



GBMA

Generic and Biosimilar
Medicines Association

Code Administration Committee Report

Operation of the GBMA Code of Practice

December 2018



Introduction

The Generic and Biosimilar Medicines Association (GBMA) is a 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 assist 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 2018 – 31 December 2018.

This annual 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

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 4th edition of the Code, now in its 3rd year, continues to be effective in formalising the high standards of conduct adhered to by GBMA members.

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

During the reporting period member companies reported in their individual 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.

A GBMA organised workshop was not conducted during this reporting period.

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 2018.

Effectiveness of the Code Complaints Process

During the period 1 January – 31 December 2018, 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 Dec 2020. The Board has recommended that the review process be initiated in 2019.

To assist the review of the Code, in November 2018 the Board approved the establishment of a Code of Practice Review Working Group (CoPRWG) to support the CAC in the review process.

The Board also approved the new CoPRWG Charter as well as nominations from GBMA member companies for representatives to sit on the working group.

Based on the absence of complaints and receipt of compliance letters from all GBMA member companies, the CAC was not convened in 2018.

This reporting period saw the appointment of a new GBMA CEO and GBMA Secretariat in March and July 2018 respectively.

Progress on appointing a new CAC membership to reflect the new Executive and GBMA member companies continued in 2018 with the GBMA Board approving the nominations for the positions of GBMA Board Representative and GBMA Representative with legal experience on the Committee in November 2018.

The Board also approved the new CAC Charter at the December Board meeting and recommended the appointment of an Independent Chair to be finalised in early 2019 with CAC convened thereafter.



Generic and Biosimilar Medicines Association

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Making medicines affordable

Generic Medicines Industry Association Pty Ltd ABN 19 096 009 540 trading as Generic and Biosimilar Medicines Association Pty Ltd