# Code of Conduct

**Annual Report** 2016-2017

REPORT ON THE
ACTIVITIES OF THE
MONITORING COMMITTEE

Medicines
Australia




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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 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 1<br>Summary of materials and activities reviewed by the Monitoring Committee 2012 – 2017 | | | | |
|---|---|---|---|---|---|
| | **2012-2013** | **2013-2014** | **2014-2015** | **2015-2016** | **2016-2017** |
| 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<br>• Corporate Websites<br>• Market Research<br>• Media Releases (HCP)<br>• CEP Audit<br>• Starter Packs | • Educational Event Reports<br>• HCO Reports | • Educational Event Reports<br>• HCO and Consultancy Reports<br>• Medical Education for HCPs<br>• Media releases to the general public | • Educational Event Reports<br>• HCO Reports<br>• Product Familiarisation Programs Consent Forms<br>• Market Research<br>• Hospitality Procedures | • Educational Event Reports<br>• Advisory Board Reports<br>• Starter Packs<br>• HCP Websites |

| Table 2: Summary of materials and activities reviewed by the Monitoring Committee in 2016 – 2017 (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** |
| Analgesia | Advertisements, Printed Promotional Material and E-Ads | 3 | 49 | 1 |
| All therapeutic classes | Starter Packs Policies and Procedures | 9 | 9 | 1 |
| All therapeutic classes | Healthcare Professional Websites | 26 | 26 | 2 |
| Alimentary | Advertisements in audiovisual, internet and eNewsletters | 1 | 2 | 1 |
| Eye & Ear, Nose and Throat | Journal Advertisements | 1 | 2 | 1 |
| All therapeutic classes | HCO Support Reports | 29 | 368 | 3 |
| **TOTAL** | | **69** | **456** | **9** |

## 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.