



GBMA

Generic and Biosimilar
Medicines Association

Generic and Biosimilar Medicines Association (GBMA)

Code Administration Committee Report

Operation of the GBMA Code of Practice
December 2020

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.

Complying members of GBMA adhere to a common set of principles:

- To support the long term sustainability of the PBS and healthcare budgets by ensuring the timely and cost-effective provision of Generic and Biosimilar Medicines to Consumers.
- To support the quality use of medicines (QUM) and quality use of medicines in partnership with other stakeholders.
- To support the development of policies that facilitate timely access to Generic and Biosimilar Medicines for all Australians.
- To support the development of policies that promote the continued viability of a local manufacturing base for Generic and Biosimilar Medicines (for domestic and export markets).
- To encourage a high level of awareness and general knowledge of the safety, efficacy and appropriate interchangeability of Generic and Biosimilar Medicines amongst Healthcare Professionals, Government and Consumers.
- To support balanced intellectual property rights in the pharmaceutical sector that enable timely, cost-effective access to Generic and Biosimilar Medicines.
- To enhance the accountability of Complying Members by establishing a complaints handling mechanism that is both readily accessible and transparent.

Members of GBMA are bound by the terms of the GBMA Code of Practice (4th Edition).

The below list details all Code complying member companies:

- Apotex Pty Ltd
- Arrow Pharmaceuticals Pty Ltd
- Celltrion Healthcare Australia Pty Ltd
- Fresenius Kabi Australia Pty Ltd
- Juno Pharmaceuticals Pty Ltd
- Mylan Australia
- 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 2020 - 31 December 2020.

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

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The Year in Review

2020 has been a significant year of unprecedented challenges on both a global and local scale.

The dual health and economic crisis resulting from the summer bush fires and the global COVID-19 pandemic has brought into sharp focus the importance of ethical business conduct.

As in all other areas of life and business, GBMA members have had to navigate through and adapt to new ways of doing things and in particular, how they interact with each other as well as Industry stakeholders, Healthcare Professionals, Government and Consumers.

The 4th Edition of the Code, now in its 5th year, continues to be effective in formalising the high standards of conduct adhered to by GBMA members.

Code Administration and Implementation Process

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 CAC was convened twice in the reporting period on 6 February and 7 December, 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. Due to COVID-19 restrictions these meetings were held via teleconference.

A review of the current Code was initiated by the CAC in 2019.

The first phase of the review process was completed in 2019 and included a series of meetings involving the GBMA Board, CAC and the Code of Practice Review Working Group (CoPRWG).

Phase two of the review process, which due to COVID restrictions involved consultation with the GBMA Board, CAC and the CoPRWG via email and telecon, was completed in 2020 and the 5th Edition of the Code was approved by the GBMA Board at the 17 December Board meeting.

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.

Due to COVID-19 restrictions the 2020 GBMA Code of Practice Training workshops were conducted on 17 and 24 September 2019, via videoconference, and were attended by representative employees from all Member companies.

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, The Purpose 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 2019 to 30 June 2020 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 2020.

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 2020.

Effectiveness of the Code Complaints Process

During the period January – 31 December 2020, 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 (4th Edition) was completed in December 2020.

A review of the new Code (5th Edition) will be due by the end of December 2025.



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