptists, who are not registered healthcare professionals to whom prescription medicine advertisements may be directed. The Complainant stated that there have been articles in mivision written by optical dispensers and directed to optical dispenser readers.

The Complainant provided two address labels for mivision magazine which he stated are addressed to optical dispensers.

Appeal Response
Each company responded that the decision of the Code Committee was correct and should not be varied. All companies stated that they had conducted their due diligence to confirm that mivision was only distributed to healthcare professionals before placing any advertisement for prescription medicine in the magazine. The companies stated that they should not be expected to conduct due diligence down to individual subscribers.

Bayer responded that one recipient of the mivision magazine identified by the Complainant had received the publication because he was a regular contributor of articles published in the magazine. The other recipient had received the magazine in error, according to the publisher, and has been removed from the distribution list.

MSD stated that the arguments raised by the Complainant in his appeal are irrelevant to any section of the Code of Conduct and appear to be more of a commercial dispute which should be arbitrated though another mechanism or directly between the relevant parties.

Appeals Committee decision
The Appeals Committee agreed by unanimous decision to confirm the decisions of the Code of Conduct Committee. The Appeals Committee determined that the placement of advertisements for Eylea, Lucentis and Saflutan in the mivision magazine had not been in breach of Section 13.3 of the Code of Conduct, Promotion to the General Public.

Sanction
As the appeal was not upheld and the Code Committee’s decision to find no breach of the Code was confirmed, no sanction was imposed.

Consideration of the Appeal
The Chairman explained the process for consideration of an appeal. The Appeals Committee must be persuaded that the findings of the Code Committee involved an error on the basis of which the decisions of the Code of Conduct Committee should be set aside or varied.

The Chairman invited the Appellant to give a presentation to the Committee. The following summarises that presentation and discussion with the Appeals Committee.

The Appellant noted that in his appeal he had provided a copy of an address label for a person who is an optical dispenser, who receives mivision. This is contrary to the claims from the mivision publishers that the publication does not go to optical dispensers. The Appellant stated that there is no evidence of cessation of delivery of mivision to orthoptists or optical dispensers, except that mivision has revised its advertising guidelines (Media Kit).

The Appellant noted that advertising prescription medicines to orthoptists had not been included in his original complaint. Orthoptists were included in his appeal. The Chairman advised that complainants may not expand or embellish their complaint on
appeal. An appeal must relate to the decisions of the Code Committee.

The Appellant stated that only 37 percent of optometrists are therapeutically endorsed by the Optometry Board of Australia. The Appellant argued that prescription medicines should not be advertised to optometrists because the majority of optometrists cannot prescribe prescription medicines. The Australian Healthcare Practitioner Regulation Agency (AHPRA) register of optometrists identifies which optometrists are therapeutically endorsed.

The Appellant argued that there is a unique working relationship between optometrists and optical dispensers. There is every chance that the mivision magazine will be sighted by an optical dispenser if it is distributed to optometrists, unless the publication is specifically directed to only be viewed by optometrists. The Appellant stated that some orthoptists receive mivision magazine directly and others may view it by reason of their employment by ophthalmologists.

The Appellant noted that in Bayer’s response to his complaint it stated that it had extensive discussions with mivision regarding its readership prior to placing advertisements in the magazine. The Appellant challenged this assertion, arguing that there had only been a handful of calls and emails. The Appellant also challenged the assertion by the publisher of mivision that the magazine is distributed to “medically qualified eye care professionals” because optometrists are not medically qualified.

The Appellant noted that in MSD’s response to his complaint it stated that the company was satisfied from its enquiries to mivision that the publication did not go to optical dispensers. However, the Appellant had provided a mailing fly sheet addressed to an optical dispenser as evidence that the publication is distributed to optical dispensers. The Appellant stated that due to the Christmas and New Year holiday period, and that the magazine is not issued again until February, he had not been able to obtain fly sheets from other optical dispensers who receive mivision. The Appellant argued that if he had more time he would be able to demonstrate that mivision is distributed to optical dispensers. The Appellant asked the Appeals Committee to grant him more time to collect more evidence of fly sheets for mivision addressed to optical dispensers. The Appeals Committee Chairman advised the Appellant that the evidence to support his complaint should have been available at the time of making his complaint. It is not possible to delay consideration of the complaint whilst the Appellant seeks further evidence to support his allegations.

The Appellant referred to Novartis’ response to his complaint, which included a page from the mivision.com.au website, “About Us”. The page is dated December 2011, yet it refers to mivision circulation data from March 2014, being 7,289 recipients. The Appellant referred to the Media Kit 2013 and Media Kit 2014 published by mivision. The Code Committee Secretary clarified that the Appellant had provided data extracted from these Media Kits in his appeal submission but had not provided copies of them with his submission. The Chairman noted that the subject companies had received the Appellant’s appeal submission but had not had the opportunity to review the Media Kits to which the Appellant now referred.

The Appellant noted that the Media Kit 2013 included a statement on page 1 that claims that mivision “connects with eye care professionals at all levels (including)… retail staff, optical dispensers, manufacturers and distributors”. The Media Kit 2014 does not include this statement. The Media Kit 2013 states that 1,622 optical dispensers received the mivision magazine, yet the publisher now claims that optical dispensers are not receiving the magazine.

The Appellant noted that the Media Kit 2014 states that 9,500 people receive the optometry only email mivision newsletter and 2,700 people receive the ophthalmology only mivision newsletter. The Media Kit does not mention optical dispensers receiving these emailed newsletters.

The Appellant referred to circulation statistics for mivision between September 2012 and September 2014, which ranged between 7,289 and 6,893. The Appellant queried why it was that if mivision no longer was distributed to optical dispensers, the circulation had not decreased by approximately 1,600?

The Appellant noted that the mivision magazine includes some 10 to 15 pages relating to frame styles for spectacles. He questioned whether this information would be of interest to ophthalmologists and optometrists, inferring that these pages were directed to optical dispensers.

The Chairman invited the companies to make their responses to the appeal, noting that it would assist the Committee if each company did not repeat arguments made by another company and confine their remarks to matters that have not been covered.

Bayer Australia presented their response to the appeal. Bayer summarised the complaint, which alleged that Bayer had placed advertisements in mivision, which was in breach of Code section 13.3 because mivision is available to optometrists who are not endorsed by the Optometry Board of Australia to prescribe and use therapeutic drugs and that these practitioners are ‘consumers’ for the purposes of the Code; and secondly that mivision is distributed to optical dispensers. The Code Committee unanimously found that Bayer had not breached the Code. Bayer noted that Code section 13.3 refers to...
promotion to the general public, which is wider than to consumers.

Bayer highlighted that the Code sets a high threshold for an appeal to be upheld. An appellant must show that the Code Committee made an error of judgement on the basis of which they should be set aside or varied. The Appeals Committee would need to find that the mivision magazine was distributed to the general public. Bayer is fully aware that companies are prohibited from promoting a prescription medicine to the general public, which is not something the company would wilfully do.

The allegation that orthoptists are not healthcare professionals should be dismissed by the Appeals Committee. The Code definition of healthcare professionals, which are people who in their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine, includes orthoptists. Optometrists and ophthalmologists are healthcare professionals according to the Code definition.

Bayer noted that the regulations for each Australian State vary with regard to definition of a healthcare professional. For example, the Poisons Act 1964 (WA) permits a prescribed class of healthcare professional to possess, use, supply, sell or prescribe a prescription medicine. The Poisons Regulations 1965 (WA) state that an endorsed optometrist is a prescribed healthcare professional. The Health (Drugs and Poisons) Regulation 1996 (Qld) state that an orthoptist may obtain, possess and administer a restricted drug. Therefore, optometrists and orthoptists are healthcare professionals as defined by the Code of Conduct.

Bayer stated that optical dispensers are not healthcare professionals as defined by the Code. Optical dispensers cannot administer or purchase prescription medicines. Bayer asserted that there is no evidence that it had placed advertisements in mivision so as to influence prescribing of Eylea by optical dispensers.

Bayer does not have access to the distribution lists for mivision magazine. A company must be able to rely on information provided by a publisher. If the publishers have misrepresented who are subscribers to mivision, this should be taken up with the publisher.

Bayer understands that the hard copy mivision magazine contains prescription medicine advertising, whereas the mivision e-newsletter, which is distributed to optical dispensers, does not include advertisements for prescription medicines.

Bayer asserted that the Appellant has changed his definition of who is considered to be a healthcare professional. Bayer referred to a letter from the Appellant dated 21 January 2013, which stated that the Appellant considered optical dispensers to be health professionals who may receive prescription medicine advertisements. At that time the Appellant had been seeking advertising by Bayer for his publication, which “goes to is subscribed optometrists, ophthalmologists, optical dispensers, orthoptists and their suppliers. It is not a publication that can be accessed by members of the general public.” Bayer argued that the Appellant at that time had accepted that optical dispensers may receive a publication that included advertisements for prescription medicines.

Bayer responded to the Appellant’s argument that mivision had been received by an optical dispenser whose address label was provided by the Appellant. Bayer noted that the recipient wrote articles published in mivision, so it was reasonable for him to receive the publication. This is not evidence that mivision is distributed widely to optical dispensers. With regard to the second optical dispenser whose mivision address fly sheet had been submitted by the Appellant, Bayer stated that mivision has removed that person from the distribution of the magazine.

An Appeals Committee member asked Bayer if they have received a breakdown of their subscribers. Bayer responded that it had not received that information. The Chairman asked Bayer if they had any comment on the circulation statistics for mivision reported by the Appellant. Bayer responded that it could not comment as it does not have access to the statistics quoted by the Appellant. Bayer advised that they understand that mivision is available as a printed magazine, an online website, an emailed newsletter and an open online version of the magazine. Bayer has limited its placement of advertisements to the print magazine as it was informed by the publisher that the magazine is only distributed to healthcare professionals who may receive prescription medicine advertising.

The Chairman invited MSD to give their response to the appeal.

MSD stated that Bayer's presentation was representative of MSD's position. MSD maintains that it has not breached section 13.3 of the Code. The finding of no breach was a unanimous decision of the Code Committee.

MSD has acted in good faith in placing advertisements in mivision magazine. It had reviewed the mivision website information regarding who may subscribe to the magazine and had a conversation with the publisher. The website states that the magazine is only distributed to optometrists, ophthalmologists, ophthalmic nurses, orthoptists and academics with a healthcare qualification. mivision publishers had informed MSD that the magazine was distributed only to healthcare professionals. MSD had made reasonable enquiries about whether
the magazine was directed to healthcare professionals.

The Chairman asked when MSD had made these enquiries to mivision. MSD responded that this had been in 2014 but the MSD representative was not aware of the precise date. Advertisements for its product Saflutan had only been placed in mivision in 2014.

Bayer advised the Committee that it had placed its first advertisement in mivision print magazine in September 2012. It had received confirmation from mivision in August 2012 that the distribution of mivision was to health professionals. Bayer had decided not to continue to advertise in the Appellant’s journal in April 2013 and had again sought and received confirmation from mivision publishers that the magazine was distributed only to health professionals. This had been reconfirmed in October 2014 when Bayer received the complaint from the Appellant. Bayer therefore had undertaken due diligence.

MSD stated that although optical dispensers work closely with optometrists and may see the mivision magazine received by an optometrist, a company cannot be held responsible for what an optometrist or other subscriber does with mivision or other health professional journals containing advertisements for prescription medicines.

The Chairman invited Novartis to give their response to the appeal.

Novartis stated that it agreed with the positions put by Bayer and MSD. Novartis considered that the Code Committee’s decision should not be changed.

An Appeals Committee member asked whether the companies have at present withdrawn their advertisements from mivision. Novartis advised that it has, at present, ceased to advertise its product in mivision. Bayer responded that it would not be appropriate or relevant to the complaint to discuss its plans for advertising its products.

The Chairman invited the Appellant to make any closing remarks, particularly with respect to the definition of a healthcare professional on which there appeared to be quite different views between the Appellant and the companies. The Chairman also asked the Appellant to comment on whether the statistics he quoted related to the print magazine as well as the online version.

The Appellant responded that figure he had quoted of 1,622 optical dispensers related to the print magazine. He stated that in the companies’ responses to his complaint they had relied on the word of the publishers of mivision.

The Appellant reiterated that orthoptists are not healthcare professionals and referred to a specialist ophthalmologist who shared this view.

Bayer noted that healthcare professionals are permitted to receive prescription medicine advertising. The Code definition of healthcare professionals takes a broad perspective, referring to “any other persons who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a Product.” The Code does not make any distinction between registered optometrists and therapeutically endorsed optometrists. With regard to the individual optical dispenser who writes articles for mivision and received the magazine, an Appeals Committee member noted that it would be normal practice to give contributors a copy of the publication.

The Chairman advised the Appellant that if his complaint is based on one or two optical dispensers receiving mivision magazine, that is not sufficient to find the companies in breach of the Code. The Appellant stated that he is sure that he could obtain evidence of many optical dispensers receiving mivision if he was given more time. The Chairman advised that the Code requires a complainant to make out their complaint. If the evidence is not available, the Code and Appeals Committee have to proceed on the evidence that is before them.

The Appellant agreed to table the print versions of the Media Kits 2013 and 2014 for the Committee. Bayer stated that as the companies had not had the opportunity to review this information, it would be concerned at the level of interpretation and weight that the Appeals Committee might place on these documents. The Chairman agreed that each party should have all the material available to the Appeals Committee.

The Chairman thanked the Appellant and company representatives for their presentations and excused them from the meeting to allow the Committee to deliberate on the appeal.

The Appeals Committee agreed to deal with the appeal by working from the Code Committee’s reasons for its decision and the evidence that was before the Code Committee, with the addition of any material that is acceptable as new evidence.

The Appeals Committee unanimously agreed to reject the extension of the scope of the complaint to include orthoptists. The Appeals Committee reviews the decisions of the Code Committee. Orthoptists had not been included in the original complaint considered by the Code Committee. However, there remained the question of whether mivision magazine was distributed to optical dispensers, which all companies had accepted were not healthcare professionals.

The Appeals Committee discussed the two Media Kits 2013 and 2014 tabled by the Appellant. These documents had not been submitted with the original complaint or with the appeal submission. The three subject companies had not had the opportunity to
review them. The issue therefore arose as to how the Appeals Committee should treat the material in the Media Kits and the Appellant’s summary of data from the Media Kit 2013 in his appeal.

The Committee decided in its discretion to not receive the Media Kits or the distribution figures contained in them for reasons of procedural fairness and because the figures referred to by the Appellant appeared to conflict with information provided by mivision to the companies. As referenced in the Code of Conduct Committee’s reasons for decision, mivision had unequivocally stated to each subject company that mivision is not distributed to optical dispensers. While the Code does permit the Appeals Committee to consider new evidence, the Media Kits did not appear to meet the requisite definition. Even if they did, the Appeals Committee, having not heard from the companies in relation to the Media Kit 2013, was not able to resolve this conflict. It follows that the Appellant had not made out his case that the Code Committee had erred in making its decision to find no breach of the Code by any of the companies. The Appeals Committee, however, asked the Secretariat to provide the Media Kits 2013 and 2014 to each company as they were tabled at the meeting.

The Appeals Committee discussed the Appellant’s request for further time in which to try to obtain address fly sheets from optical dispensers who receive mivision magazine. The Appeals Committee determined that, as was explained earlier to the Appellant, the request could not be considered by the Appeals Committee.

The Appeals Committee discussed the Code Committee’s reasons for its decision. The Appeals Committee determined that there was no basis on which to find that the Code Committee had made an error in its decision. No evidence had been provided to that Committee that mivision was being distributed to optical dispensers. The Appeals Committee therefore determined not to uphold the appeal.

The Appeals Committee agreed by unanimous decision to confirm the decisions of the Code of Conduct Committee. The Appeals Committee determined that the placement of advertisements for Eylea, Lucentis and Saflutan in the mivision magazine had not been in breach of Section 13.3 of the Code of Conduct.

Sanction

As the appeal was not upheld and the Code Committee’s decision to find no breach of the Code was confirmed, no sanction was imposed.

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**XARELTO PROMOTIONAL MATERIAL – 1124**

**Subject Company:** Bayer Australia Limited  
**Complainant:** Pfizer Australia Pty Ltd and Bristol-Myers Squibb Australia  
**Product:** Xarelto

**Complaint**

Bristol-Myers Squibb and Pfizer alleged that the claim “One less is more” for Xarelto has the potential to mislead clinicians and negatively influence patient outcomes. They alleged that the claim is not balanced, accurate, or fully supported by the Product Information, literature, data on file or an appropriate industry source.

**Sections of the Code**

The material was alleged to be in breach of the following Sections of Edition 17 of the Code:

1.1 Responsibility  
1.2 Substantiating Date  
1.3 False or Misleading Claims  
1.8 Comparative Statements

**Response**

Bayer strongly rejected the allegation that the material would mislead clinicians or negatively influence patient outcomes. Bayer argued that BMS and Pfizer have misconstrued the promotional material. Bayer stated that the claim is fully supported by the literature. Bayer further argued that the claim is not comparative and does not claim superior efficacy or safety of once-daily medicines. The claim is adequately qualified, substantiated, does not mislead, and is fully compliant with the Code.

**Code of Conduct Committee decision**

The Committee agreed by unanimous decision that the claim was in breach of sections 1.1, 1.2 and 1.3 of the Code of Conduct. The Committee also agreed by unanimous decision that the claim was not in breach of Section 1.8 of the Code of Conduct.

**Sanction**

The Committee agreed by unanimous decisions that the claim must not be used again in the same or in a similar form and imposed a fine of $30,000.

**Consideration of the complaint**

The Chairman summarised the complaint for the Committee, noting that the substance of the complaint is that the referenced study does not adequately substantiate the claim “One less is more”. The Chairman noted that Bayer had responded to the complaint stating that the claim was not about Xarelto being superior or having
greater efficacy. Bayer had argued that the claim was only that a one tablet a day regimen results in better compliance than twice daily regimens, and therefore the referenced study is sufficient to support the claim.

The Committee reviewed the referenced study – Impact of Daily Dosing Frequency on Adherence to Chronic Medications Among Nonvalvular Atrial Fibrillation Patients (Laliberte et al. 2012) (Laliberte Study). The Committee noted that the Laliberte Study was a retrospective cohort analysis of a health insurance claims database. Subjects were adult patients newly initiated on once-daily or twice daily oral antidiabetic or antihypertensive medications. The Committee noted that the study population did not include patients prescribed Xarelto, but was conducted in patients with nonvalvular atrial fibrillation (NVAF), which is one indication for Xarelto.

The Committee discussed the claim “One less is more” and the associated qualifying statement and study description. The qualifying statement was “once daily-dosing is associated with improved patient compliance vs. twice-daily dosing in NVAF” and the Laliberte study was described as: “A retrospective cohort study assessing adherence rates to once- vs. twice-daily dosing regimens of chronic medications (for diabetes or hypertension) in >10,000 patients with NVAF demonstrated that once-daily dosing was associated with a 26% higher likelihood of adherence vs. twice daily dosing”. The claim, the qualifying statement and the study description were referenced to the Laliberte Study. The Committee agreed that the placement and font size of the qualifiers appeared to be compliant with the Code of Conduct.

The Committee agreed that this complaint pivoted on whether the Laliberte Study was appropriate and sufficient to support the claim. The Committee noted that the study design, which compared adherence to once daily and twice daily regimens based on the frequency of refilling prescriptions, did not investigate other factors that will influence compliance and adherence such as the time of day the medicine should be taken and whether the medicine must be taken with food, before food or on an empty stomach. In particular, the Committee noted that the study authors had warned against extrapolating results from this study to adherence to other chronic medications for atrial fibrillation. Specifically, the Laliberte Study authors noted, “It is important to take note that the current study on adherence to antihypertensive and antidiabetic drugs only allowed indirect conclusions to be drawn regarding AF patents’ adherence to other chronic medications”. The Committee concluded that Bayer had selected the Laliberte study because it had studied patients with NVAF, one of the indications for Xarelto. However, the Committee agreed that the study results could not be extrapolated to other chronic medications. Therefore, the Committee unanimously agreed that the study was not adequate as the sole reference to substantiate the claim subject to complaint. The Committee agreed unanimously that the claim had not been adequately substantiated and was therefore misleading and was in breach of Sections 1.1, 1.2 and 1.3 of the Code of Conduct.

The Committee discussed whether the claim “One less is more” was a comparative claim. The Committee noted that whilst the claim could, on first reading, suggest that it was comparative, the qualifying statement specifically communicated that the claim related to improved patient compliance; it did not suggest any claim for better efficacy or safety. The Committee agreed unanimously that the claim was not in breach of Section 1.8 of the Code.

Sanction

Having found that the claim was in breach of Sections 1.1, 1.2 and 1.3 of the Code, the Committee discussed an appropriate sanction. The Committee considered that this advertisement constituted a moderate breach of the Code of Conduct, as there was the potential for it to influence prescribing of the product.

The Committee agreed unanimously that the advertisement should be withdrawn from use, and that the claim “One less is more” should not be used in the same or similar form in the future. Additionally, the Committee imposed a fine of $30,000.

DUROMINE PRESENTATION – 1125

Subject Company: iNova Pharmaceuticals (Australia)

Complainant: Healthcare Professional

Product: Duromine

Complaint

The healthcare professional complainant had attended an educational meeting in August 2014 at which an International Guest Speaker gave a presentation about management of obesity. The Complainant alleged that iNova had breached the Code by:

- Presenting inappropriate information regarding the off-label use of Duromine (i.e. that it is safe to use this product for longer than 6 months), which can lead to patient harm
- Lack of substantiating data for the off-label use of Duromine
- Making misleading claims by suggesting to the GP audience that long term use of Duromine...
(10-15 years) is safe, even though the study conducted and cited by the Guest Speaker was not a safety study.

Sections of the Code
The presentation/educational meeting was alleged to be in breach of the following Sections of Edition 17 of the Code:

1.1 Responsibility
1.2 Substantiating Data
1.3 False or Misleading Claims

Response
iNova denied that the company had breached any section of the Code. iNova stated that it had briefed the Guest Speaker about the company’s responsibilities under the Code of Conduct.

iNova stated that the Guest Speaker had discussed the cardiovascular safety of Duromine in response to a question at the educational meeting. iNova denied that the Guest Speaker had downplayed the cardiovascular risks of Duromine. Further, iNova responded that the Guest Speaker had not suggested that long-term use of Duromine was safe. iNova argued that the Guest Speaker had informed participants at the commencement of the meeting that the material he would present were his own opinions based on his clinical experience and were not those of the sponsor, iNova.

Code of Conduct Committee decision
The Committee agreed by majority decision that the educational event was in breach of Section 1.1 of the Code of Conduct. The Committee also agreed by majority decision that there had been no breach of Sections 1.2 or 1.3 of the Code of Conduct.

Sanction
The Committee agreed by majority decision that iNova must send a corrective letter to each healthcare professional who attended any of the capital city educational events it had organised, advising them that the International Guest Speakers’ presentation had related to a product that was not approved in Australia and that Duromine should only be prescribed for short-term use in accordance with the approved Product Information. This letter must be approved by the Code of Conduct Committee before it is issued. In addition, the Committee imposed a fine of $100,000.

Consideration of the complaint
The Chairman summarised the complaint for the Committee, noting that the complaint centred on a presentation given on 12 August 2014 where an International Guest Speaker, presented his study of the long-term use (up to 7 years) of phentermine hydrochloride. This presentation was one of a series of capital city educational meetings organised by iNova, which followed the National Obesity Forum 2014 that iNova had also sponsored. The Chairman noted that phentermine hydrochloride (immediate release) is not available in Australia, however, phentermine resin (controlled release) is marketed in Australia by iNova under the brand name Duromine. Duromine is approved in Australia for short-term use.

The healthcare professional Complainant had provided a précis of the presentation given by the Guest Speaker, which included that the Guest Speaker had advised attendees of the dose equivalence between phentermine hydrochloride and Duromine. iNova had stated in its response to the complaint that the Guest Speaker had started his presentation with a statement that the content of his presentation was his own opinion based on his clinical experience. iNova had not provided the Committee with a copy of the slides the Guest Speaker presented at the meeting or with a copy of the invitation to this educational meeting. However, the Committee noted that the presentation would not provide evidence of what the Guest Speaker had said beyond his formal presentation or in response to impromptu questions from attendees.

The majority of the Committee were concerned that iNova had organised a series of educational meetings with a presentation about a product that is not registered in Australia. The majority of the Committee considered that the purpose of these meetings was to encourage discussion about the off-label use of Duromine. The Committee agreed that this posed a serious safety risk for patients because Duromine is only indicated for short term use – the approved Duromine Product Information states that a defined course of treatment should not exceed three months. The Guest Speakers’ study, presented by him at the meetings, included patients with a treatment duration of a minimum of 12 weeks to a maximum of 12 years.

The Committee noted that in its response, iNova stated that it had briefed the Guest Speaker on the regulatory requirements in Australia and the obligation for compliance with the Medicines Australia Code of Conduct. However, no evidence was supplied by iNova to support that such a briefing had occurred or its actual content. Further, a disclaimer given at the start of a presentation will not avoid a potential breach of the Code of Conduct, nor absolve iNova of its responsibilities as the sponsor of the Guest Speakers’ speaking engagements. The Committee accepted that the Guest Speakers’ presentation at the National Obesity Forum 2014, which was organised by an independent steering group of Australian healthcare professionals, was sufficiently independent to allow the exchange of clinical and scientific information, including the Guest Speakers’ study. However, the Committee considered that in organising the capital city road
The Committee agreed by majority decision that the educational meeting was focused on a product that is not available in Australia and encouraged doctors to prescribe Duromine for long-term use, for which it is not approved.

The Committee determined by majority decision that the educational event constituted a breach of Section 1.1 of the Code of Conduct because it promoted use of Duromine that was not supported by the Product Information. The Committee also agreed by majority decision that there had been no breach of Sections 1.2 or 1.3 of the Code of Conduct.

Sanction

Having found that the educational event was in breach of Section 1.1 of the Code, the Committee discussed an appropriate sanction.

The Committee considered that this activity constituted a severe breach of the Code of Conduct, as there were potential safety implications for patients and the activity had the potential to have a major effect on how the medical profession would prescribe the product. The Committee agreed by majority decision that iNova must send a corrective letter to each healthcare professional who attended any of the capital city educational events it had organised. The corrective letter must advise them that the Guest Speakers’ presentation had related to a product that was not approved in Australia and that Duromine should only be prescribed for short-term use in accordance with the approved Product Information. The Code of Conduct Committee must approve this letter before it is issued. In addition, the Committee imposed a fine of $100,000.

### SPRYCELMATERIAL – 1126

**Subject Company:** Bristol-Myers Squibb Australia  
**Complainant:** Novartis Pharmaceuticals Australia Pty Ltd  
**Product:** Sprycel

**Complaint**

Novartis alleged that two items of promotional material for Sprycel – one for specialist haematologists and the other for pharmacists – were in breach of the Code of Conduct. Novartis alleged that a number of statements in these items made false and misleading claims, were unable to be adequately substantiated, promoted an unapproved indication and, in relation to one statement, had the potential to bring the industry into disrepute. Novartis asserted that the promotional material had the potential to have a negative effect on patient safety.

### Sections of the Code

The materials were alleged to be in breach of the following Sections of Edition 17 of the Code:

- 1.1 Responsibility
- 1.2 Substantiating Date
- 1.3 False or Misleading Claims
- 1.4 Unapproved Products and Indications
- 9.14 Discredit to and Reduction of Confidence in the Industry

### Response

BMS strongly denied that the materials breached any section of the Code of Conduct. BMS asserted that both pieces included safety messages related to Sprycel and reinforced to physicians the need for monitoring. Furthermore, BMS noted that there was no mention of other products in either piece and no comparisons between Sprycel and another product had been made.

BMS contended that Novartis had restated a number of complaints that had been resolved during the intercompany dialogue, which gave a misleading impression to the Code Committee of the scope of the complaint. Further, BMS contended that Novartis had been unwilling to accept solutions proposed during intercompany dialogue and had demanded that BMS issue a corrective letter. BMS requested the Committee to consider whether Novartis had abused the Code.

### Code of Conduct Committee decisions

Complaints relating to the promotional material for specialists, titled “How do patient comorbidities influence your TKI selection?”:

**Complaint 1 - Statement “Sprycel has been shown to lower blood glucose and some patients have discontinued hypoglycaemic medication, including insulin”**

The Committee determined by majority decisions that the statement was not in breach of the following Sections of the Code of Conduct:

- 1.2 Substantiating data
- 1.3 False or Misleading Claims
- 1.4 Unapproved Products and Indications

The Committee determined by unanimous decision that the statement was not in breach of the following Sections of the Code of Conduct:

- 9.14 Discredit to and Reduction of Confidence in the Industry
Complaint 2 – Statement “In the DASISION study...Sprycel’s safety profile was similar for patients with and without baseline diabetes”

The Committee determined by majority decisions that the statement was not in breach of the following Sections of the Code of Conduct:

1.2 Substantiating Data
1.3 False and Misleading Claims

Complaint 5 – Statement “Sprycel’s overall safety profile was similar in patients with and without diabetes mellitus, hepatobiliary disease, hyperlipidaemia and CVD”

The Committee determined by majority decision that the statement was not in breach of the following Section of the Code of Conduct:

1.3 False or Misleading Claims

Complaint 6 – Statement “A subanalysis of DASISION demonstrated no substantial effects of baseline cardiovascular conditions, other comorbidities, or use of baseline medications on the side-effects of Sprycel”

The Committee determined by unanimous decision that the statement was in breach of the following Section of the Code of Conduct:

1.3 False or Misleading Claims

Complaint 8 – Statement “Simple dosing (one pill, once daily) helps to maximize adherence...”

The Committee determined by unanimous decision that the statement was in breach of the following Section of the Code of Conduct:

1.3 False or Misleading Claims

Complaint 9 – Statement “Increased treatment restrictions and associated difficulty may affect adherence to TKI therapy”

The Committee determined by unanimous decision that the statement was not in breach of the following Section of the Code of Conduct:

1.2 Substantiating Data

Complaint 14 – Statement “Simple dosing (one pill, once daily) helps to maximize adherence...”

The Committee agreed by unanimous decisions that the statement was in breach of the following Sections of the Code of Conduct:

1.2 Substantiating Data
1.3 False or Misleading Claims

The Committee agreed that the breach in relation to Complaint 6 was a minor to moderate breach of the Code and the two breaches in relation to Complaints 8 and 14 were minor breaches of the Code.

Sanction

Having found that the two items of promotional material were in breach of the Code, the Committee imposed the following sanctions:

- Withdraw both items of promotional material from use and do not use the statements found in breach of the Code again in the same or similar form.
- Pay a fine of $45,000
- No corrective letter was imposed by the Code Committee.

Abuse of the Code

The Committee determined that, on this occasion, Novartis should not be asked to respond to the allegation that it was potentially in breach of Section 25 of the Code.

Consideration of the complaint

The Committee noted that 14 separate complaints were described in Novartis’ complaint submission, which stated in the conclusion that complaints 1, 2, 5, 6, 8, 9 and 14 had not been resolved. The Committee therefore did not consider complaints 3, 4, 7, 10, 11, 12 or 13.

Complaints 1, 2, 5, 6, 8 and 9 related to statements in promotional material for specialists titled “How do patient comorbidities influence your TKI selection?”

Complaint 1 - Statement “Sprycel has been shown to lower blood glucose and some patients have discontinued hypoglycaemic medication, including insulin”

Novartis had primarily alleged that this statement promoted Sprycel for an unapproved indication, to treat diabetes by lowering blood glucose, and was in breach of Section 1.4 of the Code. The Code Committee noted that Novartis had omitted the words “In some reports” from the start of the statement as it appeared in the material. Thus, the statement was limited to “some reports”.

The Committee reviewed the cited references to support the statement. The article by Agostino et al (2010) was a retrospective analysis of 78 patients who had been treated with tyrosine kinase inhibitors (TKI). Eight of these patients had received dasatinib (Sprycel), but only one of these patients was a diabetic. This patient had been taking three oral antidiabetic medicines which was reduced to two (a metformin combination product) whilst treated with dasatinib. Two other references were single case reports (Breccia et al (2008) and Ono et al (2012)) about two patients who had reduced their insulin...
requirements or discontinued insulin treatment whilst being treated with dasatinib for CML.

The Committee also noted that the Sprycel Product Information does not mention effects on blood glucose levels or recommend monitoring diabetic patients for changes in hypoglycaemic medicine requirements.

The majority of the Committee did not agree with the allegation that the statement was promoting Sprycel for the treatment of diabetes. These members considered that it would be very unlikely that a specialist haematologist, to whom the promotional material was directed, would start treating diabetic patients or managing their CML patients’ diabetes by choosing Sprycel. Some Committee members thought that the statement could highlight to physicians that they should be aware of Sprycel’s potential effect on blood glucose in their CML patients.

A minority of the Committee were concerned that the statement relied on just three patients in the cited references and the hypoglycaemic effect had not been mentioned in the Product Information. These members were concerned that the statement made a claim beyond the approved use of Sprycel.

In a majority decision, the Committee found that the statement was not in breach of Section 1.4 of the Code.

Some Committee members were concerned that the statement had overreached the substantiating data. Whilst there is some evidence that Sprycel and some other TKIs may lower blood glucose, as already noted the statement relies on just two case reports and one retrospective analysis of eight patients, only one of whom had diabetes. However, the majority of members considered that there was some evidence to support the statement and the statement was limited in its interpretation by the words “In some reports”. In a majority decision, the Committee determined that the statement was not in breach of Section 1.2 of the Code.

Having found in majority decisions that the statement was not in breach of Sections 1.2 or 1.4, the Committee determined in a majority decision that the statement was not false or misleading and was not in breach of Section 1.3 of the Code. Having found that the statement was not in breach of any Code provision, the Committee determined in a unanimous decision that the statement would not bring the industry into disrepute and was not in breach of Section 9.14.

Complaint 2 – Statement “In the DASISION study... Sprycel’s safety profile was similar for patients with and without baseline diabetes”

This statement appeared immediately below the statement subject to complaint 1 in the promotional material.

The Committee reviewed the cited references to support this statement. Khoury et al (2010) was an oral presentation at the American Society of Hematology (ASH) 2010 Annual Meeting. It reported a retrospective sub-analysis of the DASISION clinical trial. The Committee noted that the DASISION trial evidently did not exclude patients with diabetes. Table 5 on page 19 of the Khoury et al presentation provided data on drug-related adverse effects in dasatinib-treated and imatinib-treated patients with or without diabetes. Regrettably, this study did not include any statistical analysis, so the Committee was unable to assess if any differences between patients with or without diabetes were statistically significant. However, 33 percent of patients with diabetes reported the adverse effect ‘fluid retention’ whereas only 18 percent of patients without diabetes reported fluid retention. Clearly, more dasatinib-treated patients with diabetes experienced fluid retention compared with dasatinib-treated patients without diabetes.

Some Committee members were concerned that the statement identified in complaint 2 relied on the broad concluding statement from the Khoury et al (2010) presentation. The conclusion that “baseline co-morbidities appeared to have no substantial impact on the overall safety and efficacy of dasatinib or imatinib as first-line treatment for CML-CP” did not take into account the more detailed data analysis where some differences were shown. One member commented that the statement in the promotional material was somewhat ambiguous – it could be interpreted that Sprycel’s safety profile was similar to imatinib’s in patients with and without diabetes, or that Sprycel’s safety profile was similar between patients with and without diabetes.

The majority of the Committee accepted that overall there was not a great deal of difference in safety of dasatinib in patients with and without diabetes except for fluid retention. These Committee members noted that there are no specific precautions in the Sprycel Product Information that would suggest that diabetic patients experience more adverse effects from dasatinib than non-diabetic patients.

The Committee noted that complaint 2 was not discussed during the intercompany meeting, which suggested that Novartis had accepted BMS’ substantiation for the statement, as BMS had argued in its response to the complaint.

The Committee also referred to Hochhaus and Kantarjian (2013), which is a literature review of dasatinib in CML. This paper supported the statement subject to complaint, although, in relation to this statement, it cited Khoury et al (2010) and two other abstracts from the ASH 2010 Annual Meeting rather than published, peer-reviewed articles.
Following this detailed discussion of the complaint, the Committee concluded in majority decisions that, on balance, the statement was able to be adequately substantiated and was not false or misleading. The Committee found no breach of Sections 1.2 or 1.3.

Complaint 5 – Statement “Sprycel’s overall safety profile was similar in patients with and without diabetes mellitus, hepatobiliary disease, hyperlipidaemia and CVD” and Complaint 6 – Statement “A subanalysis of DASISION demonstrated no substantial effects of baseline cardiovascular conditions, other comorbidities, or use of baseline medications on the side-effects of Sprycel”

The statement subject to complaint 5 is similar to complaint 2, but the statement also refers to hepatobiliary disease, hyperlipidaemia and CVD (cardiovascular disease). The statement subject to complaint 6 is a direct quote from Hochhaus and Kantarjian (2013).

The Committee reviewed the supporting references for the statements, which were the same references reviewed in relation to complaint 2 with an additional abstract by Saglio et al (2010) presented at the ASH 2010 Annual Meeting. Tables 6 and 7 on slides 20 and 21 in the Khoury et al (2010) oral presentation included data relating to adverse effects in dasatinib-treated patients with or without baseline hepatobiliary disease and with or without baseline hyperlipidaemia. Once again, the proportion of patients experiencing adverse effects in each subgroup is given, but there was no statistical analysis. There were considerably more patients in the ‘no hepatobiliary disease’ subgroup than the ‘hepatobiliary disease’ subgroup. In addition, there were considerably more patients in the ‘no hyperlipidaemia’ subgroup than the ‘hyperlipidaemia’ subgroup. In the absence of any statistical analysis, this makes these data difficult to evaluate.

The Committee reviewed the Saglio et al (2010) abstract, which was a retrospective subgroup analysis of safety and efficacy in DASISION trial subjects with a cardiovascular pre-existing condition and without any pre-existing cardiovascular condition. Saglio et al concluded that although fluid retention and cardiac adverse effects were more common in patients with a baseline cardiovascular condition, overall, the authors stated, the data showed no substantial impact of baseline cardiovascular conditions on the general safety of dasatinib (or imatinib) in DASISION trial subjects.

The Committee noted that the Sprycel Product Information includes a section on Cardiac Adverse Reactions, which states that adverse cardiac reactions were more frequent in patients (in the DASISION trial) with cardiac risk factors or a previous history of cardiac disease. The Product Information recommends careful monitoring and evaluation of patients with a history of cardiac disease.

The Committee noted that the statements in complaints 5 and 6 are specific to “In the DASISION study”. Statement 5 is a compilation of the broad conclusions from Khoury et al (2010) and Saglio et al (2010) and Statement 6 is a direct quote from Hochhaus and Kantarjian (2010).

Committee members were concerned that the Saglio et al subgroup analysis made a broad brushstroke conclusion from the data and seemed to have ignored the detailed results of their retrospective subgroup analyses, particularly with respect to increased fluid retention, superficial oedema and cardiac adverse effects. Committee members were concerned that the Saglio et al study had identified higher rates of superficial oedema and pleural effusion in dasatinib-treated patients with a baseline cardiovascular condition, yet the overall conclusion was that there was no substantial impact on adverse effects from baseline cardiovascular conditions. The conclusion appears to conflict with the data presented in the abstract.

As previously noted, the Hochhaus and Kantarjian (2013) literature review, from which the statement in complaint 6 is directly quoted, references Khoury et al (2010), Saglio et al (2010) and Guilot et al (2010), which are three abstracts presented by the DASISION study group at the ASH 2010 Annual Meeting. The statement in the Hochhaus and Kantarjian paper did not refer to the higher rates of fluid retention and superficial oedema found by Saglio et al (2010) and only reflected the broad, general conclusion from that abstract. The Committee also was concerned that statement 6, whilst it was a quote, contradicted the precautions in the Sprycel Product Information about cardiac adverse reactions and fluid retention. The Committee also noted that the Product Information states that patients with uncontrolled or significant cardiovascular disease were not included in clinical studies. It would not be clear to a haematologist that patients with more significant baseline cardiovascular disease were excluded from the DASISION study and that the subanalysis referred to in statement 6 might not apply to such patients. The Committee concluded that the statement subject to complaint 6 was misleading.

Following this detailed review and lengthy discussion of the supporting evidence, the majority of the Committee accepted that the leading statement subject to complaint 5 was consistent with and reflected the conclusions of the DASISION study group’s retrospective subgroup analyses and was not misleading. However, the statement subject to complaint 6 was determined to be misleading by a unanimous decision.
In a majority decision, the Committee determined that the statement in complaint 5 was not false or misleading and was not in breach of Section 1.3 of the Code of Conduct.

In a unanimous decision, the Committee determined that the statement in complaint 6 was in breach of Section 1.3 of the Code.

**Complaint 8 – Statement “Simple dosing (one pill, once daily) helps to maximize adherence…”**

The Committee noted that this quotation is from Osterberg and Blaschke (2005), which is a general article on adherence to medication; it is not specific to Sprycel, TKIs or the treatment of CML. The Committee also reviewed the Hirji et al (2013) paper, which included an investigation of treatment adherence in CML patients treated with TKIs. In the Hirji et al study there was no statistically significant difference in non-adherence between dasatinib compared to imatinib and nilotinib patients, noting that nilotinib is taken twice daily.

Whilst it is generally accepted that more simple dosing regimens will improve adherence, in the case of Sprycel there is insufficient evidence that its ‘one pill, once daily’ regimen results in better adherence. The Committee considered that taking the statement subject to complaint 8 out of context could potentially mislead clinicians to think that it related specifically to Sprycel, particularly by the inclusion of “(one pill, once daily)”. The Committee determined by unanimous decision that the statement was in breach of the Section 1.3 of the Code of Conduct.

**Complaint 9 – Statement “Increased treatment restrictions and associated difficulty may affect adherence to TKI therapy”**

As noted in relation to complaint 8, the Hirji et al (2013) study investigated adherence to treatment with TKIs in CML. The statement subject to complaint 9 was an adapted quotation from the paper. The Committee considered that the statement was factual, directly relevant to TKI treatment for CML and could be substantiated.

The Committee determined by unanimous decision that the statement was not in breach of Section 1.3 of the Code.

Complaint 14 related to a statement in promotional material for pharmacists titled “Pharmacists play a critical role in the management of CML”.

**Complaint 14 – Statement “Simple dosing (one pill, once daily) helps to maximize adherence…”**

The Committee noted that this statement was identical to the statement subject to complaint 8. However, in this material the statement appeared under the heading “Sprycel offers simple dosing” and dot point “One tablet once daily with no fasting or ECG requirements”. This context increased the likelihood that a pharmacist would be misled to think that the statement subject to complaint was a quote from a paper that specifically had investigated adherence to Sprycel, which it did not. The Committee considered that the statement could not be substantiated with respect to adherence to Sprycel.

The Committee determined by unanimous decisions that the statement was in breach of Sections 1.2 and 1.3 of the Code.

**Sanction**

Having found that three statements subject to complaint were in breach of the Code, the Committee discussed the severity of the breaches. The Committee agreed that the breach in relation to Complaint 6 was a minor to moderate breach of the Code. The statement was misleading and may have an effect on how healthcare professionals prescribe Sprycel. The Committee did not raise concerns about patient safety. The two breaches in relation to Complaints 8 and 14 were minor breaches of the Code.

The Committee agreed unanimously that the promotional materials containing the statements found in breach of the Code should be withdrawn from use. The statements found in breach should not be used again in the same or similar form. Additionally, the Committee imposed a fine of $45,000.

The Committee discussed whether a corrective letter was required. It noted that the promotional material for physicians had been withdrawn from use in October 2014. The Committee determined that no corrective letter should be imposed.

**Abuse of the Code**

The Committee discussed BMS’ allegation that Novartis had abused the Code process, misled the Committee by including matters in its complaint submission that had been resolved in intercompany dialogue and insufficiently explaining which parts of the complaint required the Code Committee’s consideration. BMS also alleged that Novartis’ insistence on a corrective letter undermined the ability to resolve matters through intercompany dialogue.

The Committee agreed that the intercompany dialogue could have been more constructive.

Novartis could have made it clearer to the Committee which issues had been fully resolved and which not, or only included those issues which remained in dispute. The Committee was also concerned by the lack of detail in Novartis’ complaint submission. This submission only very briefly stated the nature of each complaint and relied on the Code Committee referring to intercompany correspondence and intercompany meeting minutes.
to elaborate on the basis for the complaints. Further, the Committee undertook a detailed examination of each supporting reference, identifying the data, content and issues relevant to each complaint. This analysis and explanation of the detailed rationale for each alleged breach should have been presented by Novartis in its complaint.

In spite of these criticisms of the complaint and intercompany dialogue, the Committee did not consider that the issues rose to the level of a frivolous or vexatious complaint. The Committee determined that on this occasion Novartis should not be asked to respond to the allegation that it was potentially in breach of Section 25 of the Code. However, the Committee cautioned that Novartis should carefully consider the Committee's concerns regarding this complaint.

**Code of Conduct Committee decision**

The Committee agreed by unanimous decision that the media release was in breach of Section 13.4.1 of the Code of Conduct. The Committee also agreed by unanimous decision that Section 1.8 of the Code did not apply to a media release directed at the general (consumer) media and was therefore not considered in relation to this complaint.

**Sanction**

Having found that the media release was in breach of the Code, the Committee imposed the following sanctions:

- Pay a fine of $30,000.
- Novartis must not use the statement found in breach of the Code in any future activities directed at the general public;
- If the media release is available on the Novartis Australia corporate website, Novartis must remove it.

**Consideration of the complaint**

The Chairman summarised the complaint for the Code Committee. He noted that the Monitoring Committee had reviewed two media releases for Ultibro Breezhaler; one of which was directed at Healthcare Professional media and the other to general (consumer) media. The media release subject to complaint was the latter.

In its deliberations about the complaint, the Code Committee noted that the Monitoring Committee had proposed that the media release to the consumer media was potentially in breach of Section 1.8 of the Code. The Code Committee noted that Section 1.8, Comparative Statements falls under Code Section 1: Educational and Promotional Material Directed at Healthcare Professionals. It therefore did not apply to a media statement directed to the consumer media. However, Section 13.4.1 of the Code prohibits the inclusion of comparisons with other products in product-specific media statements for the consumer media because such statements would be considered promotional. The Committee agreed unanimously that Section 1.8 did not apply to the Ultibro Breezhaler media statement to the consumer media.

The Code Committee noted that the Monitoring Committee's complaint centered on the statement "combining the treatments in one single device is a key step forward in disease management", and whether this statement was a claim or not. The Code Committee agreed that the use of the words "key step forward" inferred superiority of the combination product and that the combination of the two products into a single device was new and more efficacious in patients with COPD. The Code Committee agreed unanimously that this statement was a promotional claim for the Ultibro Breezhaler.
The Code Committee considered whether the statement could be considered to be comparative. It noted that there were other combination products registered in Australia for the treatment of COPD at the time the media statement was issued. The Code Committee acknowledged that the other combination products were for severe COPD, whereas the Ultibro Breezhaler was approved for use in less severe COPD. However, the Code Committee agreed that the statement could be interpreted as comparing the new combination inhaler with existing inhalers used to treat COPD. The Code Committee further noted that the statement, which referred to “combining the treatments” (underlining added) mentioned in the preceding paragraph, could be interpreted to be a comparison with the single ingredient inhalers now combined in the new inhaler. With either interpretation, the statement was determined to be a comparative statement.

The Committee further noted that the references supplied by Novartis showed that patients on multiple single product inhalers had lower adherence to their treatment regimen than those on combination inhalers. The Committee considered that without specific evidence to support it, the inverse – better adherence to combination inhalers – cannot be assumed. However, the question of whether the claim could be substantiated was not relevant to the principal matter before the Committee – whether the media release complied with Section 13.4.1 of the Code.

The Code Committee considered the requirements of Section 13.4.1 of Edition 17 of the Code of Conduct and noted that “Media releases must be educational and not include promotional statements or claims, or comparisons with other products”. The Committee agreed unanimously that the statement attributed to the Key Opinion Leader was a promotional claim and that it was a comparative statement. The media release was therefore in breach of Section 13.4.1 of the Code.

The Code Committee noted that in its response to the complaint, Novartis had stated that it had not included the statement in the media release with the intention of being promotional. However, the Code Committee agreed that the intent of the statement was not relevant; the question for the Code Committee was whether the media release was objectively promotional and whether a reasonable member of the audience to whom it was directed would be likely to interpret it as promotional. The Code Committee determined that the statement was promotional and would likely be interpreted as such by a reader.

The Code Committee also noted that while not specifically raised by the Monitoring Committee, the statement that the Breezhaler device had been “specifically designed for use with people who have limited airflow” was also potentially promotional. The Committee cautioned Novartis to take greater care to avoid promotional statements in materials for the general public.

Sanction

Having found the media release to be in breach of the Code, the Code Committee discussed the severity of the breach. The Code Committee agreed unanimously that the breach was minor, as there was no safety implication for patients and it was unlikely to influence the prescribing habits of healthcare professionals.

The Code Committee agreed unanimously that:

- Novartis must pay a fine of $30,000
- Novartis must not use the statement found in breach of the Code in any future activities directed at the general public
- If the media release is available on the Novartis Australia corporate website, Novartis must remove it.
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
- Analgesia
- Cardiovascular System
- Central Nervous System
- Contraceptive Agents
- Ear, Nose and Oropharynx
- Endocrine and Metabolic Disorders
- Eye
- Genitourinary System
- Immunology
- Infections and Infestations
- Musculoskeletal System
- Neoplastic Disorders
- Respiratory System
- Skin
- Surgical Preparations

In each financial year the Monitoring Committee reviews at least 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, media releases and starter packs). This is in addition to the Committee’s review of educational event reports.

Table 9 provides a summary of the Monitoring Committee reviews of materials and activities over the past five years. Table 10 provides a snapshot of the materials and activities reviewed by the Monitoring Committee in 2014-2015.

**Educational Event Reports**

Educational Event Reports for the period April 2014 – September 2014 were published on 19 December 2014; the reports for the period October 2014 – March 2015 were published on 28 June 2015. Individual Member company reports can be accessed on the Medicines Australia website.

In accordance with Section 31.2.2 of Edition 18 of the Code of Conduct, the Monitoring Committee conducts a review of educational events on an annual basis. Three months are randomly selected from the preceding 12 month review period and the Committee is then provided with those three months’ event reports in a de-identified format.

**Review of Educational Events 2013-2014**

For the 2013-2014 review, the Chairman selected at random the months of June 2013, November 2013 and March 2014. The Monitoring Committee commenced its review in July 2014 with subsequent meetings held in August and September 2014 to review responses from companies to any requests for further information. This review included close to 8,500 events from 38 companies. As a result of its review of the three months of events, the Monitoring Committee sought further information from 24 companies. The Monitoring Committee completed this review at the end of September 2014, with two events being referred to the Code of Conduct Committee for its adjudication (Complaints 1121 and 1122). The outcomes are reported in this report.
<table>
<thead>
<tr>
<th>Table 9: Summary of materials and activities reviewed by the Monitoring Committee 2010 – 2015</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>
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<tr>
<td>Analgesia</td>
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<tr>
<td>Musculoskeletal System</td>
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<tr>
<td>Endocrine &amp; Metabolic Disorders</td>
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<tr>
<td>Genitourinary System</td>
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<tr>
<td>Infections &amp; Infestations</td>
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<tr>
<td>Neoplastic Disorders</td>
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<tr>
<td>Immunology</td>
</tr>
<tr>
<td>Respiratory System</td>
</tr>
<tr>
<td>Allergic Disorders</td>
</tr>
<tr>
<td>Ear, Nose &amp; Oropharynx</td>
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<tr>
<td>Eye</td>
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<td>Skin</td>
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<tr>
<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>
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</tbody>
</table>
Table 10: Summary of materials and activities reviewed by the Monitoring Committee in 2014-2015 (excluding Educational Event Reports)

<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>All therapeutic classes</td>
<td>Medical Education for HCP</td>
<td>22</td>
<td>69</td>
<td>2</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Media Releases to the general public</td>
<td>8</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory System</td>
<td>Disease Education</td>
<td>2</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Immunology</td>
<td>Printed Ads</td>
<td>7</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Skin</td>
<td>Printed Promotional Material</td>
<td>8</td>
<td>37</td>
<td>1</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>HCO Support</td>
<td>34</td>
<td>1117</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td>81</td>
<td>1251</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 2014-2015 the Monitoring Committee referred printed promotional material from Janssen and Bayer in the Neoplastic Disorders Therapeutic Class (Complaints 1119 and 1120), educational events from Novartis and Amgen (Complaints 1121 and 1122) and a media release to the general public from Novartis (Complaint 1127) to the Code of Conduct Committee for adjudication. The outcomes can be found in this report.

Outcomes of the Monitoring Committee review of materials and activities from 2014-2015

Medical Education Material

The Monitoring Committee reviewed all medical educational material for healthcare professionals supplied for electronic media – smart phone apps and mobile media platforms in all therapeutic classes during the period June to August 2014. There were 69 items submitted to the Committee and these were reviewed over 2 meetings.

Materials were provided by the following 22 companies for review:
- A. Menarini
- Abbott
- AbbVie
- Allergan
- Amgen Australia
- Bayer Australia
- Boehringer-Ingelheim
- Bristol-Myers Squibb Australia
- Celgene
- bioCSL
- Ipsen
- GlaxoSmithKline
- Janssen
- LEO Pharma
- Merck Sharp and Dohme (Australia)
- Novartis Pharmaceuticals Australia
- Novo Nordisk Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis
- Shire
- UCB Pharma

The Monitoring Committee did not identify any general issues in relation to the reviewed medical educational materials in electronic media.

The Committee provided comments and feedback to A. Menarini, Bayer Australia, Boehringer-Ingelheim, LEO Pharma, Ipsen, Novartis Pharmaceuticals Australia, Pfizer Australia and Roche Products in relation to their materials. The matters raised with the individual companies included:
Following this review, the Monitoring Committee did not refer any matters to the Code of Conduct Committee.

**Product Media Statements**

The Monitoring Committee reviewed all product specific media statements directed to the general public media relating to products in any therapeutic class that were issued during the period September to November 2014.

Materials were provided by the following 8 companies for review:

- A. Menarini Australia
- AbbVie
- Actelion
- Astellas
- Bayer Australia
- GlaxoSmithKline Australia
- Novartis Pharmaceuticals
- Roche Products

The Monitoring Committee discussed whether the inclusion of the Minimum Product Information at the end of a media release is sufficient to provide a summary of the product's side effect profile, precautions, adverse reactions, warnings and contraindications as required in the Code. Specifically, it questioned what should be considered the 'body' of a media release, and determined that <ends>, or a version thereof, signifies the end of the body of the media release. If a Minimum Product Information appears after that indicator, it is not actually included in the body of the media release, and therefore not meeting the required standard.

The Committee also noted that background documents were included in some submissions. The Committee discussed the inclusion of a background document and whether it should be listed in the media release as an important document. The Committee agreed that best practice would be for the background document to be referred to in the media release. This could be achieved by noting it as an attachment to the media release.

The Committee provided comments and feedback to A. Menarini, AbbVie, Actelion, Astellas, Bayer Australia, GSK, Novartis Pharmaceuticals Australia and Roche Products in relation to their materials. The matters raised with the individual companies included:

- Releases not including sufficient detail of serious side effects
- Language and terminology used that was not accessible to a consumer audience
- Using language that could be considered promotional, whether direct product claims or statements attributed to key opinion leaders, patients or spokespeople
- Following this review, the Committee remained concerned with the activities of two companies, and agreed to refer the matters to the Code of Conduct Committee for adjudication. Of these two complaints, the Code of Conduct Committee has heard the complaint (Ultibro Breezhaler – 1127), and the outcome of this complaint can be found in this report.

The second complaint is ongoing at the time of this report. Full outcomes will be reported in the appropriate Quarterly report, as well as an Activity to the General Public report, at the conclusion of the complaint process.
Disease Education Activities

The Monitoring Committee reviewed Disease Education activities in any media in the Respiratory System therapeutic class available during the period October 2014 to January 2015.

Materials were provided by the following 2 companies for review:

- A. Menarini Australia
- Novartis Pharmaceuticals

The Committee did not identify any general comments in relation to disease education activities in this therapeutic class, however did commend the companies on providing useful information to consumers which draws attention to important issues.

Following this review, the Monitoring Committee did not refer any matters to the Code of Conduct Committee.

Printed Advertisements

The Monitoring Committee reviewed 10 items of printed advertisements directed at Healthcare Professionals in the Immunology therapeutic class available during the period December 2014 to February 2015.

Materials were provided by the following 7 companies for review:

- AbbVie
- Alexion Pharmaceuticals
- bioCSL
- Biogen Australia
- GlaxoSmithKline Australia
- Janssen
- Pfizer Australia

The Committee discussed the use of the words “TGA Approved” and the possibility it provides the reader with the impression that the TGA have provided an endorsement of the product. The Committee agreed that while the Code does not specifically prohibit the phrase, it suggested that the words “TGA Registered” were more appropriate.

The Committee were also concerned at the language used in the materials, specifically the use of absolute terms such as “Experience”, “Success”, “Achieve” when used to a healthcare professional audience. The Committee were of the opinion that further guidance on the use of these words needs to be provided and referred this to the next review of the Code for consideration.

Following this review, the Monitoring Committee did not refer any matters to the Code of Conduct Committee.

Printed and Electronic Promotional Material

The Monitoring Committee reviewed 37 items of printed and electronic promotional material directed at healthcare professionals in the Skin therapeutic class available during the period January to March 2015.

Materials were provided by the following 8 companies for review:

- A. Menarini Australia
- Bayer Australia
- GlaxoSmithKline Australia
- iNova Pharmaceuticals
- LEO Pharma
- Merck Sharp & Dohme (Aust)
- Novartis Pharmaceuticals
- Roche Products

The Committee discussed the significance of journals, specifically in relation to their standing in the profession, the quality of the articles included within them, whether they are peer-reviewed or otherwise and how this may influence the reader. The Committee agreed to refer this to the next Code review for exploration of the relevance and usefulness of further guidance under Section 2.2 of the Code.

Following this review, the Monitoring Committee did not refer any matters to the Code of Conduct Committee.
Health Consumer Organisation Support and Consultancies Reports

The Monitoring Committee reviewed 1117 items from Member company reports of support provided to Health Consumer Organisations (HCOs) including the monetary value of support provided and Healthcare Professional Consultancy Reports. The reports covered activities commenced on or after 1 January 2014 or ongoing on that date through to 31 December 2014.

Reports submitted by the following 34 companies were reviewed:

- A. Menarini
- AbbVie
- Actelion Pharmaceuticals
- Alcon Laboratories
- Amgen
- Astellas Pharma
- AstraZeneca
- Bayer Australia
- bioCSL
- Biogen Australia
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Celgene
- CSL Behring
- Eli Lilly Australia
- Gilead Sciences
- GlaxoSmithKline Australia
- Ipsen
- Janssen
- Lundbeck
- Merck Serono
- Merck Sharp and Dohme (Australia)
- Mundipharma
- Mylan EPD
- Norgine
- Novartis Pharmaceuticals Australia
- Novo Nordisk Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis
- Servier Laboratories (Australia)
- Shire
- Takeda
- UCB Australia

In reviewing the HCO Support Reports the Committee discussed at length the type of activities that companies were engaged with, as well as the types of organisations to which they are providing support. The Committee agreed that, on the whole, this company sponsorship is enabling HCOs to conduct activities that have positive impacts on patients. The Committee did identify a number of organisations that had been categorised by members as HCOs, that were clearly Healthcare Professional led or research based organisations, and therefore did not need to be reported in these reports.

In reviewing HCP Consultancies Reports, the Committee sought further information from companies as to the types of activities they conducted with consultants, specifically those that required registration fees because these would typically be reported as educational events and/or sponsorships rather than a consulting arrangement.

The Committee noted that the information contained in these reports was aggregated, and therefore provided limited detail, but noted the changes in reporting requirements in Edition 18 of the Code will facilitate greater transparency of these payments.

The Monitoring Committee requested additional information from 19 companies. At the time of this report, this review is still ongoing. The outcomes of this review will be reported in the 2015-2016 Annual Report.