2014-2015

Medicines Australia
Code of Conduct
Annual Report

Report on the activites 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 2014-2015.

Educational Event Reports

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

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

Review of Educational Events 2013-2014

For the 2013-2014 review, the Chairman selected at random the months of June 2013, November 2013 and March 2014. The Monitoring Committee commenced its review in July 2014 with subsequent meetings held in August and September 2014 to review responses from companies to any requests for further information. This review included close to 8,500 events from 38 companies. As a result of its review of the three months of events, the Monitoring Committee sought further information from 24 companies. The Monitoring Committee completed this review at the end of September 2014, with two events being referred to the Code of Conduct Committee for its adjudication (Complaints 1121 and 1122). The outcomes are reported in this report.

Table 9: Summary of materials and activities reviewed by the Monitoring Committee 2010 – 2015					
	2010-2011	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
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 Company controlled Websites Market Research with Healthcare Professionals Prescribing Software	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

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

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

Medical Education Material

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

Materials were provided by the following 22 companies for review:

- A. Menarini
- Abbott
- AbbVie
- Allergan
- Amgen Australia
- Bayer Australia
- Boehringer-Ingelheim
- Bristol-Myers Squibb Australia
- Celgene
- bioCSL
- Ipsen
- GlaxoSmithKline
- Janssen
- LEO Pharma
- Merck Sharp and Dohme (Australia)
- Novartis Pharmaceuticals Australia
- Novo Nordisk Pharmaceuticals
- Pfizer Australia
- Roche Products
- Sanofi-aventis
- Shire
- UCB Pharma

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

The Committee provided comments and feedback to A. Menarini, Bayer Australia, Boehringer-Ingelheim, LEO Pharma, Ipsen, Novartis Pharmaceuticals Australia, Pfizer Australia and Roche Products in relation to their materials. The matters raised with the individual companies included:

- Ensuring that hyperlinks to the Product Information and other information are functioning
- Ensuring that mandatory information required for an advertisement is displayed in the same visual frame/webpage as the advertisement
- Ensuring that the local sponsor company's details are included in apps developed overseas
- Recommending revision of certain text to ensure its correct interpretation
- Requested an explanation of the relationship between a company and the third party in relation to content published on the third party's website where the company was not identified as contributing the information
- Ensuring that the Australian Approved Name is in the correct position in compliance with the Code and is legible in an app.

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

Product Media Statements

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

Materials were provided by the following 8 companies for review:

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

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

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

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

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

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

Disease Education Activities

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

Materials were provided by the following 2 companies for review:

- A. Menarini Australia
- Novartis Pharmaceuticals

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

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

Printed Advertisements

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

Materials were provided by the following 7 companies for review:

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

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

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

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

Printed and Electronic Promotional Material

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

Materials were provided by the following 8 companies for review:

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

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

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

Health Consumer Organisation Support and Consultancies Reports

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

Reports submitted by the following 34 companies were reviewed:

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

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

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

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

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