Generic Medicines Industry Association Pty Ltd

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Generic Medicines Industry Association

Code of Practice

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2nd Edition

For further details please contact

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1. Table of Contents

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2. Introduction

2.1 The Generic Medicines Industry Association (GMiA) accepts as Members Australian entities that predominantly manufacture and/or sell Generic Medicines (Products) in the Australian Market and/or manufacture Generic Medicines for export.

2.2 Adoption of and compliance with this Code is a condition of Membership to the GMiA.

2.3 Entities that predominantly manufacture and/or sell Generic Medicines (Products) in the Australian Market and/or manufacture Generic Medicines for export who are not a member of the GMiA are able to adopt and agree to comply with the terms of this Code. Entities adopting this Code agree to contribute to the costs of administering the Code.

2.4 The GMiA Code of Practice is principle based, providing guidance in a single document, on the different legislation, regulation and guidelines with which Sponsors of Generic 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 Members, members of other associations, Healthcare Professionals or the public.

2.5 The Trade Practices Act (Cth) 1974 aims to enhance the welfare of Australians by promoting competition and fair trading and providing for consumer protection. Members of GMiA must comply with the provisions of the Trade Practices Act (Cth) 1974. In particular, Members promote competition in the Generic Medicines industry sector and 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 or generic brands. Therefore, Generic Medicines comply with the same manufacturing quality and safety standards as the Originator Medicine.

2.7 Generic medicines are as safe as the original medicines. Generic 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 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 Medicine to be listed on the ARTG, the Sponsor of the medicine demonstrates, to the TGA, the Product to be bioequivalent or therapeutically equivalent to the Originator Medicine. 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. Such medicines are marked as "a" flagged to the Originator Medicine in the PBS. 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 effect.

2.10 Generic 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 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, Members of GMiA comply with the highly sophisticated and strict TGA regulatory requirements, the 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 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 Generic 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. Members of GMiA 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 Medicines and sets out the best practice standards, aligned with that unique operating environment required of all Members.

3. Objectives

3.1 The purpose of the Code of Practice is to:

Formalise the commitment of the 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 Medicines by Consumers, Healthcare Professionals and Government.

iii. Promote timely access for all consumers to safe and cost effective Generic Medicines.

iv. Identify the unique objectives of the Generic 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 Members to promote and maintain a culture of ethical supply of Generic Medicines.

vi. Promote ethical and professional conduct by all Members and their employees in the manufacture, supply and marketing of Generic 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 Members.

ix. To establish a Code Complaints Committee to consider complaints about Members and impose sanctions in appropriate cases.

x. To establish an educational event reporting procedure that requires Members to report on the Educational Events run by Members for Healthcare Professionals responsible for prescribing prescription medicines.

4. Principles

4.1 The guiding principles of the Members of the GMiA are:

i. To support the long term sustainability of the PBS by ensuring the timely and cost effective provision of Generic Medicines to consumers.

ii. To support the quality use of medicines (QUM) in partnership with other stakeholders.

iii. To support the development of policies that facilitate timely access to Generic Medicines for all Australians.

iv. To support the development of policies that promote the continued viability of a local manufacturing base for Generic 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 Medicines.

vii. To enhance the accountability of Members by establishing a complaints handling mechanism that is both readily accessible and transparent.

viii. To reduce actual and potential conflicts of interest between Members and Healthcare Professionals responsible for prescribing prescription medicines by establishing an Educational Event reporting procedure with independent review.

5. Coverage

5.1 Members of the GMiA are bound by the Code. As at March 2010 there were 5 Members of the GMiA, which supply more than 90% of Generic Medicines prescribed through the PBS.

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5.2 The Code may also serve as guidance for the suppliers of Generic Medicines that are not Members of GMiA. Suppliers of Generic Medicines that are not Members of GMiA are encouraged to adopt and comply with the Code. Such suppliers who agree to adopt and comply with the Code will be known as Affiliate Members of GMiA.

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6.GMiA Code of Practice

6.1 Application of GMiA Code of Practice

6.1.1 This Code applies to all activities and Products of all Members and Affiliate Members of GMiA. In applying the Code, 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 Members may manufacture and/or sell other therapeutic goods in addition to Generic Medicines (Products).This Code applies to all therapeutic goods manufactured and/or sold by the Member.

6.1.3 Members conduct a range of commercial and marketing activities.

6.2 Australia's National Medicines Policy

6.2.1 The 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 Quality use of medicines

6.3.1 The 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.

6.3.2 The 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.

6.4 Manufacture

6.4.1 Members establish and maintain systems and processes to ensure that the Member manufactures and/or procures the manufacture of their Products in compliance with the Australian Code of Good Manufacturing Practice (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 March 2008 as amended or replaced from time to time) and applicable occupational health and safety, and environmental laws.

i. Members manufacturing Product in Australia comply with the Australian Code of Good Manufacturing Practice for Medicinal Products (16 August 2002), as amended or replaced from time to time.
ii. 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.

6.5 Supply and distribution of Generic Medicines

6.5.1 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 Trade Practices Act (Cth) 1974 and Regulations and the National Health Act (Cth) 1953 and Regulations.

6.5.2 Members supply, distribute and market Generic 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 and the Therapeutic Goods Advertising Council 2007.

6.6 Safety of Generic Medicines

6.6.1 All Members establish and maintain effective systems and processes to ensure compliance with the "Guidelines on the reporting of adverse drug reactions by drug sponsors" and related pharmacovigilance documents issued by the TGA, for registered prescription and registered or listed non-prescription medicines for which they are the Sponsor.

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

6.6.3 All 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. Members comply

with all recall action in accordance with the provisions of the Therapeutic Goods Act (Cth) 1989.

6.6.4 All 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.

6.7 Substitution of Generic Medicines

6.7.1 Generic Medicines are medicines that have been demonstrated to be bioequivalent or therapeutically equivalent 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.

6.7.2 Members of GMiA support the, "Guidelines for Pharmacists on PBS brand substitution" endorsed by the National Council of the Pharmaceutical Society of Australia in 2004.

6.7.3 The patient's health should always be the pharmacist's prime consideration in any brand substitution decision. Pharmacists should endeavour to be consistent in the selection of brands for patients on long-term therapy in order to avoid patient confusion. If this is not possible then the patient should be consulted.

6.8 Relationship with Stakeholders

6.8.1 Behaviour of Members recognises and supports 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.

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

6.8.3 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 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.

6.8.4 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.

6.8.5 Members recognise the joint Consumer Health Forum and Medicines Australia publication, "A Guide to relationships between Health Consumer Organisations and Pharmaceutical Companies".

6.9 Promotional and marketing activities

6.9.1 All Members shall promote and market Products in accordance with the applicable requirements of the Therapeutic Goods Act (Cth) 1989 and Regulations, the Trade Practices Act (Cth) 1974, the Therapeutic Goods Advertising Code 2007, the National Health Act (Cth) 1953 and all other applicable laws and codes.

6.9.2 Members will comply with the Medicines Australia Code of Conduct to the extent it applies to promotional material of Prescription Medicines as a condition of registration on the ARTG.

6.9.3 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 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.

6.9.4 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 Members of GMiA should be socially responsible.

6.9.5 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 Member's promotional and marketing material may be made to the Code Complaint Committee for adjudication and, in appropriate cases, imposition of sanctions.

6.9.6 Members may, from time to time, hold or sponsor Educational Events to further the medical and pharmaceutical knowledge of Prescribers and Healthcare Professionals. Educational Events must not bring the Generic Medicines industry sector into disrepute or reduce public confidence in the Industry. Members are required to report on Educational Events provided to Healthcare Professionals responsible for prescribing medicines.

6.9.7 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.

6.9.8 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.

6.10 Product availability

6.10.1 For all PBS listed Products, 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.

6.11 Research and regulatory activities

6.11.1 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.

6.12 Corporate governance

6.12.1 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 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 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 Member.

6.12.2 In addition, all 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 Medicines within Australia and the principles of the quality use of medicines.

7.Stakeholder awareness

7.1 The GMiA shall publicise the existence of the Code to Members, Healthcare Professionals, Consumers, Government departments and agencies, consumer organisations, the general public and other interested parties.

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

7.3 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 Medicines.

7.4 Information concerning a Member's Product can only be provided to Consumers according to 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, 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. Code awareness by Members

8.1 Ultimate responsibility for the observance of the GMiA Code lies with each Member. All Members will 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 medicines; and
vii. act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.

9. Implementation

9.1 The primary responsibility for the enforcement of this Code with any GMiA Member rests with the GMiA.

9.2 The primary responsibility for the enforcement of the Code against any employees, contractors, agents or representatives of a GMiA Member rests with the respective Member.

10. Educational Event reporting

10.1 Members recognise that the promotional activities of pharmaceutical companies can affect the way Healthcare Professionals make decisions in relation to the prescribing and dispensing of Generic Medicines.

10.2 In the context of Generic Medicines, it is the Prescriber who, on behalf of the patient, selects the appropriate treatment intervention, which may be a Generic Medicine. Members must observe the following principles in relation to any Educational Events which they provide to Healthcare Professionals:

i. the purpose of all Educational Events must be to provide current and relevant medical information to Healthcare Professionals;

ii. before offering any Educational Event to Healthcare Professionals the Member must be satisfied that there is a genuine medical need for the particular Educational Event;
iii. the name of the 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. 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. Members must ensure all Educational Events devote at least seventy five percent of the scheduled conference time to the provision of educational content;
vi. Members must not pay for meals, accommodation or travel for any relative or associate of a participant at an Educational Event;
vii. Members must take all reasonable steps to minimise the cost of Educational Events, for example by charging participants a registration fee, by selecting less expensive conference facilities, or by conducting educational events in major cities rather than in remote areas; and
viii. 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.

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10.3 Each Member will provide a report to GMIA on all Educational Events for Healthcare Professionals who prescribe prescription medicines which are held or sponsored by that Member:

i. by completing the table as set out at Appendix 2 to this Code; and
ii. by providing a copy of the completed table for the period 1 April to 30 September and 1 October to 31 March in each year within two months of the end of each six-month period.

10.4 GMiA will forward these reports to the Independent Reviewer for review. The Independent Reviewer will refer any educational event reports which he or she believes may contravene the provisions of this Code to the Code Complaint Committee for its consideration and, in appropriate cases, the imposition of a sanction.

10.5 The Educational Events reports provided by each Member will be posted on the GMiA website within four months of the applicable period end.

11. Internal Complaints handling

11.1 Complaints Handling Systems administered by the Member internally

11.1.1 Members will establish and maintain a system for dealing with complaints from Consumers and/or Healthcare Professionals.

11.1.2 The Members' Complaints Handling System will be consistent with the requirements of the relevant Australian Standard – *Consumer Satisfaction – Guidelines for complaints handling in organisations – AS ISO 10002 – 2006 (Relevant Standard).*

11.1.3 The Members' Complaints Handling System will adopt the following guiding principles, these guiding principles are quoted from the Relevant Standard

i. **Visibility** – 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.

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ii. **Accessibility** – Members should ensure that consumers can lodge a complaint by completing an on-line form or by telephone or letter.

iii. **Responsiveness** – Members will ensure that they acknowledge receipt of a complaint within 5 business days and that they provide a substantive response to the complaint within 15 business days.

iv. **Objectivity** – 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 no be charge for lodging a complaint by a consumer and/or a Healthcare Professional to a Member.

vi. **Confidentiality** – 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** – Members will adopt a consumer-focused approach to dealing with complaints by making their systems accessible and objective.

viii. **Accountability** – Members will retain detailed records of all complaints received, including the following information:

- Complainants 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** – 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.

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

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

12. External Complaints Handling System

12.1 Code Complaint Committee administered by GMiA

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

12.1.2 In the event that the GMiA receives a complaint from a Stakeholder which has not yet been directed to the relevant Member, GMiA will recommend to the Stakeholder that they utilise the Member's complaint handling system in the first instance.

12.1.3 If the Stakeholder is not satisfied with the action or decision of the Member, the Stakeholder may refer the complaint to the GMiA Code Complaint Committee (CCC) via the GMiA secretariat.

12.1.4 Complaints are to be made in writing to the GMiA.

12.1.5 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 GMiA keep this information confidential.

12.1.6 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.

12.1.7 On receipt of information from a Complainant, the Chief Executive Officer of GMiA or delegate shall acknowledge the complaint in writing within ten (10) business days of receipt.

12.1.8 The Member of GMiA that is the subject of the Complaint (the Respondent) shall be given full details of the Complaint lodged with GMiA to enable the 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 GMiA Secretariat.

12.1.9 All information pertaining to the Complaint is required to be kept confidential until the Complaint is deemed finalised.

12.1.10 The Respondent and Complainant will provide GMiA with whatever references or information is deemed to be reasonably necessary for the CCC to consider the Complaint.

12.1.11 All relevant information in relation to the complaint, including the initial complaint, the Member response and any response from the Complainant, shall be provided to the CCC via the GMiA secretariat within fifteen (15) business days of the Member's response being received.

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

12.1.13 The CCC will consist of eight (8) members:

i. an independent chairperson who must be legally trained and have experience in trade practices law,
ii. a Consumer representative,
iii. a Pharmacy representative,
iv. a Medical representative,
v. three representatives from member companies including a representative from the GMiA Board and wherever possible including individuals providing expertise in the disciplines of marketing, scientific and legal. Company representatives are appointed on an ad hoc basis at such times that the CCC is required to convene. Company representatives must declare any conflict of interest before their ad hoc appointment to the CCC by means of reviewing the agenda for the CCC meeting prior to accepting the position. GMiA will endeavour to appoint company representatives from different companies as far as possible.
vi. an observer nominated by the Therapeutic Goods Administration.

12.1.14 A quorum of six members of the CCC or Appeal CCC is required of which at least four members have to be independent representatives

12.1.15 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. The power to identify alternative members only applies to independent representatives and not company representatives.

12.1.16 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.

12.1.17 The CCC will convene as required to consider complaints and referrals from the Independent Reviewer. The CCC will endeavour to convene within forty (40)

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<#>a representative from a member company with marketing expertise, ¶
<#>a representative from a member company with legal expertise, and ¶
<#>a representative from a member company with scientific expertise. ¶

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business days of receiving information about a complaint from the GMiA Secretariat or a referral from the Independent Reviewer.

12.1.18 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 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.

12.1.19 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.

12.1.20 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.

12.1.21 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.

12.1.22 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.

12.1.23 The CEO of the GMiA 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 GMiA. In the case of referrals from the Independent Reviewer, the Decision is to be provided to the relevant Member and the Board of GMiA.

12.1.24 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 GMiA Secretariat within fifteen (15) business days of the Respondent and Complainant being provided the CCC's Final Decision.

12.1.25 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.

12.1.26 The Appeal CCC is to convene within forty (40) business days of the date of lodgement 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.

12.1.27 The CEO of the GMiA 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 GMiA.

12.1.28 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.

12.1.29 All Final Decisions of the CCC will be published on the GMiA website after all appeal rights have been exhausted. The GMiA 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.

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

12.1.31 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.

13. Independent Reviewer

13.1 The GMiA Board will appoint an independent reviewer for a period of two (2) years. At the end of this period, the Independent Reviewer will be eligible for reappointment.

13.2 The Independent Reviewer will be responsible for reviewing the Educational Event Reports submitted by Member. His/ her role will be to determine whether any events disclosed in Educational Event Reports may potentially breach the Code.

13.3 The Independent Reviewer will also be responsible for conducting spot audits of Member's marketing and promotional material to determine compliance with this Code. The Independent Reviewer will request copies of marketing and promotional material from Members in relation to particular products on two separate occasions each year.

13.4 If the Independent Reviewer forms the opinion that an Educational Event or marketing / promotional material may breach the Code, he or she can refer the matter to the CCC for further consideration.

13.5 In the event that the Independent Reviewer forms the view that an Educational Event or marketing / promotional material may breach the Code, he/ she is to prepare a short note outlining the basis for his or her concerns. This document is to be provided to the CCC and the relevant Member.

13.6 The Independent Reviewer will consider the Educational Event Reports from Members twice a year. The Independent reviewer will endeavour to consider the Educational Event Reports within three (3) months of the date the Reports were submitted.

13.7 The Independent Reviewer must be legally trained and have experience in trade practices law. The Independent Reviewer must not have or have had any professional or personal affiliation with either GMiA or any Member prior to being initially appointed to the role of Independent Reviewer.

13.8 There are no appeal rights from a decision by the Independent Reviewer to refer an educational event or marketing / promotional material to the CCC for its consideration.

13.9 The Independent Reviewer is to prepare a short report each year containing the following information:

a general statement on the level of compliance by Members with the Educational Event reporting obligations under the Code;

- a description of the matters he/she has referred to the CCC; and
- any suggested changes to the Educational Event reporting system which may, in his/her opinion, enhance the effectiveness or transparency of the system.

13.10 The Independent Reviewer report will be available on the GMiA website and will be distributed to interested parties including Government, peak bodies of Healthcare Professional and peak bodies of Consumer groups.

13.11 The Board of GMiA is to have due regard to any recommendations made by the Independent Reviewer in his or her report but it is not required to implement any particular recommendation from the Independent Reviewer.

14. Sanctions

14.1 Classification of breach

14.1.1 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 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 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 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 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 24 months.

14.2 Application of sanctions

14.2.1 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 15 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 of 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 GMiA 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

14.2.2 In the event that the CCC requires a Respondent to cease a 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.

14.2.3 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 Member or Complainant lodges request for a review and/or an appeal until the review and/or appeal has been determined. A Member is not required to pay a financial sanction until it has exhausted its right of appeal.

15. Code administration

15.1 Code Administration Committee (CAC)

15.1.1 The CAC comprises an independent chairperson, the CEO of GMiA, a representative from the Board of GMiA and a GMiA representative with legal expertise.

15.1.2 The CAC will convene at least once a year

15.1.3 The CAC's role is to use all reasonable endeavours to ensure the successful implementation and ongoing effectiveness of the Code.

15.1.4 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.

15.1.5 The CAC provides an annual review report summary for the GMiA 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 GMiA website. A template of the report is attached as appendix 1 to this Code.

15.1.6 The CAC will provide an annual report for the GMiA 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 GMiA website. A template of the report is attached as appendix 1 to this Code.

15.1.7 The CCC may make recommendations to the Board of GMiA to change the way the CCC operates. The Board of GMiA is to have due regard to any recommendations made by the CCC in its report but it is does not have to implement any particular recommendation made by the CCC.

16. Annual report & ongoing review

16.1 The Board will produce an annual report on the operation of this Code. The annual report will incorporate the annual report of 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; and

ii. A summary of monitoring activities.

16.2 The annual report will be available on the GMiA website and be distributed to interested parties including Government, peak bodies of Healthcare Professional, peak bodies of Consumer groups and the ACCC.

16.3 GMiA will encourage ongoing dialogue, consultation and review of the Code during the life of the Code.

16.4 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.

17. Amendment

17.1 This Code may be amended by vote of [two-thirds] of Members present and entitled to vote at a Board Meeting of the GMiA, properly convened and held.

18. Appendix 1

Annual 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 GMiA 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.

19. Appendix 2

Reporting of Educational Events template

Summary of events sponsored by [insert Member name]

Reporting Period: [insert reporting period]

Description of event	Venue	Description of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of event
	Specify location	Specify professional expertise of attendees	Include food, beverages, accommodation, entertainment, travel etc			
One row per event						

20. 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.

Board means the board of directors of GMiA.

Breach means a breach of any provision of this Code.

Code means the GMiA 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 GMiA under the Code.

Complaint means a complaint lodged with GMiA under 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 event that is supported, either financially or administratively, by a Member(s) and attended by prescribing Healthcare Professionals.

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.

GMiA means the Generic Medicines Industry Association Pty Ltd.

GMP means Good Manufacturing Practice.

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

Healthcare Professional means a health care 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 GMiA.

Originator Medicine means the medicine included as a new chemical 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 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 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 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 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.