



GBMA

Generic and Biosimilar
Medicines Association

Generic and Biosimilar Medicines Association (GBMA)

Code Administration Committee Report

Operation of the GBMA Code of Practice
December 2019

Introduction

The Generic and Biosimilar Medicines Association (GBMA) is the representative body of generic and biosimilar medicine suppliers in Australia. Its members ensure that all Australians are offered the highest quality generic and biosimilar medicines in the world whilst providing affordable community health outcomes that benefit all Australians.

Members of GBMA adhere to a common set of principles:

- To make high quality medicines affordable for all Australians, today and for the future.
- To provide ongoing education and professional development to Australian healthcare professionals to support community health outcomes that assists all Australians.
- To support high standards in the manufacture of generic medicines; making Australian generic medicines consistently safe, effective, of high quality and a global benchmark.
- To ensure high standards of conduct by adhering to a strict Code of Practice.
- To adhere to a system of best practice and ethical standards whilst providing pricing benefits to pharmacy, patients and the Australian taxpayer.
- To respect the intellectual property rights of truly innovative medicines.

GBMA member companies proactively opt to comply with the GBMA Code of Practice, 4th Edition (Code).

The below list details all Code complying member companies:

- Mylan
- Apotex Pty Ltd
- Arrow Pharmaceuticals Pty Ltd
- Juno Pharmaceuticals Pty Ltd
- Sandoz Pty Ltd
- Southern Cross Pharma Pty Ltd

Pursuant to the Code the GBMA Board produces an annual report on the operation of the Code.

Scope of Report

This report considers operations of the Code over the period 1 January 2019 – 31 December 2019.

This report is also available for download in a PDF format from the GBMA website at www.gbma.com.au.

This work is copyright. Reproduction is not permitted without direct attribution and notification to GBMA.

The Year in Review

Code Administration and Implementation Process

The 4th edition of the Code, now in its 4th year, continues to be effective in formalising the high standards of conduct adhered to by GBMA members.

The Code is administered by the GBMA secretariat.

Pursuant to the Code, administration continues to be facilitated through the Code Administration Committee (CAC) whose role it is to use all reasonable endeavours to ensure the successful implementation and ongoing effectiveness of the Code and to report on this to the Board annually.

The appointment of the CAC Independent Chair was approved by the GBMA in April 2019.

The CAC was convened twice in the reporting period on 17 May and 29 November, to oversee the successful implementation of the Code and to initiate and manage the review of the operation and effectiveness of the Code as required by the Code.

A review of the current Code is due by the end of December 2020.

The review process was initiated in 2019 with a series of meetings throughout the reporting period involving the CAC and the Code of Practice Review Working Group (CoPRWG).

A 12-month plan to manage the Code of Practice review process was developed in May 2019 and has been implemented. The first phase of review was completed according to the plan in December 2019.

The CoPRWG was convened once in the reporting period on 19 June 2019 to initiate the first phase of the Code review.

Effectiveness of the Code

The effectiveness of the Code is reviewed against the objectives of the Code as they are set out in section 3.1 of the Code.

During the reporting period the Code has been effective in formalising the high standards of conduct adhered to by Members. This has been demonstrated by all code complying GBMA member companies through their continued alignment to the GBMA common set of principles and high levels of compliance with the code.

The Code requires Compliant Members to prepare an Annual Statement declaring their compliance with the Code over the previous twelve-month period from 1 July 2018 to 30 June 2019 and their intent to comply with the Code over the next twelve month period.

Annual Statements declaring Member compliance with the Code were received by the GBMA Secretariat from all Compliant Members by 31 August 2019.

The Code also requires that the GBMA hold a training workshop covering the contents of the Code and Members' obligations under the Code for Complying Members annually.

GBMA Code of Practice Training Workshops were conducted during this reporting period on 24 and 25 July 2019, in Sydney and Melbourne respectively, and were attended by representative employees from all Member companies.

Compliant Member companies also reported in their individual 2019 annual statements of compliance with the Code that internal training on the provisions of the code and any communications were provided as appropriate to their employees.

Correspondence from Stakeholders Pertaining to the Code

GBMA has not received any material correspondence from stakeholders pertaining to the Code over the period 1 January – 31 December 2019.

Effectiveness of the Code Complaints Process

During the period 1 January – 31 December 2019, GBMA received no complaints.

No complaints have been referred to the Code Complaint Committee (CCC) since 2012.

Recommendations for Future Amendments to The Code and/or Its Implementation

Pursuant to the Code, the Board will review the operation and effectiveness of the Code at regular intervals of not more than five (5) calendar years.

A review of the current Code is due by the end of December 2020.

The review of the Code was initiated in May 2019 through the implementation of a 12- month plan to manage the review process.

A management plan is to be set in quarter 1 of 2020 by the CAC to manage the review process up to completion in December 2020.