



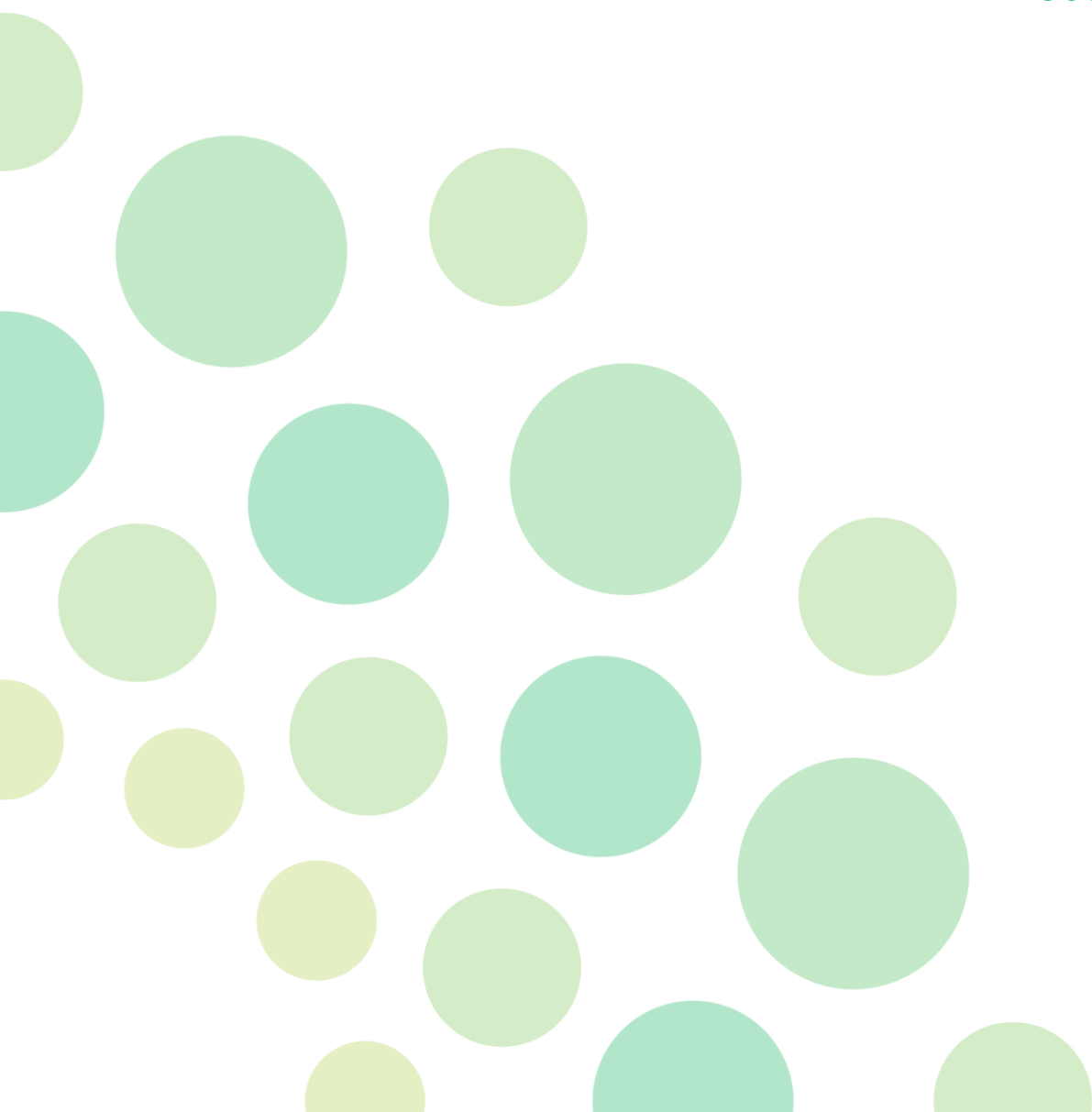
GBMA

Generic and Biosimilar
Medicines Association

Code of Practice

4th Edition

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2. Introduction

- 2.1 The Generic Medicines Industry Association Pty Ltd trading as the Generic and Biosimilar Medicines Association (GBMA) accepts as Members, Australian entities that are dedicated to the supply and/or manufacture of affordable therapeutic goods in the Australian market. Members are bound by a commonality of supply and/or manufacture of Generic and Biosimilar Medicines (Products) in the Australian market, however the portfolio of products of many Members include other affordable therapeutic goods.
- 2.2 Members of GBMA may choose to be bound by the terms of this Code.
- 2.3 Entities that predominantly manufacture and/or sell Generic and Biosimilar Medicines (Products) in the Australian Market and/or manufacture Generic and Biosimilar Medicines for export who are not a Member of the GBMA are able to adopt and may choose to be bound by the terms of this Code. Entities adopting this Code agree to contribute to the costs of administering the Code.
- 2.4 The GBMA Code of Practice is principle based, providing guidance in a single document, on the different legislation, regulation and guidelines with which Sponsors of Generic and Biosimilar Medicines listed on the Australian Register of Therapeutic Goods (ARTG) comply. The Code provides for a Code Administration Committee established to ensure the successful implementation and ongoing effectiveness of the Code and a Code Complaint Committee established to hear Complaints brought under the Code by Complying Members, Members, non-Members, members of other associations, Healthcare Professionals or the public.
- 2.5 The Competition and Consumer Act (Cth) 2010 aims to enhance the welfare of Australians by promoting competition and fair trading and providing for consumer protection. Complying Members of GBMA must comply with the provisions of the Competition and Consumer Act (Cth) 2010 and the Australian Consumer Law 2010. In particular, Complying Members promote competition in the Generic and Biosimilar Medicines industry sector and Complying Members must not engage in misleading or deceptive conduct or conduct that is likely to mislead or deceive Consumers, Healthcare Professionals and other Stakeholders.
- 2.6 The Therapeutic Goods Administration (TGA) is responsible for the administration of the Therapeutic Goods Act (Cth) 1989 and associated regulations. The Therapeutic Goods Act (Cth) 1989 and Regulations provide a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods. The TGA approves all prescription medicines before they can be marketed or supplied in Australia. All therapeutic goods must be registered and/or listed on the Australian Register of Therapeutic Goods (ARTG) in order to be sold in Australia. The TGA applies the same high standards of review to all prescription medicines regardless of whether they are originator brands, generic brands or biosimilars. Therefore, Generic and Biosimilar Medicines comply with the same manufacturing quality and safety standards as the originator medicine.

- 2.7 Generic and Biosimilar Medicines are as safe as the original medicines. Generic and Biosimilar Medicines are an equal choice and contain the same active ingredient as the originator medicine. The active ingredient is the chemical in the medicine that makes the medicine work — so medicines with the same active ingredient are expected to work in the same way (to produce the same benefits and the same potential side effects). That does not always mean they will look the same — Generic and Biosimilar Medicines may be a different colour, a different shape, or come in tablet or capsule form. This is because the binders, colours and fillers in the medicine may be different, although the active ingredient is the same.
- 2.8 It is important that the consumer know about the active ingredient in their medicines to help to make sure they avoid confusing their medicines. This is particularly important when taking multiple medicines or after a recent stay in hospital. Details of the active and inactive ingredients in medicines are explained in the Consumer Medicine Information (CMI) leaflet, or by a doctor or pharmacist.
- 2.9 For a Generic or Biosimilar Medicine to be listed on the ARTG, the TGA must assess the Product as being bioequivalent or biosimilar to the originator medicine. For oral medicines, bioequivalence or therapeutic equivalence generally is established in a clinical trial where the plasma concentration or effect of the Generic Medicine is compared to that of the originator medicine. Only when a Generic Medicine is listed on the ARTG can it be listed on the Pharmaceutical Benefits Scheme (PBS) as interchangeable with the original brand. When a Generic Medicine on the Pharmaceutical Benefits Scheme (PBS) is said to be bioequivalent then it has the same active ingredient as the originator medicine and the same amount of medicine is available in the body to give the same physiological effect.
- 2.10 Generic and Biosimilar Medicines provide patients access to safe, effective, high-quality alternatives and play an important role in introducing competition and reducing prices after the monopoly market period enjoyed by the originator Sponsor has expired. The pharmaceutical company that first develops a medicine (originator) takes out a patent to ensure its exclusive right to produce and market it. After the patent for the originator medicine expires (off patent), producers of Generic and Biosimilar Medicines introduce competition and provide Consumers with a choice of brands of the same medicine and important savings for Government and the Consumer.
- 2.11 Notwithstanding that, Complying Members of GBMA comply with the highly sophisticated and strict TGA regulatory requirements, Complying Members operate in a unique commercial environment, which is different to that of the suppliers of originator medicines and other suppliers of therapeutic goods. Ways by which the market dynamics faced by suppliers of originator medicines differ from the market dynamics faced by suppliers of Generic Medicines include:
- i. There is typically lengthy market experience, understanding and knowledge of medicines by the time Generic or Biosimilar Medicines enter

the market, which can be 15- 20 years after the originator medicine was first launched. Doctors' prescribing habits regarding an off-patent drug are usually well formed; and pharmacists are well informed as to a drug's indications and effectiveness.

- ii. Marketing of off patent medicines typically seeks to change behaviour at the point of dispensing not at the point of prescribing. The decision to substitute a patient from one brand to another brand is unlikely to create any change to the health outcomes for the patient, and is likely to create a financial saving for the patient, potentially increasing patient compliance.
- iii. Complying Members of GBMA may supply prescription and non-prescription medicines. At the time that a prescription medicine is subject to generic competition, some medicines have been rescheduled as non-prescription medicines.

2.12 This Code specifically reflects the unique operating environment of suppliers of Generic and Biosimilar Medicines and sets out the best practice standards, aligned with that unique operating environment required of all Complying Members.

3. Objectives

3.1 The purpose of the Code of Practice is to:

- i. Formalise the commitment of the Complying Members to a system of best practice self-regulation and ethical supply of Products to the Australian community, in compliance with applicable laws and standards.
- ii. Increase awareness of, and confidence in the quality, safety and cost effectiveness of Generic and Biosimilar Medicines by Consumers, Healthcare Professionals and Government.
- iii. Promote timely access for all consumers to safe and cost effective Generic and Biosimilar Medicines.
- iv. Identify the unique objectives of the Generic and Biosimilar Medicines industry sector in its relationships with Consumers, Healthcare Professionals and Government and provide guidance as to how this relationship can be developed consistent with appropriate industry, professional and ethical standards.
- v. Assist Complying Members to promote and maintain a culture of ethical supply of Generic and Biosimilar Medicines.
- vi. Promote ethical and professional conduct by all Complying Members and their employees in the manufacture, supply and marketing of Generic and Biosimilar Medicines and in their dealings with Consumers, Healthcare Professionals and Government.

- vii. Provide a mechanism for collaboration and dialogue with other Stakeholders to ensure that the Code continues to reflect high standards of conduct, consistent with established community and professional expectations.
- viii. To establish an accessible and transparent complaints handling mechanism which Consumers, Healthcare Professionals and other Stakeholders can utilise to make complaints about the conduct of Complying Members.
- ix. To establish a Code Complaints Committee to consider complaints about Complying Members and impose sanctions in appropriate cases.
- x. To establish educational event principles for Complying Members who hold such events for Healthcare Professionals responsible for prescribing and dispensing prescription medicines.

4. Principles

4.1 The guiding principles of Complying Members of the GBMA are:

- i. 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.
- ii. To support the quality use of medicines (QUM) and quality use of medicines in partnership with other stakeholders.
- iii. To support the development of policies that facilitate timely access to Generic and Biosimilar Medicines for all Australians.
- iv. 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).
- v. 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.
- vi. To support balanced intellectual property rights in the pharmaceutical sector that enable timely, cost effective access to Generic and Biosimilar Medicines.
- vii. To enhance the accountability of Complying Members by establishing a complaints handling mechanism that is both readily accessible and transparent.

5. Coverage & Code awareness by Members

- 5.1 Members of the GBMA may choose to be bound by the Code. Complying Members must pro-actively opt to comply with the Code and will provide a declaration of compliance with the Code.
- 5.2 The Code may also serve as guidance for the suppliers of Generic and Biosimilar Medicines that are not Complying Members or are not Members of GBMA. Suppliers of Generic and Biosimilar Medicines that are not Complying Members or not Members of GBMA are encouraged to adopt and decide to be bound by the Code. Non Members of GBMA who agree to adopt and decide to be bound by the Code will be known as Complying Affiliate Members of GBMA.
- 5.3 Ultimate responsibility for the observance of the GBMA Code lies with each Complying Member. All Complying Members must use their best endeavours to ensure that their employees, contractors and agents:
 - i. are fully aware of and understand the provisions of the Code;
 - ii. receive ongoing training on compliance with the provisions of the Code;
 - iii. maintain a high standard of ethical conduct and professionalism;
 - iv. conduct themselves in a manner that complies with the Code;
 - v. act in a manner that does not compromise, or appear likely to compromise the professional behaviour or independence of a Healthcare Professional;
 - vi. avoid both actual and potential conflicts of interest with Healthcare Professionals responsible for prescribing and dispensing medicines; and
 - vii. act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.
- 5.4 Complying Members will prepare an Annual Statement declaring their compliance with the Code over the previous twelve month period from 1 July to 30 June and their intent to comply with the Code over the next twelve month period. This statement is to be provided to GBMA by 31 August each year.
- 5.6 GBMA will hold a training workshop covering the contents of the Code and Complying Members' obligations under the Code for Complying Members annually.

6. GBMA Code of Practice

6.1 Application of GBMA Code of Practice

- 6.1.1 This Code applies to all activities in relation to Generic and Biosimilar Medicines (Products) of Complying Members of GBMA. Complying Members are required to comply with both the spirit and

intended purposes of the Code as well as the strict written requirements of the Code.

6.1.2 Complying Members may manufacture and/or sell other therapeutic goods in addition to Products.

6.1.3 Complying Members conduct a range of commercial and marketing activities.

6.2 Australia's National Medicines Policy

6.2.1 The Complying Members support Australia's National Medicines Policy which aims "to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians". (DHAC 1999) The Policy has four central objectives:

- i. Timely access to the medicines that Australians need, at a cost that individuals and the community can afford;
- ii. Medicines meeting appropriate standards of quality, safety and efficacy;
- iii. Quality use of medicines;
- iv. Maintaining a responsible and viable medicines industry.

6.3 Promotion of good health

6.3.1 Complying Members promote the concept of good health incorporating the quality use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties. In this context the quality use of therapeutic products means:

- Selecting diagnostic and treatment options wisely based on the best available evidence and the consumers' needs;
- Choosing suitable therapeutic products if this is considered necessary; and
- Using therapeutic products safely and effectively.

6.4 Quality use of medicines

6.4.1 Complying Members support the quality use of medicines. Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy. According to "The National Strategy for the Quality Use of Medicines", QUM means:

- i. Selecting management options wisely;
- ii. Choosing suitable medicines if a medicine is considered necessary so that the best available option is selected;
- iii. Using medicines safely and effectively to get the best possible results.

6.4.2 Complying Members promote the quality use of medicines via:

- i. The continued development of safe and effective Products to prevent, treat and cure illness or to maintain health;
- ii. The manufacturing, marketing and promoting of Products in a way that facilitates the quality use of the medicine;
- iii. Providing quality balanced information and education services that are conducive to QUM.

6.5 Manufacture

- 6.5.1 Complying Members establish and maintain systems and processes to ensure that the Complying Members manufacture and/or procure the manufacture of their Products in compliance with Good Manufacturing Practice (GMP). GMP describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.

Section 36 of the Therapeutic Goods Act (Cth) 1989 allows the Minister for Health and Ageing to determine Manufacturing Principles that are to be applied in the manufacture of therapeutic goods.

Through the Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2009, the TGA has adopted the PIC/S Guide to Good Manufacturing Practice for Medicinal Products, PE 009-8 - 15 January 2009 as the Manufacturing Principles. Through the operation of section 36 and other provisions within the Therapeutic Goods Act (Cth) 1989, the Guide has legal force in Australia.

Complying Members follow the Australian Code of GMP for Medicinal Products (or the equivalent international GMP code accepted by the TGA in accordance with the TGA Guidance on the GMP Clearance of Overseas Medicine Manufacturers dated May 2011 as amended or replaced from time to time) and applicable occupational health and safety, and environmental laws.

Complying Members manufacturing Product in Australia comply with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products, PE 009-8 - 15 January 2009 as the Manufacturing Principles, as amended or replaced from time to time.

Complying Members ensure that the Products they procure (through appropriate contractual arrangements or otherwise), and for which they are designated as Sponsor on the ARTG, are manufactured at the sites listed in the marketing approval issued by the TGA and that those sites have passed GMP audit and inspections either performed by the TGA or as authorised under a mutual recognition agreement entered into by the TGA with the applicable foreign country regulator.

6.6 Supply and distribution of Generic and Biosimilar Medicines

- 6.6.1 Complying Members are required to supply, distribute and market their Products according to all applicable legislative requirements. Without

limitation, this includes the Therapeutic Goods Act (Cth) 1989 and Regulations; the Competition and Consumer Act (Cth) 2010, the Australian Consumer Law 2010, the National Health Act (Cth) 1953 and Regulations; the Standard for the Uniform Scheduling of Medicines and Poisons 2012; and the Customs Act (Cth) 1901.

- 6.6.2 Complying Members supply, distribute and market Generic and Biosimilar Medicines in strict conformity with the conditions contained in the marketing approval issued by the TGA with respect to that medicine, and in accordance with applicable TGA Regulations.

Advertising prescription-only and certain pharmacist-only medicines to the general public is prohibited. However, government-controlled public health campaigns that have been approved by Health Ministers are exempt from this prohibition.

The advertising of therapeutic goods to consumers and health practitioners is controlled by a combination of statutory measures administered by the TGA and self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations.

Advertisements for therapeutic goods in Australia are subject to the requirements of the Therapeutic Goods Act (Cth) 1989 and Regulations, the Competition and Consumer Act (Cth) 2010 and the Australian Consumer Law 2010. Advertisements for therapeutic goods directed to consumers must also comply with the Therapeutic Goods Advertising Code (March 2007), and as amended or replaced from time to time.

- 6.6.3 The distribution of product samples must be carried out responsibly and in compliance with Product Conditions of Registration and within the principles of QUM by Complying Members.

A unit of Product samples should not exceed 1/3 of the PBS primary quantity for each strength of a Product. Where it is not practical to produce a 1/3 pack, the smallest trade pack may be used.

6.7 Safety of Generic and Biosimilar Medicines

- 6.7.1 Complying Members establish and maintain effective systems and processes to ensure compliance with “The Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines” (November 2012), and as amended or replaced from time to time.

Complying Members ensure compliance with other related pharmacovigilance documents issued by the TGA for registered prescription and registered or listed non-prescription medicines for which they are the Sponsor.

The Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines sets out requirements and guidance for the reporting of adverse reactions and significant safety issues for both registered and listed medicines regulated by the TGA.

6.7.2 Complying Members provide periodic safety update reports on a regular basis as required by the TGA.

6.7.3 Complying Members will use reasonable endeavours to establish and maintain effective systems and processes to ensure that they can account in writing for every transaction in relation to distribution of a Product and to enable compliance with the TGA Guidelines, “Uniform Recall Procedure for Therapeutic Goods” (2004 Edition), as amended or replaced from time to time. Complying Members comply with all recall action in accordance with the provisions of the Therapeutic Goods Act (Cth) 1989.

6.7.4 Complying Members will comply with applicable laws in relation to the manufacture, supply, dispensing or administration of a medicine and/or therapeutic good including but not limited to the Therapeutic Goods Act (Cth) 1989, Standards for the Uniform Scheduling of Drugs and Poisons, and related laws and regulations.

6.8 Substitution of Generic and Biosimilar Medicines

6.8.1 Generic and Biosimilar Medicines are medicines that have been demonstrated to be bioequivalent or biosimilar to the originator medicine. Since 1994, pharmacists have been able to substitute different brands of the same medicine unless the prescriber has indicated that substitution is not permitted.

6.8.2 Complying Members of GBMA support the, “Professional Practice Standards” (2010) of the National Council of the Pharmaceutical Society of Australia.

6.9 Relationship with Stakeholders

6.9.1 Complying Members recognise and support the overall goal of the National Medicines Policy, of achieving positive health outcomes for all Australians. In this regard, adherence to the principles of quality use of medicines serves as an important reference point to developing effective relationships with Stakeholders.

6.9.2 Complying Members act with honesty and integrity in all of their relationships with Stakeholders.

6.9.3 Complying Members take all reasonable steps to ensure that they avoid actual and potential conflicts of interest with Healthcare Professionals and that their behaviour and relationships with

Stakeholders do not bring discredit to the Generic and Biosimilar Medicines industry sector and must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste.

6.9.4 Complying Members take all reasonable steps to ensure their behaviour does not lead to actual or potential conflicts of interest or interfere with or impede the independence of Healthcare Professionals or their professional judgment.

6.9.5 Complying Members must not provide personal gifts to Healthcare Professionals.

Where possible, sponsorship of an educational event should be paid to the Healthcare Professional organisation, and not paid directly to an individual Healthcare Professional. Complying Members will obtain receipt and evidence of appropriate expenditure of grants and payments by the recipients.

6.9.6 Where suppliers of Generic and Biosimilar Medicines interact on a commercial basis with Healthcare Professionals, Complying Members are not required to disclose commercial arrangements and trading terms relating to the supply and purchase of Products. Details of the transactions between suppliers and their business customers must remain confidential if competition is to be maintained in relevant markets.

6.9.7 Complying Members will observe the following principles in relation to any Educational Events which they provide to Healthcare Professionals:

- i. The primary purpose of an Educational Event must be the provision of relevant medical information and/or quality use of medicines information to Healthcare Professionals;
- ii. Before offering any Educational Event to Healthcare Professionals the Complying Member must be satisfied that there is a genuine need for the particular Educational Event;
- iii. The name of the Complying Member which is funding the Educational Event must be clearly disclosed to all potential participants in any marketing material prior to the Educational Event being held;
- iv. Complying Members must ensure that the costs of Educational Events are not disproportionate to the value to be gained by participants from the educational content of the Educational Event;
- v. Complying Members must not pay for meals, accommodation

or travel for any relative or associate of a participant at an Educational Event;

- vi. Complying Members must take all reasonable steps to minimise the cost of Educational Events; and
- vii. Delegates at Educational Events must not be paid for their attendance unless they have an additional role at the event such as presenting a paper or acting as MC.

6.9.9 Complying Members recognise the joint Consumer Health Forum and Medicines Australia publication, “A Guide to relationships between Health Consumer Organizations and Pharmaceutical Companies”.

6.10 Promotional and marketing activities

- 6.10.1 Complying Members promote and market Products in accordance with the applicable requirements of the Therapeutic Goods Act (Cth) 1989 and Regulations, the Competition and Consumer Act (Cth) 2010, the Australian Consumer Law 2010, the Therapeutic Goods Advertising Code 2007, the National Health Act (Cth) 1953 and all other applicable laws and codes.
- 6.10.2 Complying Members will comply with the marketing approval letter for registration on the ARTG issued by the TGA.
- 6.10.3 Complying Members will also consider other relevant Codes of Practice, including the Medicines Australia Code of Conduct, the Australian Self-Medication Industry Code of Conduct, the Complementary Medicines Australia Marketing & Supply Code of Practice, the AusBiotech Code of Conduct and/or the Medical Technology Association of Australia Code of Practice to the extent that they relate to promotional material with respect to a Product.
- 6.10.4 Complying Members will use their best endeavours to ensure that all interactions and activities with Healthcare Professionals and Consumers are professional and support the principles of quality use of medicines. Activities of Complying Members of GBMA should be socially responsible.
- 6.10.5 All claims made in promotional and marketing materials must be balanced and not misleading. Claims should be valid and substantiated by appropriate levels of evidence. Complaints about a Complying Member’s promotional and marketing material may be made to the Code Complaint Committee for adjudication and, in appropriate cases, imposition of sanctions.

- 6.10.6 Complying Members may, from time to time, hold or sponsor Educational Events to further the medical and pharmaceutical knowledge of Healthcare Professionals. Educational Events must not bring the Generic and Biosimilar Medicines industry sector into disrepute or reduce public confidence in the Industry.
- 6.10.7 Complying Members will ensure that for Products listed on the PBS, all promotional and educational activities are in accordance with any PBS restrictions and contain accurate and current information regarding any PBS restriction.
- 6.10.8 Businesses using social media channels have a responsibility to ensure content on the pages owned or operated by Complying Members is accurate, irrespective of who put it there. Complying Members of GBMA observe the Guidelines provided by the Australian Competition and Consumer Commission and the Advertising Standards Board and content must comply with applicable laws and codes.
<http://www.accc.gov.au/business/advertising-promoting-your-business/social-media>
- 6.10.9 Ghost writing describes conduct where the contributions of professional medical writers are not identified or acknowledged in a publication, either in the authorship line or other acknowledgement of contribution. To ensure transparency of authorship or contribution to a publication, companies should follow the principles described in the IFPMA Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010).
- 6.10.10 Sponsorship can be provided to organisations that support cultural, educational, philanthropic, sporting and artistic activities or charities but Complying Members must ensure that this association is not undertaken for promotional reasons or used for promotional purposes.
- 6.10.11 Complying Members will ensure that their employees involved in promotional or marketing activities are fully trained and informed of their responsibilities under this Code and all relevant laws, guidelines and codes.

6.11 Product availability

- 6.11.1 For all PBS listed Products, Complying Members comply with the supply guarantee required under the National Health Act (Cth) 1953 Division 3C of Part VII (sections 99Ae to 99 AEL) and make all reasonable endeavours to ensure their Products remain available to pharmacy for the duration of listing on the PBS.

6.12 Research and regulatory activities

- 6.12.1 Complying Members will conduct all research and development activities in compliance with the Therapeutic Goods Act (Cth) 1989,

established medical guidelines, scientific principles and ethical requirements for clinical and pre-clinical experimentation and in accordance with the principles of Good Clinical Research Practice.

6.13 Corporate governance

6.13.1 Complying Members include subsidiaries of global organisations listed on securities exchanges such as the New York Stock Exchange, NASDAQ and/or FTSE as well as Australian companies, either listed on the Australian Securities Exchange (ASX) or privately owned. The corporate governance of Complying Members is therefore regulated at a number of levels including potentially by the listing rules of the applicable overseas securities exchanges where the ultimate parent company of the Complying Member is listed and/or the listing rules and corporate governance principles of the ASX and for privately owned companies by the Corporations Act (Cth) 2001 (if an Australian corporation) or the equivalent laws governing corporations in the home jurisdiction of the Complying Member.

6.13.2 In addition, all Complying Members are expected to encourage and support a culture of good corporate citizenship with regard to internal and external stakeholders of their organisation and encourage, where reasonable, philanthropic activities especially those that promote good health incorporating the use of Generic and Biosimilar Medicines within Australia and the principles of the quality use of medicines.

7. Stakeholder awareness

7.1 The GBMA shall publicise the existence of the Code to Complying Members, Members, non-Members, Suppliers of Therapeutic Goods, Healthcare Professionals, Consumers, Government departments and agencies, consumer organisations, the general public and other interested parties.

7.2 Complying Members use all reasonable endeavours to encourage the appropriate use of Generic and Biosimilar Medicines.

7.3 Complying Members use all reasonable endeavours to consult and work collaboratively with stakeholders to raise awareness and achieve a high understanding of quality use of Generic and Biosimilar Medicines.

7.4 Information concerning a Complying Member's Products can only be provided to Consumers in accordance with the conditions outlined in the Therapeutic Goods Act (Cth) 1989 and Therapeutic Goods Advertising Code 2007.

7.5 As required under section 9A of the regulations of the Therapeutic Goods Act (Cth) 1989, Complying Members must not supply Product without the Product Information being available that meets the requirements for a patient

information document set out in Schedule 12 of the Therapeutic Goods regulations.

8. Implementation

- 8.1 The primary responsibility for the enforcement of this Code rests with the GBMA.
- 8.2 The primary responsibility for ensuring compliance with the Code by any employees, contractors, agents or representatives of a Complying Member rests with the respective Complying Member.

9. Internal complaints handling

9.1 Complaints Handling Systems administered by the Complying Member internally

- 9.1.1 Complying Members will establish and maintain a system for dealing with complaints from Consumers and/or Healthcare Professionals.
- 9.1.2 The Complying Members' Complaints Handling System will be consistent with the requirements of the relevant Australian Standard – *Customer Satisfaction – Guidelines for complaints handling in organisations – AS ISO 10002 – 2006 (Relevant Standard)*.
- 9.1.3 The Complying Members' Complaints Handling System will adopt the following guiding principles. These guiding principles are quoted from the Relevant Standard.
 - i. **Visibility** – Complying Members will ensure that their Complaints Handling System is visible to consumers and other Stakeholders by including a reference to the existence of the Complaints Handling System on their respective websites.
 - ii. **Accessibility** – Complying Members should ensure that consumers can lodge a complaint by completing an on-line form or by telephone or letter.
 - iii. **Responsiveness** – Complying Members will ensure that they acknowledge receipt of a complaint within 5 business days and will undertake their best endeavours to provide a substantive response to the complaint within 15 business days.
 - iv. **Objectivity** – Complying Members will ensure that they fairly consider the merits of every complaint they receive and will seek to deal with the complainant in good faith.

- v. **Cost** – There will be no charge for lodging a complaint by a consumer and/or a Healthcare Professional to a Complying Member.
- vi. **Confidentiality** – Complying Members will ensure that details of each complaint, including the identity of the complainant, are kept confidential unless the complainant agrees in writing that any information they have provided can be made public.
- vii. **Consumer focused approach** – Complying Members will adopt a consumer-focused approach to dealing with complaints by making their systems accessible and objective.
- viii. **Accountability** – Complying Members will retain detailed records of all complaints received, including the following information:
 - Complainant's name and contact details
 - Description of complaint
 - A description of the way in which the complaint was resolved
 - Time taken to provide a substantive response and to finally resolve the complaint
- ix. **Continual Improvement** – Complying Members will review their Complaints Handling System on an annual basis. The purpose of this review is to identify any aspects of the Complaints Handling System which need to be improved or changed and to identify whether the complaints received demonstrate any systemic problems which need to be addressed.

9.1.4 If a consumer and/or Healthcare Professional complaint cannot be resolved through a Complying Member's internal Complaints Handling System, the Complying Member will advise the consumer and/or Healthcare Professional of their right to complain to the GBMA Code Complaint Committee.

9.1.5 In addition, Complying Members ensure that the complaints handling system complies with all applicable privacy laws.

10. External complaints handling system

10.1 Code Complaint Committee administered by GBMA

10.1.1 The GBMA seeks to use all reasonable endeavours to provide Consumers, Healthcare Professionals and other Stakeholders with an effective method to redress complaints against a Complying Member with regard to breaches of the Code.

- 10.1.2 In the event that the GBMA receives a complaint from a Stakeholder which has not yet been directed to the relevant Complying Member, GBMA will recommend to the Stakeholder that they utilise the Complying Member's complaint handling system in the first instance.
- 10.1.3 If the Stakeholder is not satisfied with the action or decision of the Complying Member, the Stakeholder may refer the complaint to the GBMA Code Complaint Committee (CCC) via the GBMA secretariat.
- 10.1.4 Complaints are to be made in writing to the GBMA.
- 10.1.5 In the interests of avoiding frivolous or trivial complaints, individuals or bodies making a complaint (the Complainant) are required to provide their name and contact details and details of affiliation with any relevant professional, industry or consumer association. The CCC may, but is not required to, consider complaints which do not provide this information. The CCC may, but is also not required to, consider anonymous complaints. The party making the complaint may request that GBMA keep this information confidential.
- 10.1.6 The complaints process is free of charge for complaints made by Consumers, Healthcare Professionals and Government. Industry representatives making a complaint must lodge a fee of \$5,000 to cover the costs associated with the administration of the Code Complaints Committee.
- 10.1.7 On receipt of information from a Complainant, the Chief Executive Officer of GBMA or delegate shall acknowledge the complaint in writing within ten (10) business days of receipt.
- 10.1.8 The Complying Member of GBMA that is the subject of the Complaint (the Respondent) shall be given full details of the Complaint lodged with GBMA to enable the Complying Member to respond. The Respondent will be invited to state within fifteen (15) business days whether or not the information supporting the complaint is correct, and to give any answer or explanation that may be deemed necessary. The response provided by the Respondent will be provided to the Complainant within ten (10) business days of receipt by the GBMA Secretariat.
- 10.1.9 All information pertaining to the Complaint is required to be kept confidential until the Complaint is deemed finalised.
- 10.1.10 The Respondent and Complainant will provide GBMA with whatever references or information is deemed to be reasonably necessary for the CCC to consider the Complaint.
- 10.1.11 All relevant information in relation to the complaint, including the initial complaint, the Complying Member response and any response

from the Complainant, shall be provided to the CCC via the GBMA secretariat within fifteen (15) business days of the Complying Member's response being received.

10.1.12 The complainant has the right to withdraw their complaint at any time.

10.1.13 The CCC will consist of five (5) members:

- i. an independent chairperson who must be legally trained and have experience in competition and consumer law,
- ii. a Consumer representative,
- iii. a Pharmacy representative,
- iv. a Medical representative,
- v. an observer nominated by the Therapeutic Goods Administration.

10.1.14 A quorum of three members of the CCC or Appeal CCC is required.

10.1.15 There will be alternative representatives nominated for the CCC in the event that a member of the CCC has a conflict of interest with a product or company, either by which, or against which a complaint has been lodged.

10.1.16 Membership of the CCC will be for a period of three (3) years, with members eligible for re-appointment at the end of this term.

10.1.17 The CCC will convene as required to consider complaints and referrals from the GBMA Secretariat. The CCC will endeavour to convene within forty (40) business days of receiving information about a complaint.

10.1.18 In assessing any Complaint, where relevant, the CCC will apply the terms of this Code. The CCC is also to have due regard to any other codes, which in its opinion is relevant to the complaint, including the Therapeutic Goods Advertising Code, Medicines Australia Code of Conduct, the Australian Self-Medication Industry Code of Conduct, the Complementary Medicines Australia Marketing & Supply Code of Practice, the AusBiotech Code of Conduct and/or the Medical Technology Association of Australia Code of Practice. In the event that there is an inconsistency between the terms of the Code and any other relevant Code, the Code is to have priority.

10.1.19 Once the CCC has met and considered the complaint and reached a decision, the Chairperson of the CCC will prepare a short summary of the Decision, including the reason/s for the decision and the proposed sanction (if any) to be imposed.

- 10.1.20 The Decision will be notified to the Complainant and the Respondent within five (5) business days of the CCC making its Decision. Either party will then be able to make any submissions it wishes to make about the Decision within ten (10) business days of receiving the Decision.
- 10.1.21 After the CCC has considered any potential submission by the Complainant and/or the Respondent in relation to the Decision it will decide whether to affirm or vary the Decision. This decision will be known as the Final Decision.
- 10.1.22 In the event that there is no submission by the Complainant and/or the Respondent concerning the Decision within ten (10) business days of the receiving the Decision, the Decision will automatically become the Final Decision.
- 10.1.23 The CEO of the GBMA or his/her delegate will within fifteen (15) business days of the CCC meeting provide the Final Decision to the Respondent, the Complainant and the Board of the GBMA
- 10.1.24 The Respondent and the Complainant have a right to appeal the CCC's Final Decision. The Respondent or Complainant must lodge their appeal with the GBMA Secretariat within fifteen (15) business days of the Respondent and Complainant being provided the CCC's Final Decision.
- 10.1.25 This appeal will be heard by a newly formed CCC to be known as the Appeal CCC. The Appeal CCC will have the same composition as the initial CCC but will consist of different individual representatives than the initial CCC.
- 10.1.26 The Appeal CCC is to convene within forty (40) business days of the date of lodgment of the appeal. The Appeal CCC will consider the matter on a de novo basis. The Appeal CCC's decision shall be known as the Appeal Decision.
- 10.1.27 The CEO of the GBMA or his/her delegate will within fifteen (15) business days of the CCC meeting provide the Appeal Decision to the Respondent, the Complainant and the Board of the GBMA.
- 10.1.28 A Decision of the CCC to uphold a complaint shall remain confidential and shall not be released to any third parties until after the Respondent and /or Complainant have exhausted all appeal procedures and the outcome of any appeal is known.
- 10.1.29 All Final Decisions of the CCC will be published on the GBMA website after all appeal rights have been exhausted. The GBMA will ensure that such Decisions are published on its website within thirty

(30) business days of the final resolution of any CCC proceeding or appeal.

10.1.30 The CCC may refer questions on the interpretation of the Code to the Board for determination. The Board of GBMA shall consider such questions at the next Board meeting and make a determination.

10.1.31 The complaints handling procedure set out in this Code is intended to be in addition to the normal rights of a Consumer and/or Healthcare Professional under applicable laws and is not intended in any way to restrict a Consumer and/or Healthcare Professional from referring the complaint to any other tribunal or agency or other complaints handling body which may be established or in existence from time to time.

11. Sanctions

11.1 Classification of breach

11.1.1 Before determining any sanction, the CCC must first classify the severity of the alleged breach as per the following criteria:

Minor Breach: a breach of the Code that has no consumer safety implications and will have no adverse effect on how Healthcare Professionals or the general public view the safety of the Product that is the subject of the Complaint, similar Products or the Complying Members.

Moderate Breach: a breach of the Code with no safety implications but which will adversely impact the perceptions of Healthcare Professionals or the general public regarding the Product that is the subject of the Complaint, similar Products or the Complying Members.

Severe Breach: a breach of the Code that has safety implications or will have a major adverse impact on how Healthcare Professionals or the general public view the Product that is the subject of the Complaint, similar Products or the Complying Members.

Repeat Breach: when a Respondent commits a breach of the Code the same as or similar to a breach found against the same Respondent within the preceding twenty four (24) months.

Serial Breach: when a Respondent breaches the Code, and the same Respondent has been found to have breached the Code on not less than two previous occasions in the preceding twenty four (24) months.

11.2 Application of sanctions

11.2.1 Where the CCC finds that a Respondent has breached the Code, the CCC may apply one or more of the following sanctions. The time periods specified for response or action are subject to any appeal that may be lodged under section 10 of the Code.

- i. A requirement that the Respondent take immediate action to discontinue or modify any practice that is determined to constitute a breach of the Code, in which event the Respondent must confirm in writing to the CCC that it has taken the required action within fifteen (15) business days of receipt of the Decision.
- ii. A requirement that the Respondent recall and destroy any offending material in which event the Respondent must confirm in writing to the CCC, within fifteen (15) business days of receipt of the Decision, that it has taken the required action, or taken steps to initiate the required action which are reasonably satisfactory to CCC.
- iii. A requirement that the Respondent issue a retraction, including corrective letters and advertising. The Respondent must confirm in writing to the CCC, within fifteen (15) business days of receipt of the Decision, that it has taken the required action and must provide a copy of the retraction once published.
- iv. A requirement that particular employees, contractors or agents of the Respondent undertake a course of study or further training on their obligations under the Code, relevant laws, guidelines or codes. The CCC is to set a timeframe for the completion of any such course of study or further training.
- v. The imposition by the CCC of a financial sanction in accordance with the following schedule. The Respondent must pay the financial sanction to the GBMA within thirty (30) business days of being advised of the Decision of the CCC.

| | | |
|-------------------------|---------|----------|
| Minor Breach: | Nil | |
| Moderate Breach: | Maximum | \$20,000 |
| Severe Breach: | Maximum | \$40,000 |
| Repeat Breach: | Maximum | \$50,000 |
| Serial Breach: | Maximum | \$75,000 |

11.2.2 In the event that the CCC requires a Respondent to cease conduct or withdraw an activity and the Respondent wishes to review and/or

appeal the Decision, the Decision of the CCC will stand and must be complied with, pending the outcome of the review and/or appeal.

- 11.2.3 In the event that the CCC requires a Respondent to pay a financial sanction and the Respondent wishes to review and/or appeal the Decision, the Decision of the CCC will be stayed from the date that the Complying Member or Complainant lodges a request for a review and/or an appeal until the review and/or appeal has been determined. A Complying Member is not required to pay a financial sanction until it has exhausted its right of appeal.

12. Code administration

12.1 Code Administration Committee (CAC)

- 12.1.1 The CAC comprises an independent chairperson, the CEO of GBMA, a representative from the Board of GBMA and a GBMA representative with legal expertise.
- 12.1.2 The CAC will convene at least once a year.
- 12.1.3 The CAC's role is to use all reasonable endeavours to ensure the successful implementation and ongoing effectiveness of the Code.
- 12.1.4 The CAC will collect data to monitor the effectiveness of the complaints process including the number of complaints, the types of complaint, how the complaint was resolved, the time taken to deal with the complaint and the type of sanction imposed.
- 12.1.5 The CAC provides an annual review report summary for the GBMA Board regarding the effectiveness of the Code and makes recommendations if amendments to the Code and/or its implementation are deemed necessary and/or desirable. The report will be made available on the GBMA website. A template of the report is attached as Appendix 1 to this Code.
- 12.1.6 The CAC will provide an annual report for the GBMA Board regarding the effectiveness of the Code and make recommendations for amendments to the Code if such changes are deemed necessary and desirable. The report will be made available on the GBMA website. A template of the report is attached as Appendix 1 to this Code.
- 12.1.7 The CAC may make recommendations to the Board of GBMA to change the way the CAC operates. The Board of GBMA is to have due regard to any recommendations made by the CAC in its report

but it does not have to implement any particular recommendation made by the CAC.

13. Annual report & ongoing review

- 13.1 GBMA will produce an annual report on the operation of this Code. The annual report will incorporate comments from the CAC and will contain as a minimum the following:
- i. A summary of complaints and the decision in relation to each of those complaints;
- 13.2 The annual report will be available on the GBMA website.
- 13.3 GBMA will encourage ongoing dialogue, consultation and review of the Code during the life of the Code.
- 13.4 The Board will review the operation and effectiveness of the Code at regular intervals of not more than five (5) calendar years. The review of the Code will be conducted under the direction of the CAC and will include such other persons, bodies, Government departments and agencies, consumers, healthcare professional and other stakeholders as the Board may reasonably determine.

14. Amendment

- 14.1 This Code may be amended by vote of at least two-thirds of Complying Members present and entitled to vote at a Meeting, properly convened and held.

15. Appendix 1

Annual CAC review report template

- i. Name of industry Code
- ii. Report on administration and implementation process of Code
- iii. Report on effectiveness of Code
- iv. Documentation of any material correspondence received from stakeholders pertaining to the GBMA Code
- v. Report on the effectiveness of the complaints process including the number of complaints, the types of complaint, how the complaint was resolved, the time taken to deal with the complaint and the type of sanction imposed.
- vi. Recommendations for future amendments to the Code and/or its implementation.

16. Dictionary

Appeal Code Complaint Committee (Appeal CCC) means the committee established to hear appeals of the Final Decision as determined by the CCC and it will have the same composition as the initial CCC but will consist of different individual representatives than the initial CCC.

ARTG means the Australian Register of Therapeutic Goods.

Association means the Generic Medicines Industry Association Pty Ltd.

ASX means the Australian Securities Exchange.

Biosimilar means a version of an already registered biological medicine that has been evaluated by the Therapeutic Goods Administration and has demonstrated similarity in physicochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies.

Board means the board of directors of GBMA.

Breach means a breach of any provision of this Code.

Code means the GBMA Code of Practice as amended from time to time.

Code Administration Committee (CAC) means the committee established to ensure the successful implementation and ongoing effectiveness of the Code.

Code Complaint Committee (CCC) means the committee established to hear Complaints brought under the Code.

Complainant means a person who lodges a Complaint with GBMA under the Code.

Complaint means a complaint lodged with GBMA under the Code.

Complying Member is any Member who voluntarily agrees to be bound by the Code.

Consumer means a person who may undergo a medical procedure or treatment in which a Product may be used or who may acquire a Product for use in relation to their own health, but does not include a Healthcare Professional or Other Professional.

Consumer Representative is a representative from a Health Consumer Organisation or patient support group.

Decision refers to the decision made by the Code Complaints Committee as written up by the Chairman of the Committee and may be reviewed by the CCC upon submission by either the Complainant and/or the Respondent.

DHAC means the Commonwealth Department of Health and Ageing.

Educational Event is any education focused event providing current and relevant medical information to prescribing or dispensing Healthcare Professionals that is supported, either financially or administratively, by a Complying Member(s).

Final decision refers to the decision made by the Code Complaints Committee including any subsequent review made by CCC as requested by the Complainant and/or the Respondent and as written up by the Chairman of the Committee.

GCRP means Good Clinical Research Practice.

Generic Medicine means a medicine that is referenced to an originator medicine and included on the ARTG. It has the same active ingredient as the originator medicine.

GBMA means the Generic and Biosimilar Medicines Association

GMiA means the Generic Medicines Industry Association Pty Ltd trading as the GBMA.

GMP means Good Manufacturing Practice.

Health Consumer Organisation means any organisation that represents the health interests of Consumers.

Healthcare Professional means a health care professional as defined in the Therapeutic Goods Advertising Code.

Industry means that sector of the healthcare and medical industry that is engaged in the manufacture, import, marketing and distribution of items included on the ARTG.

Laws and Regulations means any law or regulation in force in Australia (as applicable to the relevant association) to which any act or omission the subject of the Code applies, including without limitation, the Therapeutic Goods Act (Cth) 1989.

Member means any member or affiliate member of GBMA.

Originator Medicine means the medicine included as a new chemical or biological entity on the ARTG for a particular molecule. The originator medicine is typically patent protected at launch.

PBS means the Pharmaceutical Benefits Scheme administered by the Department of Health and Ageing (Cth).

Pharmacy Staff means an employee or agent of a pharmacy who is not a registered pharmacist.

Prescriber has the meaning given in Section 84 of the National Health Act (Cth) 1953.

Prescription Medicine means a medicine included on the Australian Register of Therapeutic Goods that requires a prescription to be written by an authorised Healthcare Professional prior to the dispensing of that medicine.

Product means a Generic or Biosimilar Medicine as that term is defined in the Therapeutic Goods Act (Cth) 1989.

Professional Association means a clinical or other professional body representing Healthcare Professionals.

Promote / Promotion(al), in relation to a Product, means any activity that, directly or indirectly promotes or encourages the use or supply of a Product for a therapeutic purpose.

QUM means the quality use of medicines.

Regulator means a government agency performing a statutory regulatory function.

Respondent means, in relation to a Complaint, the Complying Member whose conduct is the subject of the Complaint.

Scheduled Medicine has the meaning given to that phrase in the Therapeutic Goods Act (Cth) 1989.

Sponsor in relation to a product means the entity listed on the ARTG in relation to a Generic or Biosimilar Medicine as the Sponsor, as defined in the Therapeutic Goods Act (Cth) 1989.

Stakeholder covers all persons, groups and organisations that have a relevant interest in the use of Generic and Biosimilar Medicines in Australia and includes Consumers, Government, Healthcare Professionals and Industry.

Therapeutic Good has the meaning given to that phrase, in the Therapeutic Goods Act (Cth) 1989.



GBMA
Generic and Biosimilar
Medicines Association

Making medicines affordable

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