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Medicines Australia’s Ethical Conduct activities in 2016-2017 continued to focus on ensuring effective implementation of Code of Conduct Edition 18.

The Ethics and Compliance team assisted Medicines Australia Member Companies to prepare and publish their first reports under the new transparency model implemented under Code Edition 18. This transparency model continues to demonstrate the Australian innovative medicines industry’s leadership in delivering even greater transparency for the Australian community about the support provided to healthcare professionals to engage in educational activities and to compensate healthcare professionals for the valuable expertise and advisory services provided to Member Companies.

Medicines Australia Member Companies remain aligned with global standards by demonstrating high levels of compliance with the Code and an ongoing commitment to improved transparency of interactions with healthcare professionals. Further, members maintained their commitment 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.

**Transparency Reporting**

**Reporting Payments and Transfers of Value to Healthcare Professionals**

Edition 18 of the Code requires member companies to report the cost of all flights, accommodation and registration fees provided to an individual healthcare professional and any honoraria, sitting or consulting fees. Commencing on 1 October 2015, the first twelve months of reports were made with each healthcare professional’s consent to publish the information. On 1 October 2016 reporting became mandatory for Member Companies. That is, companies may not make a payment or provide an airfare, accommodation or registration fee unless a healthcare professional is notified of the company’s disclosure obligation and therefore expects the information to be disclosed.

The first publication of reports under the transparency model covered the period 1 October 2015 to 30 April 2016. On 31 August 2016, 35 Medicines Australia Member Companies published their reports on their Australian corporate websites. These reports showed that of the nearly 9,000 healthcare professionals the industry engaged during that time, almost two thirds of them consented for those interactions to be reported.

The second publication of these reports covering the period 1 May 2016 – 30 October 2016 was made on 28 February 2017 by 33 Medicines Australia Member Companies. During this period, our Member Companies engaged with some 9,000 healthcare professionals, with a consistent two thirds of healthcare professionals giving their consent.

In the lead up to the first publication of these new reports, the Ethics and Compliance team focussed its efforts on communicating with healthcare professionals, as well as peak healthcare professional and consumer organisations. Medicines Australia undertook a communication campaign which reinforced 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, in collaboration with Member companies, we sought to inform all relevant Australian healthcare professionals of the new Code and its requirements.

**Third Party Meeting and Symposium Sponsorship Reports**

In 2016-2017, the publication of Third Party Meeting and Symposia Sponsorship reports was initiated. Introduced as part of the transparency model in Code of Conduct Edition 18, this report focuses on the Australian innovative medicines industry’s sponsorship of educational meetings and symposia organised by third party organisations, such as medical, pharmacy and nursing colleges or societies. The activities captured in this report include where a company has provided a lump sum sponsorship to the event, have financially assisted an institution to hold a journal club, grand round, or in-institution meeting, and the purchase of trade displays in association with an educational event. The reporting periods for this report align with the Payments and Transfers of Value to Healthcare Professionals reports (above), with the reports published on Medicines Australia’s website.

There were 1,371 events sponsored by 34 Member companies in the period October 2015 – April 2016, and published on 31 October 2016. The second report was published on 30 April 2017, for the period May 2016 – October 2016, which reported on 1,758 events sponsored by 34 Member companies in that six month period.
Health Consumer Organisation Support Reports

In June 2017 Medicines Australia published the fourth annual reports of Member Companies’ financial support for Health Consumer Organisations (HCO). Member companies supported 127 different HCOs across Australia in calendar year 2016, ranging from national consumer organisations to small local groups, relating to 368 different projects or events to the total value of $8,243,903 of support.

Complaints, Appeals and Monitoring

Complaints handling

In 2016-2017, Medicines Australia received 6 new complaints. This is a decrease from 2015-2016, when 9 new complaints were received.

Two of the new complaints received this year were submitted by Member Companies, one complaint received from the Monitoring Committee, and one complaint was submitted by a healthcare professional. Two complaints were not finalised before the end of the financial year.

Of the four new complaints received and finalised in 2016-2017, three were found not in breach of the Code and one complaint was found to be in breach of some aspects of the alleged breaches.

There was one appeal against the Code of Conduct Committee’s decisions during the year. The appeal was not upheld.

Details of the complaints considered and finalised in 2016-2017 and the outcomes are reported in this Code of Conduct Annual Report, published on the Medicines Australia website. The outcome of the two complaints not finalised will be published in the July-September 2017 Quarterly Report.

Monitoring of Member Company activities

The Monitoring Committee continued its schedule of monitoring reviews during 2016-2017. The Committee undertook five reviews of materials associated with specific therapeutic areas:

- Advertisements, Printed Promotional Material and E-Ads in the Analgesia therapeutic class
- Starter Packs (policies and procedures) in all therapeutic classes
- HCP websites in all therapeutic classes (reviewed over two meetings)
- Advertisements in audiovisual, internet, eNewsletters in the Alimentary therapeutic class
- Journals Advertisements in the Ear, Nose, Throat and Eye therapeutic classes

The Monitoring Committee also undertook a review of Member Companies’ HCO Support reports. These reviews 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 7,947 educational events held between 1 April 2015 and 30 September 2015 reported by 37 companies. One event was referred to the Code of Conduct Committee, outcomes of this complaint can be found in this report.

In addition to these reviews, the Monitoring Committee conducted a review of Member Companies’ policies and procedures relating to the provision of hospitality to healthcare professionals, to confirm Member Companies’ compliance with the monetary limit on hospitality provided to healthcare professionals.

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 2016-2017 1,951 individual students enrolled in one or more Programs offered under the CEP; of these, 675 enrolled in their first CEP Program. This demonstrates the real value of the CEP to our Members and others. In 2016-2017 373 company personnel 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 Greg Peterson, Dr Corinna Dwan and the team at the University of Tasmania who delivered the CEP in 2016-2017 for our Members.
Communication and Training Activities

In 2016-2017 the Code Secretariat continued to improve our methods of communicating with Member companies and other stakeholders. The Code Help Desk drop box (codehelpdesk@medaus.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 confidential.

In addition, the Secretariat has continued to hold regular 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. The training webinars continue to be popular as they provide a forum for members to discuss and debate issues that impact their business decisions. More information about Code training activities can be found on the Medicines Australia website.

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 continued 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 these Committees, Medicines Australia is fortunate to have the support of Member Company personnel who help and advise the Code Secretariat on specific projects. We particularly acknowledge the ongoing work of the Guidelines Working Group members who continue to provide advice for the successful implementation of Edition 18. Additionally we acknowledge the work of the Central Database Working Group members, who have been advising on the feasibility and desirability of a centralised database for the reporting of payments and transfers of value to healthcare professionals.

I would like to especially acknowledge the strong contribution made by Ethics and Compliance team members Sophie Hibburd and Karen Patten who implement and oversee the Code of Conduct and Continuing Education Program. Sophie and Karen are consistently focussed on delivering the highest standards of efficient, fair and balanced management of complaints, appeals and monitoring activities. They also constantly strive to assist and advise Members throughout the year and together we have a strong, cohesive team. I thank Sophie and Karen for their work on behalf of the industry.

The Year Ahead

The Ethics and Compliance Team remain committed to leading the charge towards transparency for the Australian innovative medicines industry. The year ahead will see the team continue engagements with healthcare professionals, industry groups, healthcare professional groups and other key stakeholders to enhance support for these measures. We will also maintain our support of Member Companies as they continue to forge new relationships with healthcare professionals under this transparency regime. It is our firm belief that these relationships, and the education provided by the industry are valued by healthcare professionals and deliver valuable information that ultimately benefits Australian patients.

One key task the team will be undertaking is the further investigation of a central reporting system for the publication of the payments and transfers of value reports. In biannual reports to the ACCC, the team is tracking progress against this task, which is a condition of authorisation of Edition 18 of the Code. In conjunction with a working group made up of experts within the membership, the team is investigating privacy, legal, technical and feasibility requirements of implementing such a system. Reports on this activity can be found on the Medicines Australia website.
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 administration of the Code is overseen by the Code of Conduct Committee (the Code Committee), which is responsible to the Medicines Australia Board. 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>Organisation</th>
<th>Nominee/s</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chairman</strong></td>
<td>Mr Michael Daniel, Resolve&lt;br&gt;Mr Jason Korke, Owen Dixon Chambers West&lt;br&gt;Ms Catherine Bembrick, 5 Wentworth&lt;br&gt;Mr Ian Tonking SC</td>
</tr>
<tr>
<td><strong>Australian General Practice Network (AGPN)</strong></td>
<td>Dr Rod Pearce AM</td>
</tr>
<tr>
<td><strong>Australian Medical Association (AMA)</strong></td>
<td>Associate Professor John Gullotta AM</td>
</tr>
<tr>
<td><strong>Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)</strong> (One ASCEPT member selected from the panel of three members)</td>
<td>Professor Richard O Day AM&lt;br&gt;Professor John Miners&lt;br&gt;Professor David Le Couteur</td>
</tr>
<tr>
<td><strong>Consumers Health Forum of Australia (CHF)</strong> (Two CHF representatives to participate in complaints where the activity is directed at the general public or patients)</td>
<td>Ms Anne McKenzie AM&lt;br&gt;Ms Sharon Caris (Alternate)</td>
</tr>
<tr>
<td><strong>Royal Australasian College of Physicians (RACP)</strong> (One RACP member selected from the panel of three members)</td>
<td>Dr Avi Lemberg&lt;br&gt;Dr Catherine Streeton&lt;br&gt;Dr Christian Gericke</td>
</tr>
<tr>
<td><strong>Royal Australasian College of General Practitioners (RACGP)</strong></td>
<td>Dr Harry Nespolon</td>
</tr>
<tr>
<td><strong>Medicines Australia Association Representatives (maximum of 3)</strong> (Maximum two Medicines Australia Member Company Senior Executives and maximum one Medicines Australia Member Company Marketing Director)</td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td><strong>Medicines Australia Member Company Medical/Scientific Directors (Maximum of 2)</strong></td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td><strong>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)</strong></td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td><strong>Observers (No voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Therapeutic Goods Administration (TGA)</strong> (one TGA representative attends)</td>
<td>Ms Leanne McCauley</td>
</tr>
<tr>
<td><strong>Medicines Australia Member Companies’ employees (Maximum of 2)</strong></td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td><strong>Observer nominated by Medicines Australia (Maximum of 1)</strong></td>
<td>Various, depending on complaints</td>
</tr>
<tr>
<td><strong>Medicines Australia Advisors (No voting rights)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Secretary, Code of Conduct Committee</strong></td>
<td>Mrs Sophie Hibburd</td>
</tr>
<tr>
<td><strong>Medicines Australia Chief Executive Officer or delegate</strong></td>
<td>Mr Lee Hill / Mr Milton Catelin</td>
</tr>
<tr>
<td><strong>Medicines Australia Officer responsible for Ethical Conduct</strong></td>
<td>Ms Deborah Monk</td>
</tr>
</tbody>
</table>
Meeting Attendance

The Code Committee held 4 meetings to consider 4 complaints received in 2016-2017. A quorum was present at all meetings.

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><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>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) (One ASCEPT member selected from the panel of four members)</td>
</tr>
<tr>
<td>Consumers Health Forum (CHF) (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) (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><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 or delegate</td>
</tr>
<tr>
<td>Medicines Australia Officer responsible for Ethical Conduct</td>
</tr>
</tbody>
</table>

Meeting Attendance

The Appeals Committee held 1 meeting in 2016-2017 to consider 1 appeal. All permanent members of the Appeals Committee attended the scheduled meetings. A quorum was present at all 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 3: Monitoring Committee Members

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

The Committee held 9 meetings in 2016-2017. All permanent members of the Monitoring Committee attended the scheduled meetings. Two consumer representatives participated in 4 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, Ethics and Compliance
- Mrs Sophie Hibburd, Manager, Ethics and Compliance
- Mrs Karen Patten, Officer, Ethics and Compliance

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 2016-2017 Code Secretariat staff conducted or participated in 34 events pertaining to communication about the Code, with a combined audience of 1,063. See Table 4 for details on these events.

<table>
<thead>
<tr>
<th>Table 4: Communication with Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Event</td>
</tr>
<tr>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Conferences – presentations on the Code</td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
</tr>
<tr>
<td>Businesses working with industry</td>
</tr>
<tr>
<td>Presentations, webinars and workshops (including review updates, and briefings)</td>
</tr>
<tr>
<td>Member &amp; non-member companies</td>
</tr>
<tr>
<td>Businesses working with industry</td>
</tr>
<tr>
<td>Stakeholders</td>
</tr>
<tr>
<td>TOTAL</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 component of the CEP (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 self-directed program informs about the differences between the previous and current edition of the Medicines Australia Code of Conduct. This program is intended for individuals who completed Program 1 under an earlier edition of the Code.

More information on the course is available on the University of Tasmania’s CEP website.
CEP Enrolments in 2016-2017

Table 5 shows the number of enrolments in Semester 2, 2016 and Semester 1, 2017. Please note some candidates may be enrolled in more than one program in the semester.

<table>
<thead>
<tr>
<th>Program</th>
<th>Semester 2, 2016</th>
<th>Semester 1, 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program 1</td>
<td>292</td>
<td>383</td>
</tr>
<tr>
<td>Program 2</td>
<td>96</td>
<td>146</td>
</tr>
<tr>
<td>Program 3</td>
<td>62</td>
<td>75</td>
</tr>
<tr>
<td>Program 4</td>
<td>80</td>
<td>64</td>
</tr>
<tr>
<td>Program 5</td>
<td>111</td>
<td>93</td>
</tr>
<tr>
<td>Program 6</td>
<td>88</td>
<td>88</td>
</tr>
<tr>
<td>Total for Core Programs</td>
<td>729</td>
<td>849</td>
</tr>
<tr>
<td>Code Update</td>
<td>180</td>
<td>193</td>
</tr>
<tr>
<td>TOTAL</td>
<td>909</td>
<td>1,042</td>
</tr>
</tbody>
</table>

CEP Continuous Improvement

The University of Tasmania maintained its focus on the continuous improvement of the CEP during 2016-2017. As part of this process, a simulation game has been introduced into Program 1, the Code of Conduct Module which gives students a more interactive experience with the content. This has been very well received by students. In addition to the simulation, other improvements were made to Programs 4 and 6. These changes include amendments to reading materials, tutorials and exam questions. This continuous improvement process ensures that the CEP stays current, is appropriate and that modern teaching methods are incorporated.

During this year Medicines Australia undertook a project to develop and implement a new database for CEP student records. This new database has vastly improved the creation of student transcripts and now provides an online request system. For students who completed the course prior to 2011 and require a transcript, the request form is located on the Medicines Australia website. For students who have completed the course with the University of Tasmania, this information is housed within the iLearn system managed by the University.

People

We wish to thank the team at the University of Tasmania who delivered the CEP in 2016-2017 for our Members. The CEP Program team is led by Professor Greg Peterson, Deputy Dean (Research) Faculty of Health, and Dr Corinna Dwan, Projects Manager and Academic Lead (Medicines Australia CEP). Professor Peterson and Dr Dwan are ably assisted by Ms Breanett Rayner, Project Officer.

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 2016 were presented at an Awards Lunch in March 2017. Guest Speaker Dr John Gullotta, 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.

Mr Wes Cook, Managing Director of Boehringer-Ingelheim Australia, represented the Medicines Australia Board at the event. In his speech, Mr Cook 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

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.

The two UTAS Prizes for Excellence were presented to:

Ms Alex Pietzsch from Boehringer-Ingelheim for Semester 1 is pictured (left) receiving the award from Professor Gregory Peterson, Head of UMORE and Associate Dean (Research), Faculty of Health, University of Tasmania and Mr Wes Cook.

Ms Mandy Brown from GlaxoSmithKline received the award for Semester 2, however she is not pictured as she was unable to attend the event.

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:
Dr William Ho, independent student, pictured (at centre, right) receiving the award from Dr John Gullotta and Mr Wes Cook.

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 with Code of Conduct Award recipient Dr William Ho, are:

- Nishant Bakshi – Boehringer-Ingelheim
- Alex Pietzsch – Boehringer-Ingelheim
- Judy Edmondson – Hahn Healthcare
- Bessy Basso – Boehringer-Ingelheim
- Catherine Van Daele – Shire
- Matthew Douglas – Commercial Eyes
- Irina Savinykh – Seqirus
- Lucimar Nielsen – AstraZeneca

CEP Achievement Award recipients not present at the awards event:

- Marissa Otley – Mundipharma
- Matthew Jones – AstraZeneca

*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. The Monitoring Committee conducted its final review of educational event reports in July, August and September 2016. This review was of two months of reports from the final 6 month reporting period of April to September 2015. The reporting of educational event reports ceased at the conclusion of that reporting period, coinciding with the commencement of the new transparency measures. Details of these new reports will be included in future annual reports.

Table 6 provides a summary of the number of educational meetings reported in each of the 17 reporting periods 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 3: July – December 2008</td>
<td>18,060</td>
<td>July 2009 – March 2010 Review of 3 random months data 1</td>
</tr>
<tr>
<td>Report 6: January – March 2010</td>
<td>5,857</td>
<td>April 2012 – March 2013 Review of 3 random months data 0</td>
</tr>
<tr>
<td>Report 7: April – September 2010</td>
<td>16,880</td>
<td>April 2013 – March 2014 Review of 3 random months data 1</td>
</tr>
<tr>
<td>Report 8: October 2010 – March 2011</td>
<td>13,873</td>
<td>April 2014 – March 2015 Review of 3 random months data 1</td>
</tr>
<tr>
<td>Report 9: April – September 2011</td>
<td>18,175</td>
<td>April 2015 – September 2015 Review of 2 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></td>
</tr>
<tr>
<td>Report 12: October 2012 – March 2013</td>
<td>13,290</td>
<td></td>
</tr>
<tr>
<td>Report 13: April – September 2013</td>
<td>16,891</td>
<td></td>
</tr>
<tr>
<td>Report 15: April 2014 – September 2014</td>
<td>15,962</td>
<td></td>
</tr>
<tr>
<td>Report 16: October 2014 – March 2015</td>
<td>12,278</td>
<td></td>
</tr>
<tr>
<td>Report 17: April 2015 – September 2015</td>
<td>14,872</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>254,253</td>
<td>38</td>
</tr>
</tbody>
</table>

Member Company educational event reports for the last four years are available on the [Medicines Australia website](http://www.medicinesaustralia.org.au/).
Complaints Process

Rights

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

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@medaus.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)
Analysis of Complaints

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

Source of Complaints

In 2016-2017, 6 new complaints were received by Medicines Australia. Two of the 6 new complaints were not finalised before the end of the financial year. As shown in Table 7, the majority of complaints were submitted by healthcare professionals (2 complaints), member companies (2 complaints) the Monitoring Committee (1 complaint) and 1 complaint from a non-member company.

<table>
<thead>
<tr>
<th>Source of complaints</th>
<th>Number of complaints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare professionals</td>
<td>2</td>
</tr>
<tr>
<td>General practitioners</td>
<td></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>Member of the general public</td>
<td>0</td>
</tr>
<tr>
<td>Academic</td>
<td></td>
</tr>
<tr>
<td>Monitoring Committee</td>
<td>1</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td>2</td>
</tr>
<tr>
<td>Member Company</td>
<td></td>
</tr>
<tr>
<td>Non-Member Company</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>6</td>
</tr>
</tbody>
</table>

Complaint Determinations

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

Complaints carried over from 2015-2016

There were no complaints received in 2015-2016 and finalised in the 2016-2017 reporting period.

Complaints received in 2016-2017

Of the 6 new complaints received in 2016-2017, 4 complaints were considered and finalised by the end of the financial year. Of the 4 complaints finalised in 2016-2017, 3 were found not in breach of the Code and 1 complaint was 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 2016-2017, 1 of the 4 new complaints considered and finalised by the Code Committee was subject to an appeal from the healthcare professional complainant. The appeal was not upheld.
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 18; 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.

In 2016-2017 only one monetary fine of $50,000 was imposed by the Code Committee.

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 2016-2017 was 32 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 17 working days.

Code provisions subject to complaint
There was a total of 19 alleged breaches of the Code with the majority of alleged breaches falling under Section 1 (16 alleged), Section 9 (1 alleged), Section 13 (1 alleged) and Section 17 (1 alleged) of the Code. The actual breaches were 7 breaches relating to Section 1 for complaints received and finalised in 2016-2017.
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 2016-2017.

Table 8 provides a summary of each finalised complaint. Complaints received and finalised in 2016-2017 were considered under Edition 18 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>1137</td>
<td>GlaxoSmithKline</td>
<td>Educational Event</td>
<td>N/A</td>
<td>Monitoring Committee</td>
<td>No Breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1138</td>
<td>Sanofi Genzyme</td>
<td>Advertisement</td>
<td>Aubagio/ Lemtrada</td>
<td>Biogen</td>
<td>Breach of Sections 1.1, 1.3 and 1.6 of Edition 18</td>
<td>Fine of $50,000 Material to be withdrawn from use</td>
</tr>
<tr>
<td>1139</td>
<td>Amgen</td>
<td>Dosing Guide</td>
<td>Prolia</td>
<td>Healthcare Professional</td>
<td>No Breach</td>
<td>n/a</td>
</tr>
<tr>
<td>1140</td>
<td>Sanofi Genzyme</td>
<td>Promotional Material</td>
<td>Aubagio</td>
<td>Biogen</td>
<td>No Breach</td>
<td>n/a</td>
</tr>
</tbody>
</table>
GSK EDUCATIONAL EVENT – 1137

Subject Company: GlaxoSmithKline Australia Pty Ltd (GSK)
Complainant: Monitoring Committee
Product: N/A

Complaint
Following its review of Education Event Reports, the Medicines Australia Monitoring Committee had referred an educational event organised by GSK and held in July 2015 for consideration by the Code Committee. The event was a Practical Asthma Management Meeting. The Monitoring Committee considered that the provision of a three course dinner including alcoholic beverages at a restaurant had exceeded the $120 per head hospitality limit set out in the Code. The Monitoring Committee considered that the meals and beverages provided were excessive in relation to the educational content and duration of the meeting.

Sections of the Code
The conduct was alleged to be in breach of the following Sections of Edition 18 of the Code:

- 9.4.3 Meals and Beverages

Response
GSK responded that the number of attendees for the event had been incorrectly reported in the educational event report. The meeting was originally booked and catered for 28 attendees at a fixed cost per head of $98 inclusive of GST. Through a number of late cancellations, the final number of attendees was 15. However the commitment to the restaurant had been confirmed and the costs incurred for the original number of attendees. GSK stated that the company strongly enforces the $120 hospitality expenditure within the organisation, and this is reinforced through training and education provided to sales representatives.

Code of Conduct Committee Decision
The Code of Conduct Committee determined by unanimous decision that the activity was not in breach of Section 9.4.3 of the Code of Conduct.

Sanction
Having found no breach of the Code of Conduct, the Committee did not impose a sanction.

Consideration of the Complaint
The Committee discussed the Educational Event that had been held at a Chinese restaurant in Brisbane on 22 July 2015. Edition 18 of the Code of Conduct became effective in May 2015, which saw the introduction of a maximum of $120 per head excluding GST for food and beverage expenditure in relation to educational events. The Committee noted that this limit was well known to the company at the time of organising and holding this event.

The Committee reviewed the evidence provided by GSK, which detailed the planning for the event and receipt for the food and beverages, as well as the way in which the event had been reported to Medicines Australia.

The Committee noted that GSK’s records showed that the event was originally booked for 28 attendees, with email correspondence between a GSK employee and the restaurant confirming the number of attendees on 20 July 2015, two days prior to the event. The number of attendees was confirmed by GSK through the receipt of RSVPs to the invitation it had circulated. The Committee reviewed a redacted sign in sheet for the event, which showed that 28 attendees had been expected and the number who had actually attended was 15. The Committee also noted the restaurant tax invoice for the event, which showed a set menu price of $98 per head, inclusive of GST, charged for the confirmed 28 attendees.

The Committee also reviewed a report produced by GSK’s internal event tracking system, which outlined the process by which the event had been organised and approved. The Committee noted that through this tracking system GSK retrieves the data required to report the educational event to Medicines Australia. The Committee noted that in the section that outlined the confirmed number of attendees, a GSK employee had entered the following details:

<table>
<thead>
<tr>
<th>Confirmed Attendees</th>
<th>No Show</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of HCP attendees</td>
<td>15</td>
</tr>
<tr>
<td>Number of Non-HCP attendees</td>
<td>0</td>
</tr>
<tr>
<td>Number of GSK employees</td>
<td>5</td>
</tr>
<tr>
<td>Total number of confirmed attendees</td>
<td>20</td>
</tr>
</tbody>
</table>

The Committee noted that the Code of Conduct Guidelines (Edition 18, version 1 May 2015, page 99) states:

“The number of attendees reported in the table should be the number of healthcare professionals the company has paid for to attend that function. In most cases, this will be the confirmed number of attendees, however, in some instances where venues charge only for those who attend on the night the number of attendees will be lower. For example, if you invite 20 attendees, 15 confirm their attendance (and you are billed for 15) but on the day of the event 13 attend, the number reported would be 15.

The number of attendees does not include company staff.”
The Committee agreed that GSK should have excluded the 5 company staff who had attended the event from the confirmed attendees of 28 and reported 23 attendees. In addition, the hospitality costs should have been reported exclusive of GST at $89 per person (with a total cost of $2,047 for 23 healthcare professional attendees). If the event had been reported in this manner, the accurate cost per head would have been reflected in the report. However, the Committee did note that there remained a discrepancy in the number of attendees with the restaurant confirmed at 28 attendees and GSK’s reporting system showing 29 people (15 attendees, 9 ‘no-shows’ and 5 GSK staff).

Based on the information provided by GSK, the Committee agreed by unanimous decision that the event was not in breach of Section 9.4.3 of the Code as the hospitality was clearly under the $120 (exclusive of GST) food and beverage limit. However, the Committee were disappointed by the careless manner in which this event appeared to have been reported within the company and the apparent lack of any checking process that resulted in this event being misreported in the published educational event report. The Committee noted that this event was reported in the 17th ‘round’ of Educational Event Reports (which first commenced in 2007). Therefore the process for reporting these types of activities should be very familiar to Medicines Australia member companies. The Committee were of the opinion that companies should have rigorous procedures in place that prevent both conduct that would breach the Code and misreporting of activities.

The Committee noted that the reporting of educational events is no longer required by Edition 18 of the Code of Conduct. The Secretariat advised that from 1 October 2015 transparency reporting will focus on transfers of value to individual healthcare professionals. The future reporting of payments and transfers of value for individual healthcare professionals will not include hospitality expenditure. The Committee were advised that expenditures relating to airfares, accommodation, conference registration, speaker and Advisory Board sitting fees and other consultancy fees will be reported. Some members of the Committee expressed concern that food and beverages will not be reported for individual educational events and that the new reporting regime will require strong internal processes to ensure that companies adhere to the Code requirements for expenditure on food and beverages.

Sanction

Having found no breach of the Code of Conduct, the Committee did not impose a sanction.

AUBAGIO AND LEMTRADA ADVERTISEMENTS – 1138

Subject Company: Sanofi Genzyme
Complainant: Biogen Australia Pty Ltd
Product: Aubagio and Lemtrada

Complaint

Biogen alleged that five claims – two in relation to Aubagio and three in relation to Lemtrada – were in breach of the Code. The claims are “Quieting MS” and “Quietly for Aubagio and “Transformational Therapy”, “Transformational dosing” and “Transformational durability” for Lemtrada. The claims appeared either in a product tagline and/or qualifying statements for the taglines in an advertisement for Aubagio in the conference handbook and on a trade display for Aubagio and Lemtrada at the ANZAN meeting in May 2016.

Biogen alleged that the claims were not balanced, accurate or correct; not consistent with the approved Product Information; and are misleading. In addition, in relation to the claims for Lemtrada that include the word “transformational”, Biogen alleged that these claims were unqualified superlatives and hanging comparatives which were imprecise, unbalanced and unable to be substantiated.

Sections of the Code

The promotional material is alleged to be in breach of the following Sections of Edition 18 of the Code:

- 1.1 Responsibility
- 1.3 False or Misleading Claims
- 1.6 Unqualified Superlatives
- 1.8 Comparative Statements

Response

Sanofi Genzyme denied that the claims for Aubagio and Lemtrada were in breach of the Code of Conduct. It argued that the claims were balanced, had been appropriately qualified and were able to be substantiated. In its response, Sanofi Genzyme rejected Biogen’s rationale for its complaints. Sanofi Genzyme argued that Biogen had treated individual words within the claims as separate claims and had selectively interpreted their meaning in terms of their compliance with the Code.

Sanofi Genzyme responded that the claims and associated qualifying statements were consistent with the Code requirements and demonstrated balance with respect to efficacy and safety, were fair and accurate, were not misleading by error or omission, and were referenced to peer-reviewed international high impact journals.

Sanofi Genzyme further argued that the claims contained words used commonly in a medical context and, contrary to Biogen’s allegations, that
these words can be clearly defined, substantiated and supported by the medical literature. Nevertheless, without admission of breaching the Code and in the interest of resolving Biogen’s complaints, Sanofi Genzyme had made amendments to future promotional materials containing these claims to strengthen the qualifying statements and include additional references.

**Code of Conduct Committee Decision**

The Committee reviewed the complaint and found as follows:

**Complaint 1 – “Quieting MS”**
1.1 – Majority No Breach
1.3 – Majority No Breach

**Complaint 2 – “Quietly”**
1.1 – Unanimous Breach
1.3 – Unanimous Breach

**Complaint 3 – “Transformational Therapy”**
1.1 – Unanimous Breach
1.3 – Unanimous Breach
1.6 – Unanimous Breach

**Complaint 4 – “Transformational Dosing”**
1.1 – Majority No Breach
1.3 – Majority No Breach
1.8 – Majority No Breach

**Complaint 5 – “Transformational Durability”**
1.1 – Majority Breach
1.3 – Majority Breach
1.8 – Majority No Breach

**Sanction**

As several breaches had been found, the Committee determined that the claims found in breach must be withdrawn from use and must not be used again in the same or similar form in any future materials. The Committee also imposed a fine of $50,000.

**Consideration of the Complaint**

The Committee noted that the complaint related to claims for two products – “Quieting MS Quietly” for Aubagio and three claims for Lemtrada that used the word “Transformational”. The Committee also noted that it was a matter of dispute between the companies as to whether the claim “Quieting MS Quietly” was one claim or two. The words “Quieting MS” had appeared in a bold, non-italic font and “Quietly” had appeared in an italic, regular font which visually suggested the separation of “Quietly” from “Quieting MS”. The Committee further noted that during inter-company dialogue Sanofi Genzyme had stated that the claim “Quieting MS” related to efficacy data for Aubagio and “Quietly” referred to safety and tolerability data. The Committee determined to consider the complaint as set out in the submission from Biogen, considering “Quieting MS” and “Quietly” separately.

**Complaint 1: “Quieting MS”**

The majority of the Committee members were of the opinion that the term “quieting” was relatively well understood in the medical community in relation to non-curable diseases where treatments can dampen or reduce the symptoms of a disease. It was noted that Aubagio may only be prescribed by specialist neurologists. The majority of the Committee members agreed that it would be unlikely for a healthcare professional to interpret “quieting” to mean that Multiple Sclerosis (MS) would be cured by Aubagio; only that the symptoms of the disease may be reduced. These Committee members considered that the claim was not misleading and could be adequately substantiated as it is effective in reducing the symptoms of MS.

A minority of the Committee, however, were concerned that “quieting” was not something that could be quantified or measured in a medical or clinical sense. Further, some of these Committee members considered that “Quieting MS Quietly” should be considered as a single claim as it was difficult to interpret the individual elements except in their overall context. The Committee noted that there was a qualifying statement below the claim. It referred to “a significant and consistent reduction in multiple measures of disease activity…” and “its most common adverse events were transient and rarely required treatment discontinuation”. A minority of Committee members considered that this qualification was quite general and did not specify which measures of disease activity may be reduced or which side effects were transient and not a significant problem for patients and therefore did not adequately explain or justify the claim. These Committee members considered that the claim “Quieting MS Quietly” may be interpreted as to mean the silencing or cure of symptoms associated with MS, which cannot be substantiated.

The Committee agreed by majority decision that the claim “Quieting MS” was not in breach of Sections 1.1 or 1.3 of the Code.

**Complaint 2: “Quietly”**

The Committee discussed the claim “Quietly” both separately and in association with the image of a smiling woman holding her finger to her mouth making a “shhhhh” motion.

The Committee noted that the claim was referenced to the Approved Product Information and two published studies that had included safety and tolerability data. The Committee noted that there were potentially serious side effects to Aubagio which were common or very common, including elevated liver enzymes. The Committee considered that by simply referring to the most common adverse events in the qualifying statement, the claim does not communicate sufficient information about the potentially serious adverse effects, some of which require ongoing monitoring. The Committee considered that the claim downplays the potentially
serious side effects of the product. The Committee also considered that the term “quietly” did not have a clear meaning or interpretation from a medical or clinical sense. The Committee concluded that the claim, therefore, was not balanced and was misleading.

The Committee discussed the image associated with the claim. The Committee agreed unanimously that the imagery further supported its conclusion that the claim was not balanced and was misleading. The imagery reinforced the impression that side effects were not of concern as they had been “silenced” or didn’t create any “noise”. The imagery contributed to the lack of balance and misleading nature of the claim.

The Committee agreed by unanimous decision that the claim “Quietly” was in breach of Sections 1.1 and 1.3 of the Code of Conduct.

In considering the claims the Committee noted that Sanofi Genzyme had provided anonymous comments from members of its Advisory Boards in relation to both the Lemtrada and Aubagio claims. This was a select group of healthcare professionals who worked closely with the company rather than randomly selected, representative sample of doctors or neurologists. The Committee unanimously agreed that these comments did not assist it in considering whether the claims subject to complaint were compliant with the Code.

**Lemtrada claims**

The Committee decided to review the claims in a different order to that presented in the complaint. The Committee reviewed the claims for “Transformational dosing” and “Transformational durability” before considering the overarching claim for “Transformational therapy” because the dosing and durability claims were presented as qualifying statements or claims that supported “Transformational therapy”.

**Complaint 4: “Transformational dosing”**
The Committee acknowledged that the once yearly dosing regimen for Lemtrada is a significant change from other MS treatments that must be taken daily. Specifically, when compared to competitor products, which require more frequent doses, it is a significant advance. A majority of the Committee considered that the claim was able to be supported by the Product Information, was sufficiently explained by the description of the dosing regimen that followed the claim and would not mislead healthcare professionals.

A minority of the Committee members, however, were of the opinion that the use of the superlative “transformational” in this claim overstated the benefit and made too strong a claim that could not be substantiated. No evidence had been provided to substantiate that the dosing schedule was “transformational” for patients. Further, the treatment requires a daily infusion for 5 consecutive days in the first year and 3 consecutive days 12 months later, which would need to be administered in a hospital or day clinic. Although Lemtrada is currently the only once-yearly therapy for MS, there are other medicines that are administered once a year for other incurable diseases. These Committee members considered that the convenience of once yearly dosing may be beneficial, but a claim for “transformational dosing” requires more than simply a less frequent dosing regimen.

The Committee agreed by majority decision that the claim “Transformational dosing” was not in breach of Sections 1.1 or 1.3 of the Code.

The Committee discussed whether the claim was a hanging comparative. The Committee noted that the claim “transformational dosing” is explained by the description of the dosing schedule that immediately followed the claim. A majority of the Committee considered that the intended meaning of the claim was sufficiently clear and accepted that no other MS treatment was dosed in the same manner. In a majority decision the Committee concluded that the claim was not in breach of Section 1.8 of the Code.

**Complaint 5: “Transformational Durability”**
The Committee discussed the claim “transformational durability” and noted that while the referenced data were statistically significant, supporting five year durability of Lemtrada’s effects for at least sixty percent of patients, they were not of adequate quality to support the claim. Specifically, the Committee noted that the referenced studies were two conference posters that referred to two studies, but these were not peer-reviewed, published papers.

Further, the Committee considered that whilst a statistically significant proportion of patients in these studies had not required further treatment with Lemtrada at 5 years after their initial treatment, there was still a reasonable proportion of patients, up to forty percent of patients, who did require further treatments. The supporting references refer to the “durability” of efficacy and “durable” reduction of MRI activity over 5 years, but the Committee did not agree that this warranted a claim of “transformational durability”. The “transformational” nature of the durable efficacy had not been adequately substantiated and therefore the claim was not balanced and was misleading.

A minority of the Committee members considered that the claim could be substantiated by the referenced studies and that the durability of effect was a significant change.

The Committee agreed by majority decision that the claim “transformational durability” was in breach of Sections 1.1 and 1.3 of the Code because it was
misleading, could not be adequately substantiated and was not accurate or balanced.

The Committee discussed whether the claim “transformational durability” could be considered comparative, and agreed that the claim was referring to the durability of effectiveness extending to five years and would not be construed by a reader as being a comparison to other products generally or to a specific product used to treat MS. A minority of the Committee that disagreed with this assessment and considered that the claim was a hanging comparative that claimed general superiority without specifying the basis for the comparison.

The Committee agreed by majority decision that the claim was not in breach of Section 1.8 of the Code.

Complaint 3: “Transformational Therapy”
Having considered the “transformational dosing” and “transformational durability” claims, the Committee then considered the “Transformational therapy” claim.

The Committee noted that the word “unique” had been used in the studies used to substantiate the claims and the word “revolutionary” had reportedly been used by the Chief Executive of NICE in the UK. The Committee however, were of the opinion that the use of “transformational therapy” in relation to the product was overstating the advance and was misleading. Having found that the claim “transformational durability”, which was one of the claims qualifying the overarching claim for “transformational therapy”, could not be adequately substantiated and was misleading, the Committee considered that “transformational therapy” was also misleading, could not be adequately substantiated and was not balanced. Further, the Committee considered that a significant claim that a therapy is “transformational” requires more than an improved dosing schedule and durable efficacy. Whilst the claim “transformational dosing” had not been found in breach of the Code and the Committee had agreed that an annual dose given in two consecutive years was a significant change in the treatment of MS, this was insufficient to support a claim that the therapy itself was “transformational”.

The Committee also considered the claim in the context of the image of a man in the surf carrying a body/surf board. The Committee understood that not all MS patients would experience sufficient benefit from Lemtrada that would enable them to go surfing or participate in strenuous activities. The Committee considered that the imagery reinforced the “transformational” claims to give the impression that the therapy may transform MS patients’ lives, which could not be adequately substantiated. The Committee acknowledged that Lemtrada may provide an improvement in managing the symptoms of MS for some patients and that the yearly dosing may be convenient for some patients, but this was not sufficient to claim “transformational therapy”.

In relation to whether “transformational therapy” is an unqualified superlative, as the Committee had determined that the claim for the medicine being “transformational” could not be adequately substantiated with regard to a clinical outcome, the Committee unanimously agreed that the claim was an unqualified superlative and was in breach of Section 1.6 of the Code.

The Committee agreed by unanimous decisions that the claim “Transformational therapy” was in breach of Sections 1.1, 1.3 and 1.6 of the Code.

Sanction
The Committee discussed the severity of the breaches and determined by unanimous decision that they constituted a moderate breach of the Code of Conduct.

The Committee determined unanimously that the claims found in breach of the Code must not be used again in the same or similar format in any future materials. Any materials containing the claims found in breach of the Code must be withdrawn from further use or distribution. The Committee also agreed by majority decision that Sanofi Genzyme should pay a fine of $50,000.
Response

Amgen rejected the allegation that the claims for Prolia were misleading or in breach of the Code of Conduct. Amgen asserted that the use of Relative Risk Reduction (RRR) is an appropriate, well-accepted and readily understood way in which to describe the differences in observed fracture rates. Further, Amgen noted that RRR is the key parameter used in the clinical study published in the New England Journal of Medicine which described the effect of denosumab in reducing fracture risk at key skeletal sites. Further, RRR is included in the Prolia Product Information.

Amgen further argued that a RRR of 40% in hip fractures is very meaningful for patients. RRR is a well-accepted parameter and is used in many promotional materials for healthcare professionals.

Code of Conduct Committee Decision

The Committee unanimously determined that the Prolia Dosing Guide was not in breach of Section 1.3 of the Code of Conduct.

Sanction

As no breach was found, no sanction was imposed.

Consideration of the Complaint

The Committee discussed the use of Relative Risk Reduction (RRR) in the dosing guide, which was used to demonstrate fracture reduction in patients using Prolia. The Committee also discussed the complainant’s allegation that the use of RRR to describe reduction in risk of fractures was misleading and that the use of Absolute Risk Reduction (ARR) would be a more appropriate descriptor of the treatment effect.

The Committee noted that RRR historically has been misused, in many fields including medicine, to exaggerate the effects of an intervention and that it could be misleading if not used in a balanced manner, for example stating a RRR that might be significant statistically but is not clinically relevant because the effect size is relatively small. The Committee also noted that the audience for a communication using RRR is also an important factor, as the general public may not understand how to interpret RRR.

The Committee agreed, however, that the use of RRR in the Prolia Dosing Guide was appropriate and the effect on reducing fracture risk was clinically relevant. The Committee also agreed that RRR would be a familiar concept to the target audience for the Dosing Guide, general practitioners and endocrinologists, who would understand the difference between RRR and ARR. The percentage risk reductions stated in the Dosing Guide were clearly identified as RRR, with the statistical significance (p-value) stated in each case. The Committee further noted that the use of RRR in the Prolia Dosing Guide was supported by the Cummings et al study (the FREEDOM trial) published in the New England Journal of Medicine, which reported the RRR. The Committee agreed that the FREEDOM study showed long term data of three years. The Committee further noted that RRR was stated as the main descriptor of Prolia’s effect compared with placebo in the Product Information, with ARR also stated in bracketed text.

While the Committee agreed that the use of RRR in this instance was appropriate, it was also of the opinion that it would be best practice to also include ARR data where possible. It is widely accepted that ARR is the clearest way of presenting research results to assist in healthcare professional decision-making. The Committee noted that the Code does not require the use of ARR data in promotional materials; however the Committee encouraged its use where it is possible and appropriate. In this instance, the Committee noted that the ARR had been included in Tables 1 and 2 in the Approved Product Information and considered that it would be possible for this tabulated information to be communicated in a clear and meaningful manner on a promotional item. However, the Committee did not agree with the complainant that the use of RRR was misleading in the Prolia Dosing Guide.

The Committee agreed by unanimous decision that the Prolia Dosing Guide was not in breach of Section 1.3 of the Code.

Appeal

The healthcare professional disagreed with the findings of the Code of Conduct Committee and asserted that the use of risk ratios commonly exaggerates both the benefits and harms of products. Further, the Complainant contended that a relative risk ratio does not measure ‘risk’ as it does not include a risk dimension, such as “observed deaths per 1000 people” or similar measure.

The Complainant appealed the decision noting that they believed that the framing of the benefit in relative rather than absolute terms was an attempt to alter the prescriber’s perception of the product and therefore is false and misleading.

Appeal Response

Amgen reasserted its position that the use of RRR is a clinically appropriate parameter that is well-accepted and readily understood by the target audience. Amgen also noted that in its decision the Code Committee had stated that the use of RRR in this piece was appropriate.

Appeals Committee decision

The Appeals Committee was not persuaded that the decision of the Code of Conduct Committee (Code Committee) in relation to this complaint involved any error that required the decision to be altered or set aside. The decision of the Code Committee was
confirmed. The Appeals Committee agreed by unanimous decision to not uphold the appeal.

Sanction

In confirming the decision of the Code Committee, the Appeals Committee also confirmed the Code Committee’s decision to not impose any sanction.

Consideration of the Appeal

Prior to consideration of the appeal, the Chairman called for the declaration of any conflicts of interest. No conflicts of interest were declared and the meeting proceeded.

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 Committee should be set aside or varied.

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

The Complainant summarised their background, noting that as a general practitioner they were familiar with being visited by pharmaceutical industry sales representatives on a regular basis. During a visit from an Amgen representative, the Complainant received the promotional item for Prolia that they considered was very misleading. The Complainant’s concern centred on the use of RRR rather than Absolute Risk Reduction (ARR).

It was the Complainant’s opinion that health statistics are generally poorly understood by general practitioners and, in particular, that the difference between RRR and ARR is not well understood even by a learned healthcare professional.

The use of RRR had been associated with three statements in the Prolia promotional item:
- New vertebral fractures: ↓ 68% RRR (p<0.001)
- Hip fractures: ↓ 40% RRR (p<0.04)
- Non-vertebral fractures: ↓ 20% RRR (p<0.01)

The Complainant stated the key issue with using RRR is that it fails to discriminate between large treatment effects and very small treatment effects in terms of absolute numbers. The Complainant asserted that by using RRR expressed as a percentage without knowing other parameters, the information was very difficult to interpret. When reviewing the piece, the Complainant could not determine easily what the percentage risk reductions related to. It was contended that without additional information, which would need to be obtained from the Product Information or clinical study, a reader would not be able to properly interpret the potential benefit of the product. Simply stating the RRR percentage, which gives the impression that there is a large reduction in risk because the number is large (i.e. 68%), is misleading without further information that would give a better understanding of efficacy.

The Chairman sought an understanding from the Complainant, as a trained healthcare professional and the intended audience of the piece, whether their individual knowledge and training gave them the ability to understand and interpret the promotional piece. The Complainant responded that unless the parameters around the numbers are provided in the piece, it is impossible to interpret the figures without reviewing the Approved Product Information or reading the supporting paper in detail. It was the Complainant’s opinion that a busy general practitioner would not be able to calculate the absolute risk reduction from the RRR without additional information provided in an easily accessible manner, such as in the piece itself.

In their presentation, the Complainant presented data from the referenced study and data from another study in a different osteoporosis treatment. This was to illustrate that without the inclusion of additional information, Prolia may appear to be superior because the percentage RRR number is larger, whereas the higher ARR of the other product indicated that it might provide greater benefit to patients although its percentage RRR number is smaller. This demonstration, the Complainant asserted, showed that the use of a RRR without additional information is misleading to a reader. The use of ARR or Number Needed to Treat (NNT), for example, would greatly reduce the risk of healthcare professionals being misled.

An Appeals Committee Member strongly agreed with the complainant that ARR should be included in promotional materials provided to doctors.

Another Committee Member disagreed with the statement that healthcare professionals are statistically illiterate, and asserted that many would be able to understand the difference between RRR and ARR. This Committee Member queried whether it was the lack of information in the piece, or the inability of the Amgen sales representative to adequately explain the statistic that was more of concern to the complainant. The Complainant explained that they believe that all the information should be contained within the piece, and that a company representative should not be relied upon to explain the data to healthcare professionals. The quality of the information provided should be enhanced to ensure that value is derived from doctors’ interactions with company representatives. So long as the necessary information is provided, a general practitioner should be able to interpret the data. However, the Complainant contested that if they are expected to read every paper and complete complex calculations to derive the data needed to make an informed decision, most busy general
practitioners would not do so and would rely solely on the data provided in the promotional piece.

The Chairman thanked the Complainant for their presentation, and invited Amgen to make their presentation. The following summarises that presentation and discussion with the Appeals Committee.

Amgen maintained that the promotional material was not misleading. The aim of the piece was the Quality Use of Medicines, reminding healthcare professionals of the 6 month dosing regimen for Prolia and the need for patients to also receive calcium and vitamin D supplements. The Dosing Guide was for GPs and some specialists and was not to be given or shown to patients. Amgen confirmed that it took matters of compliance seriously and submit to Medicines Australia’s Code of Conduct, which is supported by a strong compliance culture in the organisation.

Amgen then invited an independent expert in management of osteoporosis to make a presentation to the Appeals Committee. This expert is a professor with a long-standing interest in the field of osteoporosis and the presentation was to assist the Appeals Committee in understanding and interpreting the knowledge base in this therapeutic area. The Professor had declined any payment from Amgen for their involvement in this matter.

The Professor provided an overview to the Appeals Committee as to the difference between RRR and ARR. In this overview, the Professor noted that:

- Relative Risk Reduction is how much a risk is reduced in the treated population when compared to the control (or placebo) population.
- Without knowing the untreated risk, the effect size of treatment cannot be assessed
- A treatment with a very large relative risk reduction will have a small absolute benefit in low risk individuals
- Modest relative risk reductions can have major clinical importance if there is a high underlying risk
- Absolute risk reduction is the absolute difference in outcomes between the treated population when compared with the control (or placebo) population
- ARR makes no explicit comparison to the untreated population but depends upon underlying risk

It was the Professor’s opinion that ARR is less intuitive to interpret than RRR. In order to make a comparison, the Professor argued that a reader needs to know the underlying risk to make the comparison meaningful. Further, the use of NNT data would not be helpful unless a reader also knows the ARR in the first instance.

The Professor noted that the Complainant’s arguments based on a comparison between the ARR and RRR for Prolia and another unnamed product in this therapeutic class were flawed. The studies that the data were derived from cannot be compared because they were studies of different patient populations, who had different baseline risk of fracture, with different study parameters and therefore the data is not comparing the same endpoints resulting in meaningless information. Further, the Professor noted that in osteoporosis, there have been no head to head studies conducted. This is not due to lack of willingness by companies, but due to the requirement of international regulators such as the US FDA for studies of osteoporosis treatments to be placebo-controlled.

The Professor noted that use of ARR may seem appealing, however it cannot be meaningfully applied to an individual patient unless their individual absolute risk is estimated. That is, unless the treating physician understands the extent to which an individual patient matches the population in a study, the use of ARR is not helpful to a physician. The Professor noted that RRR is stable over a range of underlying absolute risk levels and is intuitively understood. Further, the Professor noted that due to the expansion of treatment options in osteoporosis, more people were being treated – resulting in a shrinking control population. This is resulting in a reduction of absolute risk in patients being enrolled in clinical trials.

The Amgen representatives then addressed the Appeals Committee and restated that they rejected the assertion that by omitting the ARR or NNT that Amgen had breached Section 1.3 of the Code. Amgen firmly believed that the Prolia piece was fair, balanced, and was not misleading. They, too, contested the allegation that healthcare professionals were statistically illiterate.

Amgen asserted that it had used RRR as it was meaningful and relevant to physicians, and well understood by the target audience. As explained by the Professor, RRR is readily applicable to the clinical environment and supports informed decision making. In the absence of knowing an individual patient’s risk, the RRR is a clearer and more interpretable than ARR.

Amgen further rejected the assertion that the figure of 68% RRR for new vertebral fractures was grossly misleading, as asserted by the Complainant, as this was the primary end point of the study used to support the claim. The study was adequately powered to detect a statistical difference. The Cummings et al study (2009) was in low risk patients and showed that the treatment effect for hip fracture was a 0.5% reduction (0.7% cumulative incidence of hip fracture in the treatment group vs 1.2% cumulative incidence in the placebo group), which represented a relative decrease of 40%. Amgen

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argued that a relative risk reduction was an important effect of treatment. Finally, given the financial impact of hip fractures in Australia of approximately $700m per annum in direct and indirect costs, the relative risk reduction represents a significant potential cost saving.

Amgen concluded its presentation by restating that they contest the assertion that the Prolia Dosing Guide was in breach of Section 1.3 of the Code through the use of RRR alone. Amgen noted that the Code does not specify the use of RRR, ARR or NNT and that Amgen believe the use of RRR to be appropriate in this promotional material.

Amgen highlighted to the Appeals Committee that the Code Committee’s decision was unanimous, and this was reflected in the Committee’s reasons for decision which stated that the use of RRR in this piece was appropriate. Amgen stated that no evidence had been provided by the Complainant to show that the Code Committee’s decision had been in error.

The Chairman then queried Amgen regarding the Complainant’s assertion that the company representative had not been able to provide more clarity about AAR during their visit in 2016. Amgen noted that this allegation was not made in the original complaint, nor the subsequent appeal submission and therefore Amgen had not had the opportunity to conduct an internal investigation on the matter.

The Chairman then invited the Complainant to respond to the information provided in Amgen’s presentation and to provide their closing comments. The Complainant took the opportunity to restate that they believed most healthcare professionals do not understand statistical concepts such as RRR and ARR. The Complainant considered that the promotional piece was designed to show a large number to GPs, which was misleading. The Complainant remained firmly of the opinion that the promotional material should have included ARR and NNT or a simple statement communicating this information in order to assist in the understanding of the information provided. The Healthcare Professional concluded by stating that they believed the Code Committee fell into error by overestimating the ability of the average general practitioner to interpret the information presented in the way that it was. Relying on a doctor to read the Product Information and read the clinical evidence in order to correctly interpret the promotional material is misleading.

The Chairman thanked both the Complainant and Amgen for their presentations and excused them from the meeting.

The Appeals Committee considered that it was unusual for ARR or NNT figures to be stated in promotional materials, in part because these data might not be always provided in referenced studies.

The Appeals Committee acknowledged that communication of risk reduction is a contentious area and noted that the use of RRR over ARR has been debated at length. The Appeals Committee noted that significant effort is spent in educating healthcare professionals during their training about clinical statistics and, indeed, newer graduates often have better skills in this area due to this greater focus in their training.

The Appeals Committee determined that it could not find that Amgen had breached the Code of Conduct as the Code does not at present require the inclusion of ARR or any other risk parameter in promotional materials. The Appeals Committee agreed with the Code Committee that RRR is a widely used way of communicating risk reduction and that the evidence used to support the RRR claims in the Prolia Dosing Guide was appropriate. The Appeals Committee noted that just providing the ARR could also mislead a GP, because a prescriber must also consider the risk of an individual patient and how they compare to the relevant study population. The Appeals Committee unanimously agreed to confirm the Code Committee’s decision to find no breach of Section 1.3 of the Code. The appeal was not upheld.

The Appeals Committee recommended, however, that Medicines Australia should provide further guidance on the use of clinical statistics by pharmaceutical companies in promotional and other materials. Specifically, the Appeals Committee considered that the inclusion of additional parameters and presenting information in a clear way would enhance the quality use of medicines and would assist a healthcare professional to make an informed decision about prescribing a medicine. The Appeals Committee recommended that any future iteration of the Code of Conduct should incorporate additional guidance on the communication of risk using statistics such as ARR, RRR and NNT.

Sanction

In confirming the decision of the Code Committee, the Appeals Committee also confirmed the Code Committee’s decision to not impose any sanction.
Subject Company: Sanofi Genzyme
Complainant: Biogen
Product: Aubagio

Complaint
Biogen asserted that images used by Sanofi Genzyme in material promoting Aubagio, which depicted a female holding a finger to her lips, constituted graphical representations and promotional claims that conveyed positive attributes of the product. The imagery appeared on a number of items: banners displayed at healthcare professional conferences, an information guide distributed at those conferences, and a patient support program leaflet for patients. Biogen asserted that the images were to represent that the patient’s experience on the product will be a quiet, calm and uneventful one. Biogen further asserted that the images downplayed serious side effects of the product or conveyed that side effects were minimal. Biogen argued that some side effects of the product could be fatal, and require regular monitoring.

Biogen argued that the images were in breach of the Code because they were not accurate, balanced, did not make a responsible claim and were misleading by implying that the product is without serious side effects. Further, Biogen asserted that the images should be considered promotional claims, and therefore should not appear on materials intended for patients, such as the patient support program leaflet.

Sections of the Code
The educational event is alleged to be in breach of the following Sections of Edition 18 of the Code:

- 1.1 Responsibility
- 1.3 False or Misleading Claims
- 13.7 Materials for Use with Patients (Patient Aids)
- 17 Patient Support Programs

Response
Noting that the images were not accompanied by any written claims, Sanofi Genzyme rejected the allegations that the images in the Aubagio materials constituted a promotional claim with reference to Section 1.1 of the Code, which refers to “any statement ... whether verbal or written”. Sanofi Genzyme denied that the imagery on its own conveyed a promotional claim in relation to efficacy or safety. Sanofi Genzyme asserted that the material in which the imagery appeared contained valuable and balanced information for clinicians and patients who have been prescribed Aubagio. In rejecting the allegation that the images are promotional claims, Sanofi Genzyme also rejected the assertion that the images should not be used in materials intended for patients.

In their response, Sanofi Genzyme asserted that the complaint submitted by Biogen was vexatious and frivolous and alleged that Biogen was therefore in breach of Section 27, Abuse of the Code.

Code of Conduct Committee Decision
The Committee unanimously determined that the Aubagio Promotional Material was not in breach of Section 1.1, 1.3, 13.7 or 17 of the Code of Conduct.

The Committee agreed unanimously that the action taken by Biogen in submitting the complaint to Medicines Australia was not frivolous or vexatious.

Sanction
As no breach was found, no sanction was imposed.

Consideration of the Complaint
The Chairman opened the meeting with a summary of the complaint presented to the Committee for its adjudication. The Chairman explained that there were originally two parts to the complaint, which were described in the complaint submission as Complaint A and Complaint B. He noted that subsequent to the submission of the complaint, and after intercompany dialogue, Complaint B had been withdrawn by the complainant and therefore did not require consideration by the Committee.

The Chairman noted that Complaint A related to the use of two images, both of which were described by Biogen in its complaint as a “female making a ‘shh’ gesture”. These images are of two different women in two different depictions. The first is a close-up headshot of a woman, which was cropped to focus only on the lower portion of her face. In this image, the woman is smiling with closed lips and holding the index finger of her right hand to her lips. This image will be identified as Image 1 in this statement of the reasons for decision. The second image is of a woman aged approximately in her twenties, appearing in a social setting with three other individuals. The image is captured in a documentary style, with the other individuals in the image facing away from the camera, while the woman is facing the camera. As in the other image, the woman is smiling with her lips closed while holding the index finger of her left hand to her lips. This image will be identified as Image 2 in this statement of the reasons for decision.

Image 1 appeared on:
- two banners displayed at educational events for healthcare professionals
- an Information Guide for patients
- a Patient Support Program leaflet for patients

Image 2 appeared only in the Information Guide for patients.
The Chairman noted that Biogen had alleged that these images were making promotional claims about the product, Aubagio. Specifically, it was alleged that the images conveyed that a patient using the product will have an experience that is ‘quiet’ and ‘uneventful’, which had minimised the potentially serious side effects of the product. The Chairman noted that there is no allegation of lack of substantiation as to the effectiveness of the product; the complaint related primarily to the images being promotional and to possible claims about side effects.

The Chairman reminded the Committee that some of the material had been subject to a previous complaint (1138 – Aubagio and Lemtrada Advertisements; September 2016) considered by the Committee. Those materials utilised Image 1, but in that case the image was accompanied by certain claims in written form. One of the claims (“quietly”) had been found, in association with Image 1, to be in breach of the Code of Conduct as being false and misleading and unable to be substantiated. The Chairman noted that in complaint 1138, the image had been mentioned, but only in conjunction with the claims and not as a separate alleged breach of the Code. In finding a breach for one claim in complaint 1138, the Code Committee had required that Sanofi Genzyme withdraw the claim found in breach and to not use the claim again in the same or similar form in any future materials. The Chairman noted that, because of the form that complaint had taken, the sanctions imposed by the Committee had related to cessation of the use of a claim conveyed by the word “quietly”, and had not referred expressly to the imagery that accompanied it. The Chairman then recommended that the Committee consider a number of fundamental questions in its adjudication of this complaint:

1) whether the images could be regarded as conveying any representations;
2) if so, what the images conveyed in each context raised in the complaint;
3) whether the material for healthcare professionals breached the Code in the ways alleged; and
4) whether the material for consumers breached the Code in the ways alleged.

In considering these questions, the Committee determined that it appeared likely that an image on its own, even without any captions or written claims, could in some contexts convey representations that promoted a product, and that whether this was so would depend on both the image and the full context in which it appeared. The Committee noted that there are often widely different interpretations that may be taken from an image if it appears by itself.

As to the two images subject to complaint, the Committee agreed that the either image could be regarded as depicting a ‘shh’ gesture as alleged by Biogen in the complaint. However, the Committee also agreed that other interpretations relating to keeping a secret or the number one could be taken from the images. The Committee did not find that any interpretation relating to the side effects of Aubagio could reasonably be drawn from either image. The Committee agreed unanimously that the images were ambiguous in their meaning and did not convey anything specific about the product. In particular, a majority of the Committee was satisfied that no reasonable view of the images conveyed anything about side effects.

A minority of the Committee suggested that use of Image 1, even by itself, at approximately the same time as the distribution of the Aubagio materials subject to complaint 1138 might act as a reminder of the “quietly” claim in that material, and would therefore contribute to healthcare professionals recalling that claim. However, a majority of the Committee did not agree with this proposition.

The Committee specifically considered the use of the images within the materials intended for patients. The Committee did not consider that the inclusion of the images was making promotional claims about the product to patients. Rather, the Committee considered that the inclusion of the images was more likely to be, simply, to make the materials more visually appealing to patients or to make patients more comfortable with the materials they were reading. The Committee found that the materials were not in breach of Sections 13.7 or 17 of the Code.

The Committee agreed by unanimous decisions that image 1 and image 2 did not make promotional claims for Aubagio and therefore were not in breach of Sections 1.1, 1.3, 13.7 and 17 of the Code of Conduct.

The Committee then turned to consider Sanofi Genzyme’s allegation that the submission of this complaint was frivolous or vexatious. The Committee considered that overall the complaint was difficult to navigate and somewhat disorganised. The Committee felt this was underscored by the fact that intercompany dialogue did not appear to have been concluded before the complaint was submitted, noting that a substantial part of the complaint had been resolved between the companies only after the complaint had been submitted to Medicines Australia. Further, the Committee noted that Biogen had made an erroneous statement in its complaint, in alleging that the Aubagio Product Information states that the product has “serious adverse effects (AEs) such as hepatotoxicity and peripheral neuropathy, and has resulted in patient fatality…” The Committee agreed with Sanofi Genzyme that this was a misrepresentation of the data contained in the Product Information.
However, the Committee also noted that this complaint related to an image that had appeared in promotional material previously the subject of complaint 1138, as well as a second, similar image, and that these circumstances gave a reasonable basis to the argument made by the complainant. The Committee acknowledged that it was Biogen’s right to make the complaint in the manner in which it did. However, the Committee recommended that Biogen should in future focus on ensuring that a complaint had been fully explored through intercompany dialogue prior to submitting it.

The Committee agreed unanimously that the complaint was not frivolous or vexatious.

Sanction

As no breach was found, no sanction was imposed.
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 and printed promotional material) 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 2016-2017.

Educational Event Reports

In accordance with Section 31.2.2 of Edition 18 of the Code of Conduct, the Monitoring Committee has undertaken a review of educational events on an annual basis. Three months from the preceding 12 month reporting period were randomly selected, which represents a quarter of the dataset. The Monitoring Committee is then provided with those event reports in a de-identified format.

Review of Educational Events 2015-2016

For the 2015-2016 review, the final reports comprised six months of educational events, from 1 April to 30 September 2015. The Chairman selected at random the months of April and July 2015, representing a third of the reported events. The Monitoring Committee commenced its review in July 2016 with subsequent meetings held in August and September 2016 to review companies’ responses to any requests for further information. This review included close to 8,000 events from 37 companies. As a result of its review of the two months of events, the Monitoring Committee sought further information from 11 companies. The Monitoring Committee completed this review at the end of September 2016, with 1 event being referred to the Code of Conduct Committee for its adjudication (Complaint 1137). The outcome of this complaint is reported earlier in this report.
| Table 9: Summary of materials and activities reviewed by the Monitoring Committee 2012 – 2017 |
|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|
| Alimentary System | | | | |
| Cardiovascular System | | | | |
| Central Nervous System | | | | |
| Analgesia | | | | |
| Musculoskeletal System | | | | |
| Endocrine & Metabolic Disorders | | | | |
| Genitourinary System | | | | |
| Infections & Infestations | | | | |
| Neoplastic Disorders | | | | |
| Immunology | | | | |
| Respiratory System | | | | |
| Allergic Disorders | | | | |
| Ear, Nose & Oropharynx | | | | |
| Eye | | | | |
| Skin | | | | |
| Surgical Preparations | | | | |
| Contraceptive Agents | | | | |
| Reviews across all therapeutic classes | • Educational Event Reports | • Educational Event Reports | • Educational Event Reports | • Educational Event Reports | • Educational Event Reports |
| | • Corporate Websites | • HCO Reports | • HCO and Consultancy Reports | • HCO Reports | • Product Familiarisation Programs |
| | • Market Research | | • Medical Education for HCPs | | • Consent Forms |
| | • Media Releases (HCP) | | • Media releases to the general public | | • Market Research |
| | • CEP Audit | | | | • Hospitality Procedures |
| | • Starter Packs | | | | |
| | | | | • Educational Event Reports |
| | | | | • Advisory Board Reports |
| | | | | • Starter Packs |
| | | | | • HCP Websites |
Table 10: Summary of materials and activities reviewed by the Monitoring Committee in 2016 – 2017 (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>Analgesia</td>
<td>Advertisements, Printed Promotional Material and E-Ads</td>
<td>3</td>
<td>49</td>
<td>1</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Starter Packs Policies and Procedures</td>
<td>9</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>Healthcare Professional Websites</td>
<td>26</td>
<td>26</td>
<td>2</td>
</tr>
<tr>
<td>Alimentary</td>
<td>Advertisements in audiovisual, internet and eNewsletters</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Eye &amp; Ear, Nose and Throat</td>
<td>Journal Advertisements</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>All therapeutic classes</td>
<td>HCO Support Reports</td>
<td>29</td>
<td>368</td>
<td>3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>69</strong></td>
<td><strong>456</strong></td>
<td><strong>9</strong></td>
</tr>
</tbody>
</table>

Referrals to the Code of Conduct Committee

The Monitoring Committee may refer any material or activity to the Code of Conduct Committee for review if it considers there is a potential breach of the Code of Conduct. From its reviews of materials and activities in 2016-2017 the Monitoring Committee did not refer any materials or activities to the Code of Conduct Committee for adjudication.

As a result of its review of educational events in 2015-2016, one matter was referred to the Code of Conduct Committee for adjudication. This matter was heard in 2016-2017, and the outcomes are contained within this report.

Submissions to the Monitoring Committee

A key change to the activities of the Monitoring Committee under Edition 18 of the Code was the implementation of a limit on the number of submissions to the Committee each Member company is required to make in a calendar year. The Code of Conduct sets out that companies will only be required to provide promotional materials or information associated with other activities for review by the Monitoring Committee on no more than three occasions in a calendar year. This provision came into effect on 1 January 2016. By 30 June 2016, 18 companies had each made three submissions for the Committee’s review. Therefore, in the second half of calendar year 2017 fewer companies were required to make submissions to the Monitoring Committee. As at 30 June 2017, there were no companies that had made three submissions to the Monitoring Committee for its review.
Outcomes of the Monitoring Committee review of materials and activities from 2016-2017

Advertisements, Printed Promotional Materials and E-Ads

The Monitoring Committee reviewed advertisements and promotional material directed at healthcare professionals in the analgesic therapeutic classes that meet the requirements as described under Sections 2.1.1, 2.1.2, 2.4.1 and 2.4.3 of Edition 18 of the Code of Conduct.

Materials were provided by the following 3 companies for review:

- A.Menarini Australia
- Janssen
- CSL Limited

The Monitoring Committee made general comments to all respondents that the materials did not contain sufficient safety information. Particularly, the Committee found that due to the sensitive nature of the products in this therapeutic class, safety should be addressed more thoroughly in these materials. The Committee did, however, recognise that these materials included comprehensive information about alternative measures which support a more actively lifestyle and potential decrease medication use.

The Committee provided comments and feedback to CSL and A Menarini in relation to location of qualifiers and seeking greater specificity in dosing charts to provide clarity to the reader.

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

Starter Packs Policies and Procedures

The Monitoring Committee reviewed Member Company policies and procedures relating to the distribution of Starter Packs in all therapeutic classes. This review applied to all Member Companies, however only 9 companies were required to make a submission to this review. This is in line with the introduction in Edition 18 of the Code of Conduct clause 31.2.1 which requires that member companies will make a submission to the Monitoring Committee on no more than 3 occasions in the calendar year. At the time of this review by the Monitoring Committee, the majority of member companies had made three submissions and were therefore not included in the review.

Materials were provided by the following 9 companies for review:

- Actelion Pharmaceuticals
- Astellas Pharma
- Biogen Idec Australia
- Bristol-Myers Squibb
- CSL Limited
- Eisai Australia
- GlaxoSmithKline
- iNova Pharmaceuticals
- UCB Australia

The Monitoring Committee reviewed member company policies and procedures relating to the distribution of starter packs (also known as samples, or sample packs), and therefore submissions did not include all materials (such as request forms, etc) that is associated with the management of starter packs. The Monitoring Committee was pleased to note that a number of policies and procedure documents included references to the provision of Consumer Medicines Information documents (CMI).

The Monitoring Committee provided feedback to companies on ensuring policies contained sufficient detail as to reconciliation and recalls, and ensuring that this information is captured adequately in a policy document.

Following this review, the Monitoring Committee did not refer any matters to the Code of Conduct Committee.
Member Company Websites for Healthcare Professionals

The Monitoring Committee reviewed Member Company websites directed at Healthcare Professionals under Section 2.4.1 of the Code in all therapeutic classes.

Websites were provided by the following 26 companies for review:

- A.Menarini
- Actelion Pharmaceuticals
- Amgen Australia
- Astellas Pharma
- AstraZeneca
- Bayer Australia
- Biogen Idec Australia
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Celgene
- CSL Limited
- Eisai Australia
- Eli Lilly Australia
- GlaxoSmithKline Australia
- iNova Pharmaceuticals
- Janssen
- Merck Serono Australia
- Merck Sharp & Dohme Australia
- Norgine
- Novartis Pharmaceuticals
- Novo Nordisk Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis Australia
- Shire Australia
- Vifor Pharma

The Monitoring Committee did not make any general comments in relation to its review of member company websites directed at healthcare professionals. It did, however, provided feedback to nine companies on:

- Ensuring PBS boxes are included on sites, and contained correct information
- Ensuring that pop ups that advise readers they are being directed to external sites are present on all outlinks
- Australian Approved Names need to be on the most prominent representation of the logo
- The use of the statement “TGA Approved” should be amended to “TGA Registered” to ensure a reader is not given the impression that the site is approved by the TGA, only that the product is
- Ensuring that readers are directed to the Product Information before prescribing.

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

Advertisements in audiovisual media, the internet and eNewsletters

The Monitoring Committee reviewed advertisements for prescription medicines in the Alimentary therapeutic class which appear in audio-visual media, restricted access television, eNewsletters or on internet websites with access restricted to healthcare professionals through a password protection mechanism. The review relates to advertisements which were published in these electronic media in the period December 2016 to February 2017.

Materials were provided by Takeda Pharmaceuticals for review.

The Monitoring Committee provided feedback in relation to the hyperlinks used to access the product information and PBS information, the font used in the advertisement appeared to be in a narrow font, and currency of product information provided.

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

Journal Advertisements

The Monitoring Committee reviewed advertisements for prescription medicines in the Eye and ENT therapeutic classes which appear in journals directed at healthcare professionals. The review relates to advertisements which were published in healthcare professional journals in the period February to April 2017.

Materials were provided by Bayer Australia for review.

The Monitoring Committee provided feedback in relation to ensuring that claims are sufficiently substantiated, and that any broad claims are suitably qualified to enable the reader to easily interpret the claim.

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

The Monitoring Committee reviewed Member Company reports of support provided to Health Consumer Organisations (HCOs) including the monetary value of support provided. The reports covered activities commenced on or after 1 January 2016 or ongoing on that date through to 31 December 2016, which comprised 368 activities conducted by companies with HCOs during the period.

Reports published by the following 29 companies were reviewed:

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

In this review, the Committee noted that Section 14 of the Code requires that the objective of relationships with Health Consumer Organisations (HCOs) should be to enhance quality use of medicines and supporting better health outcomes for Australians. It was the Committee’s opinion that all the activities reported by member companies supported those objectives.

The Committee sought clarification from 13 companies as to:

- The appropriate report for some activities and whether some activities should be included in another report such as a third party educational meeting sponsorship.
- Understand the activity reported, and seek more detail as to the objectives and outputs to ensure compliance with the Code.
- Identify events that may have been duplicated in the report.

The Committee also commended 2 companies on the extensive detail included in their reports, which provided a clear understanding of activities and the company’s involvement. Overall, the Committee were pleased with the submissions made by member companies and thanked them for their comprehensiveness of these reports.