GBMA
Generic and Biosimilar Medicines Association

Generic and Biosimilar Medicines Association (GBMA)

Code Administration Committee Report

Operation of the GBMA Code of Practice

December 2025

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 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) individually as members, and 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 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.

GBMA member companies proactively opt to comply with the GBMA Code of Practice, 5th Edition (Code).

Complying Members for the 2025 reporting period were:

- Accord Australia
- Arrotex Pty Ltd (Apotex, Arrow and Juno)
- Fresenius Kabi Australia Pty Ltd
- Jamp Pharma
- Neo Health
- Organon
- Pearce IP (Associate member)
- Sandoz Pty Ltd
- Teva Pharmaceuticals
- Viatris

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 2025 – 31 December 2025.

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

The Year in Review

2025 saw the ongoing implementation of the GBMA 5-year Strategic Agreement with the Australian Government, with patient access to medicines at the core of its objectives.

The GBMA and its members have always advocated for patient access to affordable medicines and highlighted the vulnerabilities in the global and local supply chains.

GBMA recognises that its Code must be fit for purpose and provide a set of principles to guide its members through the environment in which they operate. In 2025, the GBMA with the support of the Code Administration Committee (CAC) conducted and completed a full review of the Code, required every 5 years under the Code.

The CAC further conducted Code education workshops and the Secretariat did not receive any complaints under the Code during the year.

Importantly, the GBMA Code of Practice will continue to reflect the high standards of conduct expected of its members, along with the established complaints handling process.

Further details are set out in the following sections.

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 on the below dates 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.

CAC meeting dates:
February 12, 2025
June 17, 2025
July 8, 2025
July 31, 2025
September 9, 2025
December 9, 2025.

A full review of the current Code was initiated by the CAC in February 2025, as required under the code every 5 years.

The first phase of the review process was completed in April 2025 by the GBMA Secretariat and presented to the Code Administration Committee for initial review and discussion. Phase two of the review took place from May 2025 to November 2025 and included a series of meetings involving the GBMA Board, Marketing and Ethics committee, Members Committee and Code Administration Committee.

The review was completed in December 2025 and the 6th Edition of the Code was approved by the GBMA Board in December 2025.

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

The 2025 GBMA Code of Practice Training workshops were conducted via videoconference on September 17 and September 25, 2025, with CAC facilitators delivering training as a live panel from a single location. An additional recorded workshop was held October 17, 2025, for members who were unable to attend the scheduled dates in September.

The training included case studies, interactive polling and were attended by just over 140 representative employees from all required Member companies across the three workshops.

Effectiveness of the Code

The effectiveness of the Code is reviewed against its purpose as set out in section 3.1.

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 2024 to 30 June 2025 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.

Correspondence from Stakeholders Pertaining to the Code

GBMA has not received any material correspondence from stakeholders pertaining to the Code other than general enquiries on the Code and how it is enacted over the period 1 January – 31 December 2025.

Effectiveness of the Code Complaints Process

During the period 1 January – 31 December 2025, the GBMA has 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.

Following full review of the Code in 2025, GBMA's Code of Practice 6th edition will be finalised and ratified early 2026.

A review of the Code (6th edition) will be due before December 2030.

GBMA
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Medicines Association

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