MEDICINES Australia

CODE OF CONDUCT

ANNUAL REPORT 2015-2016

REPORT ON THE ACTIVITIES OF THE MONITORING COMMITTEE

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Monitoring Committee Report

The aims of the Monitoring Committee are to encourage compliance with the Code, provide advice on compliance where necessary, obtain and publish statistical data on the degree of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code.

The Monitoring Committee may review materials across a range of therapeutic areas and types of activities. If the Committee has concerns about an activity or material, or wishes to seek further information, Committee members must direct the Secretariat to write to the company identifying the issues of concern and what additional information should be provided to the Committee. After the review of this additional information, if the Committee still has significant concerns, a formal complaint may be lodged with the Code Committee for a determination. The Monitoring Committee cannot find a company in breach of the Code.

The therapeutic classes for the Monitoring Committee reviews are derived from the Therapeutic Class Index used by MIMS Australia:

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

In each financial year the Monitoring Committee reviews at least three types of promotional material (for example advertisements, printed promotional material, brand name reminders) across three different therapeutic classes (for example alimentary system, eye and contraceptive agents); and three different types of conduct covered by the Code across all therapeutic classes (for example websites, media releases and starter packs). This is in addition to the Committee's review of educational event reports.

Table 9 provides a summary of the Monitoring Committee reviews of materials and activities over the past five years. Table 10 provides a snapshot of the materials and activities reviewed by the Monitoring Committee in 2015-2016.

Educational Event Reports

Educational Event Reports for the period April 2015 – September 2015 were published on 18 December 2015. Individual Member Company reports can be accessed on the Medicines Australia website.

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

Review of Educational Events 2014-2015

For the 2014-2015 review, the Chairman selected at random the months of June 2014, August 2014 and November 2014. The Monitoring Committee commenced its review in July 2015 with subsequent meetings held in August and September 2015 to review responses from companies to any requests for further information. This review included close to 8,000 events from 36 companies. As a result of its review of the three months of events, the Monitoring Committee sought further information from 14 companies. The Monitoring Committee completed this review at the end of September 2015, with 4 events being referred to the Code of Conduct Committee for its adjudication (Complaints 1130-1134). The outcomes of these complaints are reported earlier in this report.

	Table 9: Summary of materials and activities reviewed by the Monitoring Committee 2011 – 2016				
	2011-2012	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**
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	Patient Education and Patient Support Programs Company websites for healthcare professionals Disease Education Activities Product Specific media releases in the lay press	Educational Event Reports Corporate Websites Market Research Media Releases (HCP) CEP Audit Starter Packs	Educational Event Reports HCO Support Reports	Educational Event Reports HCO Support and HCP Consultancy Reports Medical Education for HCPs Media releases to the general public	Educational Event Reports HCO Support Reports Product Familiarisation Program Consent Forms Market Research for HCPs Procedures for providing Hospitality at educational events

Table 10: Summary of materials and activities reviewed by the Monitoring Committee in 2015-2016 (excluding Educational Event Reports)				
Therapeutic Class	**Types of material or activity subject to review**	**Number of companies**	**Number of items**	**Number of meetings to undertake review**
Genitourinary & Contraceptive classes	Websites for the general public	4	6	1
All therapeutic classes	Product Familiarisation Program Consent Forms	5	5	1
Endocrine & Metabolic Disorders therapeutic class	Patient Support Materials	18	134	2
All therapeutic classes	Market Research with HCPs	31	31	1
All therapeutic classes	Hospitality Procedures	36	36	1
All therapeutic classes	HCO Support Reports	33	411	1
TOTAL		**127**	**623**	**7**

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 2015-2016 the Monitoring Committee did not refer any materials or activities to the Code of Conduct Committee for adjudication.

Submissions to the Monitoring Committee

A key change to the activities of the Monitoring Committee made in Edition 18 of the Code was the implementation of a limit on the number of submissions each 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, and to 30 June 2016 18 companies had reached this milestone.

Outcomes of the Monitoring Committee review of materials and activities from 2015-2016

Company Websites

The Monitoring Committee reviewed all Member Company websites available to the general public in the Genitourinary System and Contraceptive Agents therapeutic classes that meet the requirements as described under Section 13.9 of Edition 18 of the Code of Conduct. There were 6 websites submitted to the Committee.

Materials were provided by the following 4 companies for review:

- Bayer Australia
- Merck Sharp and Dohme (Australia)
- Novo Nordisk Pharmaceuticals
- Pfizer Australia

The Monitoring Committee did not identify any general issues in relation to the reviewed websites, but commended companies on providing relevant and valuable information in a clear and concise manner.

The Monitoring Committee provided comments and feedback to Bayer, Merck Sharp and Dohme (Australia), and Pfizer in relation to their websites. The matters raised with the individual companies included

- Recommending the inclusion of references or links to mental health services in conjunction with the information contained on the site

- Ensuring that statements were adequately referenced, and the location of those references were easily identifiable
- Ensuring that content on the site is up to date

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

Product Familiarisation Programs

The Monitoring Committee reviewed consent forms used in Product Familiarisation Programs in any therapeutic class that were active during July to September 2015.

Materials were provided by the following 5 companies for review:

- Alcon Laboratories
- Celgene
- Novartis Pharmaceuticals
- Pfizer Australia
- Sanofi-aventis Australia

The Monitoring Committee reviewed consent forms associated with Product Familiarisation Programs, and therefore submissions did not include all materials provided by companies in association with these programs. The Committee, however, agreed that there were a number of items that should appear on a patient consent for these programs should include reference to:

- receipt of the program materials
- confirmation that the program and product have been discussed with the patient
- receipt of a CMI for the product
- the length of the program
- the cost and/or availability of product at the expiry of the program should PBS reimbursement not be achieved. The Committee agreed that the inclusion of an end-date for the program is not sufficient information for patients to make an informed decision, and that the inclusion of a statement that the product may only be available on private prescription at the cessation of the program would be clearer.

The Monitoring Committee provided feedback to four companies regarding:

- ensuring consistency of terminology used in referring to medical professionals
- ensuring clarity of ensuring that forms are not returned to the company, but retained by the healthcare professional

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

Patient Support Materials

The Monitoring Committee reviewed Patient Support Materials under Section 13.7 of the Code in the Endocrine and Metabolic Disorders therapeutic class in use during the period October to December 2015. This review was conducted over two meetings with 134 items submitted for review.

Materials were provided by the following 18 companies for review:

- AbbVie
- Amgen Australia
- AstraZeneca
- Bayer Australia
- Besins Healthcare Australia
- Boehringer Ingelheim
- Eli Lilly Australia
- Genzyme Australasia
- Merck Serono Australia
- Ipsen
- Merck Sharp & Dohme Australia
- Novartis Pharmaceuticals
- Novo Nordisk Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis Australia
- Shire Australia
- Vifor Pharma

The Monitoring Committee commended those companies who included a reference to the Consumer Medicines Information leaflet in their materials. While the Monitoring Committee agreed that it was not required in the Code, they were of the opinion that it is best practice to do so.

The Monitoring Committee provided feedback to five companies regarding:

- Following the review of the list of items provided in the patient support program as detailed in the enrolment pack, the Committee queried the types of items and their relevance to the program and the disease state.
- Ensuring that the terminology when referencing healthcare professionals is clear and consistent throughout the information provided.
- Ensuring that the Australian Approved Name of any product is included at the most prominent presentation of the name.

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

Market Research

The Monitoring Committee reviewed 31 items of market research with Healthcare Professionals in all therapeutic classes in use during the period July to December 2015. Companies were asked to submit their most recent market research activity conducted during the specified period, meaning only one research activity was reviewed per company.

Materials were provided by the following 31 companies for review:

- A.Menarini Australia
- AbbVie
- Actelion Pharmaceuticals
- Amgen Australia
- Astellas Pharma Australia
- AstraZeneca
- Bayer Australia
- Besins Healthcare Australia
- Biogen Australia
- Boehringer Ingelheim
- Bristol-Myers Squibb Australia
- Celgene
- Eli Lilly Australia
- Genzyme Australasia
- Gilead Sciences
- GlaxoSmithKline Australia
- iNova Pharmaceuticals
- Ipsen
- Janssen
- Merck Sharp & Dohme Australia
- Norgine
- Novartis Pharmaceuticals
- Novo Nordisk Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis Australia
- Servier Laboratories Australia
- Shire Australia
- Takeda Pharmaceuticals Australia
- UCB Australia
- Vifor Pharma

The Monitoring Committee noted that market research were permitted under the Code and that they were able to assess healthcare professional's beliefs, opinions and knowledge about products while casting a wide ranging net on those topics. The Committee noted that promotion of products was strictly prohibited and that the information must be relevant and enhance the quality use of medicines.

The Monitoring Committee sought clarification from 5 companies relating to the following:

- Explanation of remuneration provided to participants engaged for the activity
- Understanding the rationale for the activity and the way it was conducted
- Ensuring that Australian Privacy statements were included when market research was conducted as part of a global research activity.

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

Company Procedures for providing Hospitality at educational events

The Monitoring Committee reviewed companies' procedures for providing hospitality at educational meetings and symposia under Sections 9.3, 9.4.3 and 9.7.7, which include both Australian and international educational events.

Materials were provided by the following 36 companies for review:

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

The Monitoring Committee sought member companies to provide a response that outlined; a description of the policies and procedures in place; training; identification of appropriate venues; process for initiation and approval; and monitoring compliance. It was noted that many companies provided detail in their procedures that specified a different level for different types of hospitality – such as a lower limit for breakfast, lunch, and specifying when the $120 cap would be appropriate. While the Code does not mandate this, the Committee recommends it would be best practice for companies to consider implementing similar ranges in their own policies.

The Committee sought clarification from 5 companies on the following:

- Ensuring that policies were relevant to an Australian market, rather than a straight implementation of global policies
- Queried training provided to employees by companies, and details of international event policies
- Commendation to companies who included flow charts or screen shots of approval systems

Following this review, the Monitoring Committee did not refer any matters 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 2015 or ongoing on that date through to 31 December 2015, which comprised 411 activities conducted by companies with HCOs during the period.

Reports submitted by the following 33 companies were reviewed:

- A.Menarini
- AbbVie
- Actelion Pharmaceuticals
- Alcon Laboratories
- Amgen
- Astellas Pharma
- AstraZeneca
- Bayer Australia
- Biogen 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)
- Mundipharma
- Mylan EPD
- Norgine
- Novartis Pharmaceuticals Australia
- Novo Nordisk Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis
- Seqirus Australia
- Shire
- Takeda
- UCB Australia

When embarking on this review, the Chairman directed the Committee to the Code noting that Section 14 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 Committees opinion that the activities reported by member companies supported those objectives.

The Committee sought clarification from 8 companies or to provide clarification as to the appropriate reporting location from some activities reported. Overall, the Committee were pleased with the submissions made by member companies and thanked them for their thoroughness in these reports.