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REVIEW OF MATERIALS BY THE MONITORING COMMITTEE

Overview

During each reporting period the Monitoring Committee will review three types of promotional material (For example: advertisements, printed promotional material, brand name reminders) across three different therapeutic classes (For example: cardiovascular, respiratory and immunology); and three different promotional activities covered by the Code across all therapeutic classes.

The review of promotional material will be according to the Therapeutic Class Index:

- 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
- Contraceptive Agents

The Monitoring Committee may also review materials or activities across all therapeutic classes in any review.

Member companies are required to submit to the Monitoring Committee copies of the selected type of promotional material used during the three-month period under review. For example, the Monitoring Committee may review journal advertisements in the cardiovascular therapeutic class in one review, items of printed promotional material in the analgesia therapeutic class in the second review and brand name reminders across all therapeutic classes in the next review.

Table 13 provides a summary of materials reviewed between 2002 and 2007 and Table 14 provides a summary of the materials reviewed by the Monitoring Committee in 2006/2007.

Table 13: Summary of the Monitoring Committee Review of Materials 2002- 2007

Therapeutic Area	Year				
	2002/2003	2003/2004	2004/2005	2005/2006	2006/2007
Alimentary System		■		■	
Cardiovascular System			■		
Central Nervous System	■				
Analgesia					■
Muscular Skeletal System	■				
Endocrine and Metabolic Disorders					■
Genitourinary System		■			
Infections and Infestations				■	
Neoplastic Disorders					
Immunology				■	
Respiratory System		■			
Allergic Disorders					
Ear, Nose and Oropharynx					
Eye					
Skin		■			■
Contraceptive Agents					■
Review across all therapeutic classes*	Company Websites	Educational Meetings Press Releases Competitions	Educational Meetings Market Research Prescribing Software	Educational Meetings Websites Patient Education	Patient Support Programs Educational Meetings Brand Name Reminders Websites

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

Outcomes of the Monitoring Committee Review of Materials

In the 2006/2007 reporting period the Monitoring Committee held 12 meetings and reviewed a total of 2723 items.

The Committee reviewed materials in the Analgesia; Endocrine and Metabolic Disorders; Contraceptive Agents; and Skin therapeutic classes. In addition the Committee reviewed invitations to educational meetings, patient support programs, brand name reminders and websites (which will be finalised in the 2007/2008 reporting period) across all therapeutic classes.

Table 14: Summary of the materials reviewed by the Monitoring Committee in 2006/2007

Therapeutic Class	Type of materials subject to review	Number of Companies	Number of Items	Number of meetings to complete review
Infections and Infestations	Advertisements	2	14	1*
Analgesics	Advertisements	6	62	1
All therapeutic classes	Invitations to company sponsored educational meetings	28	2128	4
All therapeutic classes	Patient Support Programs	20	48	2
Endocrine and Metabolic Disorders	Advertisements - specifically insulin preparations and hypoglycaemic agents	4	80	1
Contraceptive Agents	Printed promotional material	2	32	1
Skin	Advertisements	4	17	1
All therapeutic classes	Brand Name Reminders	15	239	1
All therapeutic classes	Websites	26	103	1†
			2723	13

* Reviewed in 2005/2006 and finalised in 2006/2007

† One meeting held in 2006/2007 with second meeting in 2007/2008

Outcomes of the Monitoring Committee Review of Materials

Patient Support Programs (across all therapeutic classes)

Over two meetings the Monitoring Committee reviewed 48 patient support programs undertaken by 20 different member companies. Overall members of the Committee were impressed by the array of quality materials available to patients. The Committee requested further information in relation to seven company programs. Following responses from the companies concerned the Committee did not forward any matters to the Code of Conduct Committee.

The Committee advised that where “patient testimonials” or “patient stories” are used it should be stated whether these are “real” patients or actors. If actual patients the company should ensure that consent was obtained for their names, photos and information to be used.

Members recommended that information going to healthcare professionals and recipients of the patient support materials should clearly state the length of time that the program will last.

The Committee also commented that references used in patient materials should be easily accessible to patients or include a statement to the effect that they are available from the company and include a telephone number or email address.

The Committee was of the view that information available to the general public should always recommend that the patient also “Talk to your doctor”.

Websites (across all therapeutic classes)

The Monitoring Committee was of the view that a company should not use the product name as the password for a site restricted to healthcare professionals as this would probably be the first word a member of the general public would use to try and gain access to the restricted site.

The Committee noted that a few companies made available a list of doctors’ names on a company website. Members were advised that after discussion at a Code of Conduct Committee meeting which considered a complaint in which one aspect was the provisions of doctor’s names on a company website the Code of Conduct Committee asked Medicines Australia to meet with the AMA Therapeutics Committee to discuss this issue.

The members of the AMA Therapeutics Committee were of the view that companies should not include lists of doctors’ names on their website or a search tool for doctors or clinics on a company website. Should a third party, for example a College or Society, have a list of clinics or doctors on their website and formally agree to the company providing a link from the company website to the College of Society website this would be acceptable. Medicines Australia has written to all companies to provide this advice.

The review of websites will be finalised in July 2007.

Advertisements for Infections and Infestations, Analgesia, Endocrine and Metabolic Disorders, and Skin Therapeutic Classes

Over four meetings the Monitoring Committee reviewed 173 advertisements placed by 17 member companies. The Monitoring Committee requested further information from nine companies. Following responses from the companies concerned the Committee did not forward any matters to the Code of Conduct Committee.

The Committee requested that in future all advertisements should be submitted in the original size to enable assessment of compliance with letter size requirements for specific aspects of an advertisement and to ensure readability by members.

Members were of the view that there should be a consistent system of referencing within an advertisement which was not always the case.

The Committee discussed whether 'teaser' advertisements should refer to the Product Information as this links the advertisement to a product which includes a claim. The Committee was of the view that this matter should be considered by the Code Review Panel when the Code is next revised.

The Committee was of the view that any advertisement in a reference manual for a product which has a Boxed Warning should make reference to the Boxed Warning within the body of the advertisement. For example *"Before prescribing, please review Product Information, Boxed Warning and PBS Information in Section 6(e)."*

Members also questioned the use of the acronyms in promotional materials and whether all the terms are regularly used and understood by general practitioners. Some members were of the view that in the interest of quality education it would be better if all acronyms were spelt out in full or at least used in full on the first occasion and subsequently by the acronym.

Educational Meetings (across all therapeutic classes)

The Monitoring Committee reviewed 2128 invitations to educational meetings from 28 member companies at four Committee meetings. The Committee commented that the design and the level of information on the educational component of the meeting had improved since the previous review and also noted that most companies had a template which medical representatives must use when providing invitations for educational meetings to healthcare professionals.

While not a breach of the Code members noted that some invitations to educational meetings did not include a level of information on the educational component of the meeting that would allow the reader to be assured of the duration of the presentations, information on the speakers and an approximate finish time for the event.

The Monitoring Committee was also of the view that it is good policy to include the name of the sponsoring company and some form of contact details on an invitation.

The Committee requested further information in relation to 27 invitations to educational meetings with 17 requests relating to venue selection, hospitality or entertainment and 10 invitations where the Committee sought further

information on the program or agenda. Following responses from the companies concerned the Committee did not forward any matters to the Code of Conduct Committee.

The following cases detail aspects that raised concern in relation to venue selection, hospitality or entertainment.

Meeting 1

Members commented that the invitation to the meeting “A New Approach to Persistent Non-Cancer Pain” at the Pettavel Winery and Restaurant included good reference to the educational component of the meeting but the Committee expressed some concern over the choice of a winery as a venue and sought clarification from the company on this matter.

The company responded that the reason for selecting this venue was its geographic convenience for the doctors from surrounding towns. The venue is the only facility within the area that caters to the numbers which had been invited (30) and that has a private room to ensure members of the general public would not be exposed to any component of the educational presentation. The cost was \$80 per head and there was no wine tasting component to the evening.

Having reviewed the response from the company the Monitoring Committee agreed not to refer this matter to the Code of Conduct Committee.

Meeting 2

Members commented that the invitation to the “3rd Haemostasis Update” weekend was an example of a weekend meeting with quality education over the two days. Members noted that the invitation referred to wine tasting with the case presentations and sought clarification from the company on this matter.

The company responded that the session was entirely clinical and did not include any formal wine tasting course or lectures nor was there any specific presentation from the winery. What occurred was that 3 different wines were available and offered during the clinical case sessions. The arrangement allowed them to combine a rather intensive clinical case series (7 in total) with what would normally be classed as pre-dinner drinks and so extended the educational component of the meeting. The cost was \$12 per head.

Having reviewed the response from the company the Monitoring Committee agreed not to refer this matter to the Code of Conduct Committee.

Meeting 3

Members commented on the invitation to the meeting “Understanding Complicated Cardiovascular Disease” at the Palazzo Versace Hotel and expressed some concern over the choice of venue and sought clarification from the company on this matter.

The company responded that the event was held on a Thursday evening and no overnight accommodation for any healthcare professional was provided. The hospitality was \$74.52 for 42 confirmed attendees. The educational event comprised peer oriented clinical case discussions led by a cardiologist for 1.5 hours followed by a 30 minute presentation and discussion of the ACTION Trial.

Having reviewed the response from the company the Monitoring Committee agreed not to refer this matter to the Code of Conduct Committee.

Meeting 4

Members commented on the invitation to the meeting “Vytorin Get the Latest News” which was held at Jupiters Casino and expressed some concern over the choice of venue and sought clarification from the company on this matter.

The company responded that Jupiters Casino was chosen as a suitable site for the Vytorin dinner primarily because a RACGP meeting was being held immediately prior to the Vytorin dinner allowing doctors to attend both events easily. In addition the availability of secure parking on site and facilities for electronic presentations in a private room made the venue suitable for educational events. Jupiters was not chosen for its entertainment purposes, rather for its superior package deal for venue hire in comparison to other venues. The company confirmed that no entertainment or accommodation was provided at the meeting.

Having reviewed the response from the company the Monitoring Committee agreed not to refer this matter to the Code of Conduct Committee.

Meetings 5 - 12

Members commented on a number of invitations to educational meetings and expressed some concern over the choice of venues and sought clarification from the company on these matters and whether wine tasting or information on available wines was provided to attendees.

- Dead reckoning, Demystifying the Forensic Autopsy – Sheraton Noosa
- Anxiety & Depression in Adolescence, Exploring the Mindset – Concord Golf Club
- Anxiety in General Practice: A Problem Focused Approach – Palandri Winery
- Real Life Management Strategies for Anxiety Disorders – Perugino
- Treatment & Management of Peri & Postnatal Depression – Bacash
- Substance Abuse, Mental Disorders & Violent Offending – Pettavel Winery and Restaurant
- Assessment & Management of Anxiety Disorder: A Practical Approach to General Practice Dealing with Challenging Psychiatric Problems in General Practice – Chesser Cellars
- Disorders of Passion: Jealousy & Violence – Henry Jones Art Hotel

The company responded that there was no wine tasting or entertainment provided and at each venue a private function room was used.

Having reviewed the response from the company the Monitoring Committee agreed not to refer this matter to the Code of Conduct Committee.

Meetings 13 – 16

Members commented on a number of invitations to educational meetings and expressed some concern over the choice of venue and sought clarification from the company on this matter and whether wine tasting or information on available wines was provided to attendees.

- Auge (50 attendees)
- Assagio (70 attendees)
- Magill Estate (80 attendees)
- Fremantle Golf Club (50 attendees)

The company responded that there was difficulty in finding a suitable venue in Western and South Australia to accommodate the number of doctors that attend their educational programs. The venues were chosen as they were within appropriate costs, \$80-\$100 per head, and provided private rooms away from the public. Wine was supplied with meals in accordance with cost constraints; however no wine tasting or further information about wines were available to attendees.

Having reviewed the response from the company the Monitoring Committee agreed not to refer this matter to the Code of Conduct Committee.

Invitation 17

Members commented on the invitation to the educational meeting “ACD 2006 Melbourne” and expressed some concern that the invitation made reference to wine tasting and sought clarification from the company on this matter.

The company responded that the wine tasting was clearly outlined as being secondary to the educational event and optional for all attendees. A broad selection of wines was supplied for attendees who preferred to drink wine with dinner.

Having reviewed the response from the company the Monitoring Committee agreed not to refer this matter to the Code of Conduct Committee.

CPD Points

The RACGP representative suggested that Medicines Australia meet with the College to discuss the level of information required when submitting an application for CPD points to determine if collaboration on this matter would be suitable. Medicines Australia has held one meeting with RACGP approved education providers to discuss this issue. Additional meetings will be held in the second half of 2007.

Printed Promotional Material (Contraceptive Agents Therapeutic Class)

Over one meeting the Monitoring Committee reviewed 32 items from four member companies. The Monitoring Committee requested further information in relation to seven items. Following responses from the companies concerned the Committee did not refer any matters to the Code of Conduct Committee.

Brand Name Reminders (across all therapeutic classes)

The Monitoring Committee reviewed 239 brand name reminders at one meeting. The Monitoring Committee requested further information in relation to 17 items. Following responses from the companies concerned the Committee did not refer any matters to the Code of Conduct Committee.

The Committee raised the following general issues.

Use of the company name and/or contact details on a Brand Name Reminder

The Committee debated whether it was permissible to include a company name and contact details (such as a website address) on a Brand Name Reminder. Members of the Code Secretariat advised that during discussions at the Code Review Panel meetings a deliberate decision had been made to limit what could be included on a Brand Name Reminder. This decision followed general debate and a Code complaint relating to advertising in prescribing software which alleged this was advertising to the general public. Following the review of Edition 14, Edition 15 specifically removed any reference to therapeutic category or indication.

The Monitoring Committee's consensus view was that as the provisions do not include any reference to the use of a company name and/or contact details these should not be included. The Committee asked the Code Secretariat to refer this matter to the Code of Conduct Committee for their comments and also to the next Code Review Panel.

Inclusion of product strength on a Brand Name Reminder

The Committee also referred this matter to the Code of Conduct Committee for their comments and also to the next Code Review Panel.

Use of confectionary as a Brand Name Reminder

Some members of the Committee considered that confectionary should not be placed in packaging which in any way resembles or is similar to the medicine packaging, such as for use as a Brand Name reminder where the packaging includes a medicine brand name. If confectionary is used it should be in clear jars or containers that could not be confused with medicine packaging and particularly not in packaging of similar colour and design to the actual medicine.