



GBMA

Generic and Biosimilar
Medicines Association

Generic and Biosimilar Medicines Association (GBMA)

Code Administration Committee Report

Operation of the GBMA Code of Practice
December 2022

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) 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 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).

Code compliant members for the 2022 reporting period were:

- Accord Australia
- Apotex Pty Ltd
- Arrow Pharmaceuticals Pty Ltd
- Celltrion Healthcare Australia Pty Ltd
- Fresenius Kabi Australia Pty Ltd
- Gedeon Richter (joined October 2022)
- Juno Pharmaceuticals Pty Ltd
- Organon
- Viatrix
- Sandoz 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 2022 – 31 December 2022.

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

2022 saw the commencement 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. This has especially come to the forefront in the current pandemic environment.

The measures negotiated in this Agreement aim to ensure access to medicines, without disruption, providing healthcare professionals and patients with confidence that continuity of therapy will be preserved. This, together with reforms aimed to drive further savings to the PBS, will also allow the generic and biosimilars industry to continue delivering the fiscal headroom required to help subsidise new and innovative treatments for Australian patients.

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.

The 5th edition of the Code continues to reflect the unique operating environment of suppliers of generic and biosimilar medicines, especially as the marketing of these medicines typically seeks to change behaviour at the point of dispensing not at the point of prescribing.

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.

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 4 April and 14 November 2022, 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 the meeting was held via teleconference.

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

The 2022 GBMA Code of Practice Training workshops were conducted via videoconference on 8 and 15 September 2022 and were attended by just over 100 representative employees from all Member companies across the two 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 2021 to 30 June 2022 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 2022.

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 2022.

Effectiveness of the Code Complaints Process

During the period 1 January - 31 December 2022, 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.

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



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Generic Medicines Industry Association Pty Ltd
ABN 19 096 009 540 trading as
Generic and Biosimilar Medicines Association
PO Box 87 Deakin West ACT 2600