

# Monitoring Committee Reviews

*The Monitoring Committee proactively reviews selected promotional materials and activities on a regular and ongoing basis.*

During each reporting period the Monitoring Committee reviews:

- different types of promotional material - for example advertisements, printed promotional material, brand name reminders, across particular therapeutic classes - for example cardiovascular, respiratory and immunology;
- plus other activities across all therapeutic classes - for example websites, advertisements in prescribing software, educational events.

The therapeutic classes are derived from the Therapeutic Class Index used by MIMS Australia:

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

Member companies are required to provide copies of the requested promotional material/educational material or activity for the three month period under review. Each company must provide a signed verification statement confirming that all information requested has been identified and submitted to the Monitoring Committee.

In 2007/2008 the Monitoring Committee reviewed the following materials and activities:

- Company websites for the general public and patients (excluding corporate websites)
- Advertisements in prescribing software
- Invitations to educational meetings (this is in addition to the Educational Event Reports)
- Advertisements in the Central Nervous System therapeutic class
- Printed promotional material in the Neoplastic Disorders therapeutic class
- Educational Event Reports
- Competitions in the Cardiovascular therapeutic class
- Corporate websites

**Table B: Summary of materials and activities reviewed between 2003 & 2008**

	2003/2004	2004/2005	2005/2006	2006/2007	2007/2008
Alimentary System					
Cardiovascular System					
Central Nervous System	Reviewed 2002/2003				
Analgesia					
Muscular Skeletal System	Reviewed 2002/2003				
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	Invitations to Educational Meetings  Media releases  Brand Name Reminders  Competitions	Invitations to Educational Meetings  Market Research  Prescribing software	Invitations to Educational Meetings  Websites  Patient Education	Invitations to Educational Meetings  Patient Support Programs  Brand Name Reminders  Websites	Invitations to Educational Meetings  Patient Websites  Corporate Websites  Competitions  Prescribing Software  Educational Event Reports

For some therapeutic areas where no reviews have been conducted, the majority of products are not prescription medicines. Therefore the therapeutic areas may not be relevant to Medicines Australia member companies.

**Table C: Summary of materials and activities reviewed by the Monitoring Committee in 2007/2008.**

Therapeutic Class	Type of materials or activity subject to review	Number of companies	Number of items	Number of meetings to complete review
All therapeutic classes	Company websites available to the general public & patients*	26	103	1*
All therapeutic classes	Advertisements in prescribing software	10	25	1
All therapeutic classes	Invitations to educational meetings	32	683	2
Central Nervous System	Advertisements	7	36	1
Neoplastic Disorders	Printed Promotional Material	13	234	1
All therapeutic classes	Educational Event Reports	42	951	3
Cardiovascular System	Competitions	9	22	1
All therapeutic classes	Corporate websites	33	33	1
<b>TOTAL</b>			<b>2087</b>	<b>11</b>

\* Reviewed in 2006/2007 and finalised in 2007/2008 (1 meeting in 2006/2007 )

# Outcomes of the Monitoring Committee review of materials and activities

## Company websites for the general public and patients

The Committee reviewed 103 websites. The Committee did not review corporate websites at this meeting.

The websites reviewed were provided by the following companies:

- Actelion
- Alcon
- Allergan
- Altana
- Amgen
- AstraZeneca
- Bayer Schering
- Bristol Myers Squibb (BMS)
- CSL
- Eli Lilly Australia
- GlaxoSmithKline (GSK)
- Ipsen
- Lundbeck
- Merck Serono
- Merck Sharp & Dohme (Australia)
- Mundipharma
- Novartis
- Novo Nordisk
- Organon
- Sanofi Pasteur
- Smith & Nephew
- Pfizer
- Roche
- Solvay
- UCB Pharma
- Wyeth

The Monitoring Committee raised a number of general issues arising from the review of websites.

### General Issues

#### Company name and contact details

Members were of the view that a company controlled website should include the company name and contact details. Section 3.8.5 of the Code states that where a company website includes information about a product, the address and identity of the company should be provided.

#### Passwords

Members stated that a company should not use the product name as a password to access secure information. The purpose of a password is to provide a secure site and prohibit access by an unauthorised person. Passwords or other forms of secure access to healthcare professional only sites or patient support program sites may include the provider number for healthcare professionals; product bar code numbers; ARTG number or a password that would not be easily identifiable by a member of the general public.

#### Pack Shots

Members were of the view that a company should not include pack shots on a website accessible to the general public - this may be deemed advertising to the general public.

#### Code of Conduct Guidelines state:

Companies should not provide pack shots for publication/broadcast by the media. The TGA has previously provided advice to the Pharmacy Board of NSW that a brochure for consumers that includes pictorial representation of products is an advertisement.

*TGA - Price Information Code of Practice (Applies to S3, 4 and 8 medicines)*

Illustrations

Price information cannot be accompanied by, or located near, pictures, photographs or illustrations of any medicines to which this Code applies.

It is not permissible to include packs shots as this makes it an advertisement and advertising to the general public is prohibited.

Links to other sites

Members were of the view that links from disease state websites or patient support program websites should only be to reputable sites providing non-promotional education relevant to Australia. It was not appropriate to provide a link or series of links provided by a parent company where these may be to sites that advertise prescription medicines or make comparisons with other treatments. As the advertising of prescription medicines is prohibited in Australia a company should not attempt to circumvent the Code or Commonwealth law.

Consumer Medicine Information (CMI)

The Committee noted that many companies were not using the correct wording for a CMI - must always be referred to as Consumer Medicine Information.

Accessing patient information

A member raised a concern that a company was charging a \$50 fee for a patient to access personal information held by the company. Some members were of the view that a company should not charge a patient a fee - not a significant expense to a company but may be an imposition to a patient. Another member indicated that it is possible to charge a fee for the time taken to search for the data; however it is not permissible to charge for releasing this information.

Use of "find a clinic" or "find a healthcare professional"

Following a complaint in 2006, Medicines Australia consulted with the AMA on the use of lists of doctors' names or clinics on a company website. Both the Code of Conduct Committee and members of the AMA Therapeutics Committee were strongly of the view that this practice was not acceptable. Healthcare professionals were of the view that the list can be seen as an endorsement of a company or product. If a patient does not find their doctor's name of the list they may be misled into thinking that their doctor does not have an interest in the specialty area eg 'children's health' or 'men's health'. This may result in the patient presenting to an unknown doctor for treatment. It was the view of both the Code Committee and the AMA that it is acceptable for a company to include a link to an Australian College or Society which may include a list of doctors or clinics on their site. This link could only be provided with the express permission of that College or Society.

The Monitoring Committee sought further information from nine companies in relation to 12 websites. Following its review of company responses, the Monitoring Committee determined that no websites should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

## **Advertisements in prescribing software**

The Committee reviewed 23 advertisements and two items of patient education placed by member companies in prescribing software which was available to healthcare professionals in August 2007. The Committee did not review advertisements for information placed by non-member companies or for non-prescription medicines.

The advertisements were placed by:

- AstraZeneca
- Boehringer Ingelheim
- CSL
- GlaxoSmithKline
- Merck Sharp & Dohme (Australia)
- Merck Sharp & Dohme (Australia) & Schering Plough
- Novo Nordisk
- Pfizer
- Sanofi-aventis
- Servier Laboratories

The Committee noted that in three advertisements the generic name was difficult to read. Members were of the view that if companies wish to place advertisements in this small space the content must be legible.

The Committee was pleased to note that there were no advertisements for prescription medicines in the CMI section or with clinical tools which may be used with patients.

No advertisements were forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

## Invitations

Prior to the Australian Competition Tribunal decision in relation to the Medicines Australia appeal (in June 2007), the Monitoring Committee reviewed invitations to educational events held in one month in 2007. The decision on the month was at the discretion of the Monitoring Committee. This was an interim review prior to the reporting of educational events as set out by the ACCC in its final determination on authorisation of Edition 15 of the Code.

The Monitoring Committee reviewed 683 invitations for events in the month of February 2007. This review was conducted in September and October 2007.

Companies providing invitations:

- Abbott Australasia
- Actelion
- Alcon Laboratories
- Allergan
- Amgen
- AstraZeneca
- Bayer Schering
- Biogen Idec Australia
- Boehringer Ingelheim
- Bristol Myers Squibb (BMS)
- CSL
- Eli Lilly Australia
- Gilead
- GlaxoSmithKline (GSK)
- iNova
- Janssen Cilag
- Lundbeck
- Novartis
- Novo Nordisk
- Merck Serono
- Merck Sharp & Dohme (Australia)
- Mundipharma
- Nycomed
- Organon
- Pfizer
- Roche
- Sanofi-aventis
- Sanofi Pasteur
- Schering Plough
- Solvay
- UCB Pharma
- Wyeth

The Committee made a general observation that the general standard of invitations had improved with the majority of companies including a greater level of information about the educational component of the meeting.

Members noted that some companies were attributing Medicines Australia as prohibiting certain activities. Companies should not misrepresent company policy as a Medicines Australia policy. Activities that are prohibited under the Code of Conduct, for example payment for partners travelling with a healthcare professional who is attending an educational event, should be referenced to a statement such as *"In accordance with the Code of Conduct for the prescription medicines industry in Australia any costs (for example travel or meals) incurred by a partner/spouse travelling with a healthcare professional must not be paid for or subsidised by the company."*

Companies should review the educational component of a meeting which requires travel and accommodation costs to be met by the company to ensure that the education is the primary purpose of the event.

Having reviewed the invitations the Monitoring Committee requested further information from 12 companies. Having reviewed this additional information the Monitoring Committee forwarded one event to the Code of Conduct Committee for a determination on a potential

breach of the code. The outcomes of the Code of Conduct Committee's determination in relation to the Allergan Educational Event can be read at page 84 of this report.

### **Advertisements in the Central Nervous System therapeutic class**

The Committee reviewed advertisements from seven member companies covering 10 medicines in this therapeutic class - 36 advertisements.

Companies providing advertisements:

- AstraZeneca
- Eli Lilly Australia
- Janssen Cilag
- Pfizer Australia
- Solvay Pharmaceuticals
- UCB Pharma
- Wyeth Australia

The Committee raised a number of issues that should be considered by all companies when preparing promotional materials.

- The mandatory text must not be in a narrow font which makes the information difficult to read
- The PBS dispensed price should be current - if the price is changed, advertisements must be updated
- The Australian Approved Name must be included adjacent to the most prominent presentation of the brand name as set out in Section 3.1.1.3(b)
- Care should be taken when using referencing symbols which are very similar and in close proximity, making it difficult to identify them easily, for example †††<sup>‡</sup>

The Committee also advised companies that materials provided to the Committee must be in the original size, because a reduced size makes the content difficult to read.

The Committee sought feedback in relation to six advertisements. Following the review of company responses, the Committee determined that no advertisements should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

### **Printed promotional material in the Neoplastic Disorders therapeutic class**

The Committee reviewed 234 items of printed promotional material from 13 member companies.

Companies providing items of printed promotional material:

- Abbott Australasia
- AstraZeneca
- Bayer Australia
- Bristol Myers Squibb
- Eli Lilly Australia
- GlaxoSmithKline Australia
- Janssen Cilag
- Merck Sharp & Dohme (Australia)
- Novartis Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis
- Schering Plough

The Committee raised a number of issues that should be considered by all companies when preparing promotional materials.

- The Committee expressed concern that companies were making claims, often very significant claims, and then qualifying them with a statement that results "..... was not statistically significant"
- Similarly with graphs or tables evidently comparing products, which are qualified with a statement "....the studies are not head-to-head and therefore cannot be used to make a direct comparison". Members were of the view that this is misleading - if they can't be compared, don't use them!
- Members also noted that many tables and graphs did not include a p-value.

The Committee sought feedback in relation to materials from 3 companies (4 items). Following the review of company responses the determined that no items should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

### **Educational Event Reports**

The decision of the Australian Competition Tribunal requires the Monitoring Committee to conduct a review of the Educational Event Reports provided by the members at the end of each financial year (three months selected at random for the preceding 12 month period), the Board of Medicines Australia decided to proactively conduct a review of the July - December 2007 reports. Under the provisions of the Code the Monitoring Committee is empowered to request information concerning a particular event such as a copy of the invitation to the meeting and a copy of any printed material provided to attendees.

Where the Monitoring Committee considers that the conduct of the member company with regard to a meeting may breach the Code of Conduct, it can refer a report about the meeting and the member company's response to the Code of Conduct Committee which, after giving notice to the member company, may deal with it as though it were a complaint.

As set out on page 25 the Monitoring Committee reviewed 951 educational events. The Committee requested further information in relation to 312 events. Having reviewed the additional information the Monitoring Committee referred 52 events to the Code of Conduct Committee for a determination on potential breaches of the Code of Conduct. The outcomes of these events can be viewed on pages 31 - 36 of this report.

In considering the events before them, the Monitoring Committee provided the following commentary.

The Medicines Australia Monitoring Committee, which includes healthcare professionals, consumer and industry representatives, reviewed all educational events that had been identified by the independent auditors (Deloitte) using forensic accounting and statistical techniques.

#### Role of the Monitoring Committee

The role of the Monitoring Committee was to identify any potential breaches of the code. The Monitoring Committee was empowered to request further information in relation to any event and, if not satisfied with the company's response, to forward the event to the Code of Conduct Committee for adjudication.

#### Review Process

The Monitoring Committee met three times during March 2008 to review the events identified by the auditor. After the first of these three meetings the Monitoring Committee asked the auditor to provide a further subset of events. The Monitoring Committee reviewed 951 events in total, which is approximately 6% of the total dataset of 14,633 events.

During the Monitoring Committee's review, it soon became clear that the level of detail provided by companies varied considerably, although it complied with the requirements stipulated by the Australian Competition Tribunal. In order to undertake the review of events, the Monitoring Committee requested further details from companies. There were 312 events for which further information was requested and provided by companies

#### Analysis of Data

Assessed initially on the cost of hospitality (meal costs, travel and accommodation); and the quality and duration of medical education provided in proportion to the level of hospitality provided

Where companies appeared to provide excessive hospitality in proportion to the education provided, these events were referred back to companies to provide reasons as to why the event should not be referred to the Medicines Australia Code of Conduct Committee.

Upon reviewing the responses from companies, it was clear that many system, human and IT errors had been made in compiling the event reports as companies tried to combine data sets that had not been designed for this purpose. Following review of the further information and explanation provided by companies, the majority of events appeared to comply with the Code once the corrected expenditure and number of confirmed attendees was examined. Most companies noted that they had reviewed or were reviewing their data collection processes in order to make sure similar errors do not occur in the future.

#### Cost Guidance

The Committee agreed that all service fees should be considered as part of the cost of provision of hospitality, but all taxes such as GST or taxes imposed in other countries should be disregarded.

#### Education Component

Where accommodation was required, the Monitoring Committee suggested:

- minimum of 8 hours education (education session times only) was generally necessary to justify 2 nights of accommodation, but if delegates need to travel from remote locations this should also be considered;
- minimum of 5 hours education (education session times only) was generally necessary to justify 1 night of accommodation; and
- 4 hours education was generally insufficient to justify any overnight accommodation unless the attendee was from rural/remote region or interstate.

#### Venue Selection

The location for providing education was also discussed by the Monitoring Committee. Members generally considered that location was irrelevant unless the rationale for choice of location was not immediately obvious, based on the attendees' origin and/or the specific conference facilities.

In a majority decision the Monitoring Committee referred the event to the Code Committee on the rationale that the significant majority of attendees had been provided travel from capital cities both near and distant and it was considered that the popular holiday location was not adequately justified in preference to a capital city location. The same holiday location had been considered acceptable for a regional meeting for Queensland HCPs.

The Monitoring Committee referred 52 educational events to the Code of Conduct Committee for deliberations. The outcomes of the Code of Conduct and Appeals Committees are summarised on pages 31 - 36 of the Report.

### **Competitions in the Cardiovascular therapeutic class**

The Committee reviewed 22 competitions from nine member companies.

Companies conducting competitions:

- AstraZeneca
- Bayer Schering
- Boehringer Ingelheim
- CSL
- Merck Sharp & Dohme (Australia) & Schering Plough
- Pfizer
- Sanofi-aventis
- Servier
- Solvay

The Committee noted a number of general issues in relation to the review of competitions.

#### Privacy Guidelines

Members noted that some competitions did not include a privacy statement and those that did varied in the manner in which the statement was made. The Committee was of the view that whenever a pharmaceutical company is collecting information from a healthcare professional, a privacy statement on how that data may be used should be a mandatory inclusion. This information, with possible examples should be included in the Code Guidelines.

#### Competition/Printed Promotional Material

Members discussed “when does a competition become a piece of printed promotional material”. The Committee was of the view that where promotional claims are made in a competition the mandatory requirements for printed promotional material should also apply. That is, the inclusion of the Minimum Product Information and PBS disclosure information.

#### Competition Results

One member of the Committee questioned whether companies should provide the winning entries to ensure that the ‘Terms & Conditions’ of the competition had been fulfilled. This matter should be referred to the Code Review Panel for further guidance.

#### Market research and request for starter packs

The Committee was concerned that some companies had not heeded the advice from the previous review of competitions. Market research, surveys or requests for starter packs should not be confused with competitions.

Members were of the view that surveys and competitions should be kept quite separate, that is, not on the same page; and that competitions should not ask the healthcare professional whether they want samples of a product or which products they prescribe. Any request for starter packs should not be linked to entry to a competition.

#### Distribution of competition prizes

The Committee re-iterated the view that receipt of a competition prize must not be dependent on making an appointment with a company representative (page 22 Code Guidelines). Members noted that a few competitions offered this as an option for delivery. A representative may deliver a competition prize, that is, leave the prize at reception.

#### Level of difficulty of questions

Members of the Committee commented that there had been an improvement in the level of difficulty of the questions and hoped that this level would be maintained or exceeded.

#### Competition Prizes

The Committee did not raise any issues in relation to prizes being offered in the competitions reviewed.

The Committee requested a response from two companies in relation to two competitions. At the time of publication this information has not yet been reviewed by the Monitoring Committee. A final report will be included in the 2008/2009 Code Annual Report.

### **Australian Corporate Websites**

The Committee reviewed 33 member company websites. Four of these companies did not have an Australian website.

Company websites reviewed:

- Abbott Australasia
- Actelion
- Alcon Laboratories
- Allergan
- Amgen
- AstraZeneca
- Baxter
- Bayer
- Biogen Idec Australia
- Boehringer Ingelheim
- Bristol Myers Squibb
- Celgene
- CSL
- Eli Lilly Australia
- Genzyme
- Gilead
- GlaxoSmithKline
- Ipsen
- Janssen Cilag
- Lundbeck
- Merck Serono
- Merck Sharp & Dohme (Australia)
- Mundipharma
- Novartis
- Novo Nordisk
- Nycomed
- Pfizer
- Roche

- Sanofi-aventis
- Schering Plough
- Servier
- Solvay
- Wyeth

The Committee made a number of general comments in relation to company corporate websites.

#### Use of disclaimers when leaving an Australian company site

The Committee noted that there were numerous versions of the recommended disclaimer as set out in Section 9.6.4 of the Code.

Reference or linkages to other reputable information sources that provide valuable educational information that would enhance a member of the general public's understanding of a disease area. When making such a reference or linkage a clear screen displaying the following statements must appear before the information can be accessed:

- *that the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should refer to the CMI for products to fully understand the terms of a product's registration in Australia;*
- *that the intent of providing this material is informational and not as advice; and*
- *any information provided by this source should be discussed with the reader's healthcare professional and does not replace their advice.*

Members were of the view that a statement to the effect "*This website may not comply with the Medicines Australia Code of Conduct*" is not appropriate.

Where a linkage is made to a third party site, whether through a list or within the text, it must be clear that the reader is leaving the Australian company site.

#### Links to global homepages or sections of a global website

Members were of the view that it is acceptable to provide a link to a global company home page; however an Australian company must not provide a link to a specific section of a global site that may include advertising or promotional information. Similarly a company may include a link from the Australian news or media release page to the global news page, however companies must not include a link from the Australian news page to a specific media release or news item on the global page that makes reference to a non-approved product or indication.

#### Pack Shots

The Committee reiterated the view that a company must not include pack shots of their medicines on their website. A company may include a list of their products available in Australia plus a brief statement of the indications or a link to the CMI.

#### Consumer Medicine Information

The Committee recommended that where a company has a list of products and links to the CMI, there should be a statement explaining what a CMI is. The Committee noted that the correct term is 'Consumer Medicine Information'. Members were of the view that companies should refrain from using other terms as all stakeholders are trying to encourage awareness of CMIs.

The Committee requested further information in relation to two websites. At the time of publication this information has not yet been reviewed by the Monitoring Committee. A final report will be included in the 2008/2009 Code Annual Report.