# Form A

Commonwealth of Australia

*Trade Practices Act 1974 — subsections 88 (1A) and (1)*

## EXCLUSIONARY PROVISIONS AND ASSOCIATED CARTEL PROVISIONS: APPLICATION FOR AUTHORISATION

To the Australian Competition and Consumer Commission:
Application is hereby made under subsection(s) 88 (1A)/88 (1) of the *Trade Practices Act 1974* for an authorisation:

- to make a contract or arrangement, or arrive at an understanding, a provision of which would be, or might be, a cartel provision within the meaning of Division 1 of Part IV of that Act and which would also be, or might also be, an exclusionary provision within the meaning of section 45 of that Act.

- to give effect to a provision of a contract, arrangement or understanding that is, or may be, a cartel provision within the meaning of Division 1 of Part IV of that Act and which is also, or may also be, an exclusionary provision within the meaning of section 45 of that Act.

- to make a contract or arrangement, or arrive at an understanding, where a provision of the proposed contract, arrangement or understanding would be, or might be, an exclusionary provision within the meaning of section 45 of that Act.

- to give effect to a provision of a contract, arrangement or understanding where the provision is, or may be, an exclusionary provision within the meaning of section 45 of that Act.

*(Strike out whichever is not applicable)*

PLEASE FOLLOW DIRECTIONS ON BACK OF THIS FORM

**1. Applicant**

(a) Name of Applicant:
*(Refer to direction 2)*

A91218 **Generic Medicines Industry Association Pty Ltd.**

(b) Description of business carried on by applicant:
*(Refer to direction 3)*

**Industry body representing the interests of suppliers of generic medicines in Australia.**

(c) Address in Australia for service of documents on the applicant:

**GMiA Pty Ltd**
**PO Box 222**
**Pymble BC NSW 2073**

AUST. COMPETITION & CONSUMER COMMISSION CANBERRA
31 MAR 2010

## 2. Contract, arrangement or understanding

(a) Description of the contract, arrangement or understanding, whether proposed or actual, for which authorisation is sought:
*(Refer to direction 4)*

**GMiA Members are proposing to introduce and be bound by a Code of Conduct which includes provisions for taking disciplinary action against GMiA Members who breach the Code.**

**See the attached GMiA Code of Conduct.**

(b) Description of those provisions of the contract, arrangement or understanding described at 2 (a) that are, or would or might be, exclusionary provisions and (if applicable) are, or would or might be, cartel provisions:
*(Refer to direction 4)*

**GMiA Members are proposing to introduce and be bound by a Code of Conduct which includes provisions for taking disciplinary action against GMiA Members who breach the Code.**

**See the attached GMiA Code of Conduct.**

(c) Description of the goods or services to which the contract, arrangement or understanding (whether proposed or actual) relate:

**Generic medicines.**

(d) The term for which authorisation of the provision of the contract, arrangement or understanding (whether proposed or actual) is being sought and grounds supporting this period of authorisation:

**Five years.**

## 3. Parties to the proposed arrangement

(a) Names, addresses and descriptions of business carried on by other parties or proposed parties to the contract or proposed contract, arrangement or understanding:

**See attached GMiA Member list.**

(b) Names, addresses and descriptions of business carried on by parties and other persons on whose behalf this application is made:
*(Refer to direction 5)*

**Not applicable.**

## 4. Public benefit claims

(a) Arguments in support of application for authorisation:
*(Refer to direction 6)*

**See Part 9 of the GMiA Submission to the ACCC dated 30 March 2010 (GMiA Submission)**

(b) Facts and evidence relied upon in support of these claims:

**See Part 9 of the GMiA Submission.**

**5. Market definition**

Provide a description of the market(s) in which the goods or services described at 2 (c) are supplied or acquired and other affected markets including: significant suppliers and acquirers; substitutes available for the relevant goods or services; any restriction on the supply or acquisition of the relevant goods or services (for example geographic or legal restrictions):
*(Refer to direction 7)*

**See Part 7 of the GMiA Submission.**

**6. Public detriments**

(a) Detriments to the public resulting or likely to result from the contract arrangement or understanding for which authorisation is sought, in particular the likely effect of the contract arrangement or understanding, on the prices of the goods or services described at 2 (c) and the prices of goods or services in other affected markets:
*(Refer to direction 8)*

**See Part 10 of the GMiA Submission.**

(b) Facts and evidence relevant to these detriments:

**See Part 10 of the GMiA Submission.**

**7. Contracts, arrangements or understandings in similar terms**

(a) This application for authorisation may also be expressed to be made in relation to other contracts, arrangements or understandings or proposed contracts, arrangements or understandings, that are or will be in similar terms to the abovementioned contract, arrangement or understanding:

(b) Is this application to be so expressed?

**No**

(c) If so, the following information is to be furnished:

(i) description of any variations between the contract, arrangement or understanding for which authorisation is sought and those contracts, arrangements or understandings that are stated to be in similar terms:
*(Refer to direction 9)*

**Not applicable**

(ii) Where the parties to the similar term contract(s) are known — names, addresses and descriptions of business carried on by those other parties:
*(Refer to direction 10)*

**Not applicable.**

(iii) Where the parties to the similar term contract(s) are not known — description of the class of business carried on by those possible parties:

**Not applicable.**

**8. Joint Ventures**

(a) Does this application deal with a matter relating to a joint venture (See section 4J of the *Trade Practices Act 1974*)?

**No.**

(b) If so, are any other applications being made simultaneously with this application in relation to that joint venture?

**Not applicable.**

(c) If so, by whom or on whose behalf are those other applications being made?

**Not applicable.**

**9. Further information**

(a) Name, postal address and telephone contact details of the person authorised by the applicant seeking authorisation to provide additional information in relation to this application:

**Kate Lynch**
**CEO**
**Generic Medicines Industry Association**
**PO Box 222**
**Pymble BC NSW 2073**
**Email: kate.lynch@gmia.com.au**
**Phone: 0432 500 308**

**Michael Terceiro**
**Terceiro Legal Consulting**
**PO Box 488**
**Haberfield NSW 2045**
**Email – michael@terceiro.com.au**
**Phone – (02) 8086 2006**

Dated **30 March 2010**

Signed by/on behalf of the applicant

**Kate Lynch**
(Full Name)

**GMiA**
(Organisation)

**Chief Executive Officer**
(Position in organisation)

**DIRECTIONS**

1. Use Form A if the contract, arrangement or understanding includes a provision which is, or might be, a cartel provision and which is also, or might also be, an exclusionary provision. Use Form B if the contract, arrangement or understanding includes a provision which is, or might be, a cartel provision or a provision which would have the purpose, or would or might have the effect, of substantially lessening competition. It may be necessary to use both forms for the same contract, arrangement or understanding.

   In lodging this form, applicants must include all information, including supporting evidence, that they wish the Commission to take into account in assessing their application for authorisation.

   Where there is insufficient space on this form to furnish the required information, the information is to be shown on separate sheets, numbered consecutively and signed by or on behalf of the applicant.

2. Where the application is made by or on behalf of a corporation, the name of the corporation is to be inserted in item 1 (a), not the name of the person signing the application and the application is to be signed by a person authorised by the corporation to do so.

3. Describe that part of the applicant's business relating to the subject matter of the contract, arrangement or understanding in respect of which authorisation is sought.

4. Provide details of the contract, arrangement or understanding (whether proposed or actual) in respect of which the authorisation is sought. Provide details of those provisions of the contract, arrangement or understanding that are, or would or might be, exclusionary provisions. Provide details of those provisions of the contract, arrangement or understanding that are, or would or might be, cartel provisions.

   In providing these details:

   (a) to the extent that any of the details have been reduced to writing, provide a true copy of the writing; and

   (b) to the extent that any of the details have not been reduced to writing, provide a full and correct description of the particulars that have not been reduced to writing.

5. Where authorisation is sought on behalf of other parties provide details of each of those parties including names, addresses, descriptions of the business activities engaged in relating to the subject matter of the authorisation, and evidence of the party's consent to authorisation being sought on their behalf.

6. Provide details of those public benefits claimed to result or to be likely to result from the proposed contract, arrangement or understanding including quantification of those benefits where possible.

7. Provide details of the market(s) likely to be effected by the contract, arrangement or understanding in particular having regard to goods or services that may be substitutes for the good or service that is the subject matter of the application for authorisation.

8. Provide details of the detriments to the public, including those resulting from any lessening of competition, which may result from the proposed contract, arrangement or understanding. Provide quantification of those detriments where possible.

9. Where the application is made also in respect of other contracts, arrangements or understandings, which are or will be in similar terms to the contract, arrangement or understanding referred to in item 2, furnish with the application details of the manner in which those contracts, arrangements or understandings vary in their terms from the contract, arrangements or understanding referred to in item 2.

10. Where authorisation is sought on behalf of other parties provide details of each of those parties including names, addresses, and descriptions of the business activities engaged in relating to the subject matter of the authorisation, and evidence of the party's consent to authorisation being sought on their behalf.

Schedule of Members of GMiA

| Member organisation | Board representative | Representative of Body Corporate |
|---|---|---|
| Alphapharm Pty Ltd<br>ABN 93 002 359 739<br><br>Cnr Wentworth Park Rd & Bay St<br>Chase Building 2<br>Glebe NSW 2037 | | Same as Board representative |
| Apotex Pty Ltd<br>ABN 52 096 916 148<br>L2 / 66 Waterloo Road<br>North Ryde NSW 2113 | | Same as Board representative |
| Genepharm (Australia) Limited<br>ABN 17 003 854 626<br><br>151-153 Clarendon St<br>South Melbourne VIC 3205 | | Same as Board representative |
| Hospira Pty Limited<br>ABN 13 107 058 328<br><br>Level 6, 390 St Kilda Road<br>Melbourne VIC 3004 | | Same as Board representative |
| Sigma Pharmaceuticals Limited<br>ABN 15 088 417 403<br><br>96 Merrindale Drive<br>South Croydon VIC 3136 | | Same as Board representative |

# Form B

Commonwealth of Australia

*Trade Practices Act 1974 — subsections 88 (1A) and (1)*

## AGREEMENTS AFFECTING COMPETITION OR INCORPORATING RELATED CARTEL PROVISIONS: APPLICATION FOR AUTHORISATION

To the Australian Competition and Consumer Commission:
Application is hereby made under subsection(s) 88 (1A)/88 (1) of the *Trade Practices Act 1974* for an authorisation:

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- to give effect to a provision of a contract, arrangement or understanding that is, or may be, a cartel provision within the meaning of Division 1 of Part IV of that Act (other than a provision which is also, or may also be, an exclusionary provision within the meaning of section 45 of that Act).

  to make a contract or arrangement, or arrive at an understanding, a provision of which would have the purpose, or would or might have the effect, of substantially lessening competition within the meaning of section 45 of that Act.

- to give effect to a provision of a contract, arrangement or understanding which provision has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45 of that Act.

  *(Strike out whichever is not applicable)*

PLEASE FOLLOW DIRECTIONS ON BACK OF THIS FORM

**1. Applicant**

(a) Name of Applicant:
*(Refer to direction 2)*

A91219 **Generic Medicines Industry Association Pty Ltd.**

(b) Short description of business carried on by applicant:
*(Refer to direction 3)*

**Industry body representing the interests of suppliers of generic medicines in Australia.**

(c) Address in Australia for service of documents on the applicant:

**GMiA Pty Ltd**
**PO Box 222**
**Pymble BC NSW 2073**

## 2. Contract, arrangement or understanding

(a) Description of the contract, arrangement or understanding, whether proposed or actual, for which authorisation is sought:
*(Refer to direction 4)*

**GMiA Members are proposing to introduce and be bound by a Code of Conduct which includes provisions for taking disciplinary action against GMiA Members who breach the Code.**

**See the attached GMiA Code of Conduct.**

(b) Description of those provisions of the contract, arrangement or understanding described at 2 (a) that are, or would or might be, cartel provisions, or that do, or would or might, have the effect of substantially lessening competition:
*(Refer to direction 4)*

**GMiA Members are proposing to introduce and be bound by a Code of Conduct which includes provisions for taking disciplinary action against GMiA Members who breach the Code.**

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(c) Description of the goods or services to which the contract, arrangement or understanding (whether proposed or actual) relate:

**Generic medicines.**

(d) The term for which authorisation of the contract, arrangement or understanding (whether proposed or actual) is being sought and grounds supporting this period of authorisation:

**Five years.**

## 3. Parties to the proposed arrangement

(a) Names, addresses and descriptions of business carried on by other parties or proposed parties to the contract or proposed contract, arrangement or understanding:

**See attached GMiA Member list.**

(b) Names, addresses and descriptions of business carried on by parties and other persons on whose behalf this application is made:
*(Refer to direction 5)*

**Not applicable.**

## 4. Public benefit claims

(a) Arguments in support of authorisation:
*(Refer to direction 6)*

**See Part 9 of the GMiA Submission to the ACCC dated 30 March 2010 (GMiA Submission)**

(b) Facts and evidence relied upon in support of these claims:

**See Part 9 of the GMiA Submission.**

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**See Part 7 of the GMiA Submission.**

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(a) Detriments to the public resulting or likely to result from the authorisation, in particular the likely effect of the contract, arrangement or understanding, on the prices of the goods or services described at 2 (c) and the prices of goods or services in other affected markets:
*(Refer to direction 8)*

**See Part 10 of the GMiA Submission.**

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(a) Is this application to be so expressed?

**No.**

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**Not applicable**

(ii) Where the parties to the similar term contract(s) are known — names, addresses and descriptions of business carried on by those other parties:

**Not applicable**

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**No.**

(b) If so, are any other applications being made simultaneously with this application in relation to that joint venture?

**Not applicable**

(c) If so, by whom or on whose behalf are those other applications being made?

**Not applicable**

**9. Further information**

(a) Name and address of person authorised by the applicant to provide additional information in relation to this application:

**Kate Lynch**
**CEO**
**Generic Medicines Industry Association**
**PO Box 222**
**Pymble BC NSW 2073**
**Email: kate.lynch@gmia.com.au**
**Phone: 0432 500 308**

**Michael Terceiro**
**Terceiro Legal Consulting**
**PO Box 488**
**Haberfield NSW 2045**
**Email – michael@terceiro.com.au**
**Phone – (02) 8086 2006**

Dated **30 March 2010**

Signed by/on behalf of the applicant

**Kate Lynch**
(Full Name)

**GMiA**
(Organisation)

**Chief Executive Officer**
(Position in organisation)

## DIRECTIONS

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4. Provide details of the contract, arrangement or understanding (whether proposed or actual) in respect of which the authorisation is sought. Provide details of those provisions of the contract, arrangement or understanding that are, or would or might be, cartel provisions. Provide details of those provisions of the contract, arrangement or understanding that do, or would or might, substantially lessen competition.

   In providing these details:

   (a) to the extent that any of the details have been reduced to writing, provide a true copy of the writing; and

   (b) to the extent that any of the details have not been reduced to writing, provide a full and correct description of the particulars that have not been reduced to writing.

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7. Provide details of the market(s) likely to be effected by the contract, arrangement or understanding, in particular having regard to goods or services that may be substitutes for the good or service that is the subject matter of the authorisation.

8. Provide details of the detriments to the public which may result from the proposed contract, arrangement or understanding including quantification of those detriments where possible.

9. Where the application is made also in respect of other contracts, arrangements or understandings, which are or will be in similar terms to the contract, arrangement or understanding referred to in item 2, furnish with the application details of the manner in which those contracts, arrangements or understandings vary in their terms from the contract, arrangements or understanding referred to in item 2.

GMiA

*Generic Medicines Industry Association Pty Ltd*

ABN 19 096 009 540

PO Box 222
Pymble BC
NSW 2073

Generic Medicines Industry Association

# Submission to ACCC in support of Applications for Authorisation of the Generic Medicines Industry Association Code of Practice

30 March 2010

For further details
Please contact
Kate Lynch, CEO
kate.lynch@gmia.com.au

# 1. Table of Contents

# 2. Executive Summary

This submission is being made by the Generic Medicines Industry Association (GMiA) in support of applications for authorisation of the GMiA Code of Conduct (the Code) pursuant to subsections 88 (1A) and (1) of the *Trade Practices Act* 1974 (Cth) (the TP Act).

The second edition of the GMiA Code of Practice for which authorisation is being sought was formally adopted by GMiA members in March 2010.

The second edition of the Code has been built upon previously existing documents. In December 2009, the Board of GMiA endorsed the first edition of the GMiA Code of Practice that was publicly released 1 March 2010. Prior to this, Members endorsed a set of Significant Operating Principles that were drafted in 2005.

The Code seeks to formalise the commitment of GMiA Members to a system of best practice self-regulation and ethical supply of generic medicines to the Australian community in compliance with applicable laws and standards.

The Code also introduces internal and external complaints handling systems, educational event guidelines and reporting requirements and an independent disciplinary Code Complaints Committee (CCC).

Certain provisions of the Code have the potential to contravene section 45 of the TP Act. Accordingly, GMiA is seeking authorisation of the Code. The operation of the Code provides significant public benefits and minimal public detriment.

# 3. Generic Medicines Industry Association

The Generic Medicines Industry Association (GMiA) was established in 2001 to represent the interests of suppliers of generic medicines in Australia.

GMiA seeks to develop good relationships with all constituencies involved in the continued delivery of pharmaceutical care to the Australian community and to contribute to the long-term sustainability of the Pharmaceutical Benefits Scheme (PBS) through support of the principles of the National Medicines Policy.

Members of GMiA:

- Supply > 90% of prescriptions from generic sponsors (PBPA annual report 2008/09)
- Sold 50 million or 33% of prescriptions on PBS (PBPA annual report 2008/09)
- Sold 100 million packs in Australia; a large proportion of the generic sector is below the PBS co-payment (GMiA survey 2009)
- Employ 5,000 Australians; almost half in manufacturing or R&D roles representing functions that generate strong economic multiplier benefits (GMiA survey 2009)
- Exports $470 million in value of pharmaceuticals (GMiA survey 2009) which represents 12% of current pharmaceutical export market or 17% of forecast pharmaceutical market in 2010

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 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.

# 4. The regulatory framework for prescription medicines

The principal Commonwealth statute regulating the manufacture, promotion and supply of medicines and medical devices in Australia is the *Therapeutic Goods Act* 1989 (Cth)(TG Act). The TG Act is administered by the Therapeutic Goods Administration (TGA) which is part of the Commonwealth Department of Health and Ageing.

The TG Act establishes the Australian Register of Therapeutic Goods (the Register) for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use by humans (s 9A). The Register contains three parts:

(1) registered goods;
(2) listed goods; and
(3) medical devices.

The TG Act requires that medicines must be listed or registered on the Register before they can be sold in Australia. Registered medicines can only be supplied if they are accompanied by patient information (reg 9A).

Applications for registration or listing of therapeutic goods are made to the TGA. The TGA issues a marketing approval letter to a pharmaceutical company when the company's application for a particular prescription medicine to be listed or registered on the Register has been approved.

There is a statutory requirement that advertising of registered goods to healthcare professionals must comply with the Therapeutic Goods Advertising Code (ss 42DM and 42DO). Advertising of medicines directly to members of the public is generally prohibited (s 42AA).

The advertising of prescription-only medicines to healthcare professionals is permitted by the TG Act provided that the advertising only refers to the approved uses of product registered in the Australian Register of Therapeutic Goods. Part 5.1 of Chapter 5 of the Act, which deals with advertising and generic information, does not apply to advertisements directed at healthcare professionals (s 42AA).

The *National Health Act 1953* (Cth) (NH Act) established the Pharmaceutical Benefits Scheme in Part VII. When a medicine is "listed" under the PBS the medicine can be supplied for a fixed statutory charge by an approved pharmacist on presentation of a prescription written by a medical practitioner.

# 5. GMiA Code of Conduct

The following section provides a commentary on each of the main clauses of the Code.

***Clause 2 – Introduction***

The purpose of this clause is to provide introductory information about the Code and the generic medicines industry sector.

Clause 2.2 states that adoption and compliance with the Code is a condition of Membership of GMiA.

Clause 2.4 states that the Code is intended to be a principled based Code. It is intended to provide Members and the public in a single document guidance on the different legislation, regulation and guidelines with which sponsors of generic medicines listed on the ARTG comply.

Clause 2.9 discusses one of the unique characteristics of the market for the supply of generic prescription medicines. For a generic medicine to be listed on the ARTG, the relevant manufacturer must demonstrate to the TGA that the product is bioequivalent or therapeutically equivalent to the original branded product. This means that the relevant generic product will have the same active ingredient as the original branded product and the same amount of medicine is available in the body to give the same effect.

Clause 2.10 explains the way in which generic medicines contribute to greater competition in the market for the supply of prescription medicines.

Clause 2.11 lists a number of unique features of the market for the supply of generic medicines as follows:

- 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.
- 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.
- 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.

***Clause 3 – Objectives***

Clause 3 sets out the major objectives of the Code. Clause 3(1)(a) states that a primary objective of the Code 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.*

While a significant objective of the Code is to formalise aspects of the existing system of best practice regulation, an additional objective is to introduce a number of new obligations.

These include:

- Clause 3(1)(h) states that the Code will introduce "an accessible and transparent complaints handling system which consumers can utilise to make complaints about the conduct of Members";
- Clause 3(1)(i) states that the Code is to establish a Code Complaints Committee (CCC) to consider complaints about Members and to impose sanctions in appropriate cases. This CCC will be able to impose sanctions on Members for conduct which breaches existing relevant laws, such as the TG Act and the TP Act, as well as conduct which does not breach any laws but which breaches the Code, relevant guidelines and other codes.
- Clause 3(1)(i) refers to the establishment of an Educational Event guideline and reporting system which Members must follow.

***Clause 4 – Principles***

Clause 4 sets out the guiding principles of the Members of GMiA which are reflected in the Code provisions.

Clause 4(a)(g) states that a guiding principle is to enhance the accountability of Members. This principle is to be given effect by establishing internal and external complaints handling systems which are both accessible and transparent.

Clause 4(a)(h) states that a guiding principle is to reduce both actual and potential conflicts of interest between Members and Healthcare Professionals. This principle is to be put into effect by the establishment of Educational Event guidelines and an educational event reporting mechanism which is subject to independent review.

***Clause 5 – Coverage***

The current members of GMiA account for more than 90% of all generic medicines prescribed through the PBS. Therefore the Code will have significant coverage of the relevant generic medicine sector.

Smaller manufacturers of generic medicines will also be encouraged to adopt and be bound by the Code. GMiA has actively approached six companies and encouraged these companies to become Affiliate Members of the GMiA Code of Practice.

These companies have been kept updated on the progress of the development of the Code of Practice document and have been provided draft copies of the Code document during the development of the Code. These companies have also been advised of key milestones, including advanced notice that GMiA would formally release the first edition of the Code of Practice on 1 March 2010 along with an advanced copy of the first edition of the Code and advanced notice of the intention of GMiA to seek authorisation from the ACCC of the Code of Practice.

GMiA forwarded a formal written invitation extending the opportunity of Affiliate Membership to the GMiA Code of Practice on 26 February 2010 to six companies that supply generic medicines that are not members of GMiA. The CEO has also extended an invitation to meet with the heads of these companies to discuss the benefits of adopting the GMiA Code of Practice.

***Clause 6 – GMiA Code of Practice***

The purpose of this clause is to outline the overarching obligations of Members. For example, clause 6.1.1 makes it clear that Members are expected to abide by both the written requirements of the Code and also the spirit and intended purpose of the Code.

Clause 6.1.2 makes it clear that where Members manufacture and/or sell other therapeutic goods in addition to generic medicines, the Code will apply to all products manufactured and sold by that Member. Clause 6.9 outlines a similar obligation in relation to the promotion and marketing of generic medicines.

Clause 6 also states that Members support:

- the National Medicines Policy;
- the Quality Use of Medicines;
- the Australian Code of Good Manufacturing Practice for Medicinal Products;
- the Guidelines for the Reporting of Adverse Drug Reactions by Drug Sponsors;
- the Uniform Recall Procedures for Therapeutic Goods; and
- the Guidelines for Pharmacists on PBS brand substitution

The clause also makes it clear that Members are committing to the supply and distribution of generic medicines in accordance with the TG Act, TP Act and NH Act. While members are already bound by these laws, in the future it will also be a breach of the Code if Members contravene these laws in relation to the supply of generic medicines.

Clauses 6.8.1 to 6.8.5 outline the way in which Members are to interact with relevant stakeholders. The overriding obligation on Members is to ensure that they avoid actual and potential conflicts of interest in their interactions with stakeholders.

For example, clause 6.8.5 makes it clear that Members recognise the joint Consumer Health Forum and Medicines Australia publication entitled "A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies".

Clause 6.9.5 establishes a system whereby parties can make a complaint to the Code Complaint Committee (CCC) about a Member's promotional material. The role and composition of the CCC will be explained in more detail below. For present purposes, it should be noted that the CCC will be able to adjudicate and impose sanctions on Members in relation to any promotional and marketing material which breaches the Code or other relevant laws, guidelines or codes.

Clause 6.9.6 states that Members are required to report on Educational Events which they provide to Healthcare Professionals responsible for prescribing prescription medicines. The guidelines for Educational Event reporting are explained more fully below.

Clause 6.9.9. places an obligation on Members to ensure that all relevant employees, contractors and agents receive appropriate training about the Code and all other relevant laws, guidelines and codes.

***Clause 7 – Stakeholder Awareness***

This clause requires both Members and the GMiA to publicise the existence of the Code amongst stakeholders and the general public. This clause also requires Members to raise the public's awareness and understanding of generic medicines.

***Clause 8 – Code awareness amongst members***

This clause establishes an obligation on Members to provide on-going training to their employees, contractors and agents so they can develop a full understanding of their obligations under the Code.

The clause also makes it clear that Members have an obligation to avoid actual or potential conflicts of interest in their dealings with Healthcare Professionals.

***Clause 9 – Implementation***

This clause states that the primary responsibility for implementation of the Code rests with the Member.

***Clause 10 – Educational Event Reporting***

This clause establishes a system of Educational Event reporting which Members are bound to implement. The Educational Event reporting applies to events for Healthcare Professional which prescribe generic medicines to patients.

The reporting obligation applies to the Healthcare Professionals which prescribe medicines and not to the Healthcare Professionals which **dispense** medicines. The reason for this approach is because the potential anticompetitive detriments arising from the provision of Educational Events only manifests itself at the prescribing level. As stated by the Tribunal in *Re Medicines Australia Inc.:*

> *In our opinion there is a significant detriment associated with the unrestricted development of non-arms length relationships between pharmaceutical companies and healthcare professionals and particularly those relationships which involve the receipt of benefits by healthcare professionals. The detriment lies in the effect that such conduct may have upon the prescribing practices of healthcare professionals directly influenced by it or by the views of professional opinion leaders who have links to particular companies. If the prescribing practices of healthcare professionals are influenced directly or indirectly by sympathies for particular products because of benefits derived from or links to the manufacturer or distributor of those products, patient care may be compromised. Patients in need of treatment will not necessarily be provided with that which is best for them. In an indirect sense there is also an anti-competitive detriment to the extent that key decisions in the relevant market may be affected by factors extraneous to the quality of the product and its cost*[1].

The dispensing decision made by the Healthcare Professional 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.

Clause 10.5 sets out a number of principles which Members must follow when offering any educational event to Healthcare professionals:

- the purpose of all Educational Events must be to provide current and relevant medical information to Healthcare Professionals;
- before offering any Educational Event to Healthcare Professionals the Member must be satisfied that there is a genuine need for the particular Educational Event;
- 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;
- Members must ensure that the costs of Educational Events are not disproportionate to the value to be gained by participants from the Educational Event;
- Members must ensure that all Educational Events devote at least seventy five percent of the scheduled conference time to the provision of educational content;
- Members must not pay for meals, accommodation or travel for any relative or associate of a participant at an Educational Event, except in exceptional circumstances;
- 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
- 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.

[1] *Re Medicines Australia Inc* [2007] ACompT 4 (27 June 2007) – paragraph 315 - http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/cth/ACompT/2007/4.html

Each Member will be required to report twice a year on the educational events which they sponsor. These reports will be forwarded to the Independent Reviewer who will assess each report for compliance with the Code. The Independent Reviewer will refer any particular event which he or she believes does not comply with the Educational Event guidelines to the CCC. Further detail about this process will be provided below.

***Clause 11 – Internal Complaints Handling***

Clause 11 sets out the complaints handling system which each Member is to implement to deal with complaints. This system has been modelled on the relevant Australian Standard, *Consumer Satisfaction – Guidelines for complaints handling in organisations – ASO ISO 10002 – 2006.*

These internal complaints handlings systems adopt the guiding principles set out in the Australian Standard; namely

- Visibility
- Accessibility
- Responsiveness
- Objectivity
- Cost
- Confidentiality
- Consumer focused approach
- Accountability
- Continual improvement.

The Member's internal complaints handling system will be the first option available to stakeholders who have a complaint about a Member's conduct. If the stakeholder is not satisfied with the response they receive from the Member through their internal complaints handling system, they will be advised by the Member of their right to complain directly to the CCC.

***Clause 12 – External Complaints Handling System***

This clause establishes the external complaints handling system. The primary mechanism for complaints handling will be the Code Complaints Committee (CCC).

If GMiA receives a complaint from a consumer about a Member, they will first suggest to the stakeholder that they utilise the Member's internal complaints handling system.

Under clause 12.1.4, all complaints are required to be in writing.

Under clause 12.1.5, complainants are required to provide their name and contact details and the details of any affiliation which they have with any relevant professional, industry or consumer association. The purpose of this requirement is two fold. First, it seeks to ensure that complaints

are not made on behalf of another group without the identity of that other group being disclosed to the CCC. Second, the clause is intended to discourage frivolous and vexatious complaints.

The CCC is not required to consider complaints which do not provide the information required under clause 12.1.5 or anonymous complaints. However, the CCC has a discretion to consider such complaints in appropriate circumstances.

Under clause 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.

The sequence of dealing with a complaint, is as follows:

| | | |
|---|---|---|
| 1. | Complaint received | |
| 2. | GMiA Secretariat acknowledges receipt of complaint | 10 days |
| 3. | Member to provide response to complaint | 15 days |
| 4. | Member response provided to complainant | 10 days |
| 5. | Complaint and Member response provided to CCC<br>(nb 15 days from Step 3 but only 10 days from Step 4) | 15 days |
| 6. | CCC to convene to consider complaint | 40 days |

Therefore, the process from the date the complaint has been received to the date the CCC convenes to consider the complaint will be a maximum of 80 days.

Clause 12.1.12 establishes the membership of the CCC. 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. a representative from the GMiA Board,
vi. a representative from a member company with marketing expertise,
vii. a representative from a member company with legal expertise, and
viii. a representative from a member company with scientific expertise.

The CCC will consider complaints and referrals from the Independent Reviewer. In considering any matter, the CCC is to apply the terms of the Code and to have regard to any other relevant laws, guidelines or codes which the CCC believes may be relevant.

The CCC will meet to consider the complaint and determine whether the Code or any other applicable law, guideline or code has been breached. The CCC will also determine a proposed sanction to be imposed. The Chairman of the CCC will prepare a short summary of the decision, including the reasons for the decision, and details any proposed sanction.

The decision and proposed sanction will be notified to the Complainant and the Respondent within 5 days of the CCC making its decision. The Complainant and/or the Respondent will be able to make any submissions it wishes to make about the decision within 10 business days of receiving the CCC's decision.

The CCC will consider any potential submission by the Complainant and/or the Respondent concerning the decision and make its final decision about the appropriate sanction within 15 days of receiving the Member's submission.

The Complainant and/or the Respondent will have the right to appeal the CCC's decision. The decision to appeal a final decision of the CCC must be made in writing to GMiA within 15 days of receiving the final decision. Any appeal of the CCC's decision, will be heard by a newly formed CCC. This CCC will have the same composition as the original CCC, but will have different individual representatives. The CCC will consider the matter on a de novo basis.

All final decisions of the CCC and Appeal CCC will be published on the GMiA website within 30 days of the CCC's decision becoming final. All decisions imposed by the CCC shall remain confidential until all appeal rights have been exhausted.

Under clause 12.1.17 the CCC is 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.

Under clause 12.1.29, the CCC may refer questions on the interpretation of the Code to the GMiA Board. It is expected that this power will only be used in exceptional circumstances.

***Clause 13 – Independent reviewer***

Clause 13 establishes the role of the Independent Reviewer.

In broad terms, the Independent Reviewer's role is to review Educational Event reports from Members to determine whether these events comply with Educational Event guidelines. In the event that any particular event does not comply with the Educational Event guidelines, the Independent Reviewer is to refer that event to the CCC.

The Independent Reviewer is also empowered to conduct on-the-spot audits of Member's marketing and promotional materials to ensure compliance with the Code, and relevant laws, guidelines and codes The Independent Reviewer may request copies of marketing and promotional material from Members on two separate occasions each year. In the event that the Independent Reviewer identifies any marketing or promotional material which raise concerns under the Code or relevant laws, guidelines or codes, he or she may refer this material to the CCC for its consideration.

Prior to referring any educational event or marketing and promotional material to the CCC, the Independent Reviewer is to prepare a short note outlining his or her concerns about the Educational

Event or the marketing and promotional material. The purpose of this note is to provide the CCC with some guidance as to the potential areas of concern.

The Independent Reviewer must be legally trained and have experience in trade practices law.

There is no right to appeal the decision of the Independent Reviewer to refer a matter to the CCC.

The Independent Reviewer is also required under clause 13.9 to prepare a short report each year on (1) the level of compliance by Members with the Educational Event reporting requirements of the Code, (2) a short description of the matters which he or she has referred to the CCC and (3) details of any suggested changes to the Educational Event Reporting system which, in his or her opinion, would enhance the effectiveness and/or transparency of the system.

The GMiA Board is to have regard to the recommendations made by the Independent Reviewer but it is not required to implement those recommendations.

***Clause 14 – Sanctions***

Clause 14 sets out the sanctions which can be imposed by the CCC for various breaches of the Code. The five categories of breach with the corresponding financial penalty are:

| | | |
|---|---|---|
| 1. | Minor Breach | Nil |
| 2. | Moderate Breach | $20,000 |
| 3. | Severe Breach | $40,000 |
| 4. | Repeat Breach | $50,000 |
| 5. | Serial Breach | $75,000 |

The CCC can direct a Member to take immediate action to discontinue or modify any practice or recall and destroy any offending material which it considers in breach of the Code or any relevant laws, guidelines or codes.

In addition to financial penalties, the CCC may also require a member to publish corrective letters or advertising and/or require staff and contractors to undertake further training.

The Member must pay any sanction imposed by the CCC within 30 days of receiving a final decision from the CCC.

Any decision by the CCC that a Member carry out pay a sanction will be stayed pending the resolution of any appeal.

***Clause 15 – Code Administration***

Clause 15 sets out the arrangements for the administration of the Code.

Cause 15.1.1 establishes a Code Administration Committee (CAC) comprising of:

- an independent Chairman;
- the CEO of GMiA;
- representative of the Board of GMiA; and
- a Member representative with legal expertise.

The CAC's main function is to use all reasonable endeavours to ensure the successful implementation of the Code. The CAC will collect relevant data on the operation of the Code to determine whether any changes to the Code need to be made to improve the effectiveness and/or transparency of the Code.

The CAC will also be responsible for preparing an Annual Report for the GMiA Board on the effectiveness of the Code and providing recommendations for amendments to the Code to improve its operation.

***Clause 16 – Annual report and ongoing review***

The GMiA Board will prepare an Annual Report on the operation of the Code which will draw on the work done by both the CAC and Independent Reviewer. The Annual Report must contain:

- a summary of the complaints received by the CCC;
- a summary of the CCC decisions in relation to each complaint where a sanction has been imposed; and
- a summary of the monitoring activities conducted by the Independent Reviewer.

The GMiA Board will also review the operation of the Code at regular intervals.

**Clause 17 – Amendment**

The Code can be amended by a two-thirds majority vote of Members present and entitled to vote at a GMiA Board meeting.

# 6. Statutory framework for authorisation

Part VII of the TP Act deals with authorisations and notifications in respect of restrictive trade practices. Section 88(1A) and (1) provide:

*S.88(1A) Subject to this Part, the Commission may, upon application by or on behalf of a corporation, grant an authorisation to the corporation:*

*(a) to make a contract or arrangement, or arrive at an understanding, if a provision of the proposed contract, arrangement or understanding would be, or might be, a cartel provision; or*

*(b) to give effect to a provision of a contract, arrangement or understanding if the provision is, or may be, a cartel provision...*

*S.88(1) Subject to this Part, the Commission may, upon application by or on behalf of a corporation, grant an authorisation to the corporation:*

*(a) to make a contract or arrangement, or arrive at an understanding, where a provision of the proposed contract, arrangement or understanding would be, or might be, an exclusionary provision or would have the purpose, or would have or might have the effect, of substantially lessening competition within the meaning of section 45; or*

*(b) to give effect to a provision of a contract, arrangement or understanding where the provision is, or may be, an exclusionary provision or has the purpose, or has or may have the effect, of substantially lessening competition within the meaning of section 45.*

The effect of authorisation is set out in paragraphs (c) and (d) of section 88(1A) and paragraphs (c), (d) and (e) of s 88(1A) and is in substance to disapply the prohibitions imposed by s 45 on contracts, arrangements or understandings of the kind referred to in sections 88(1A)(a) and (b) and 88(1)(a) and (b).

Relevant criteria for the grant of authorisations of the kind sought in this case are set out in section 90(5B) and 90(6) which provides:

*S. 90(5B) The Commission must not make a determination granting an authorisation under subsection 88(1A) in respect of a provision of a contract, arrangement or understanding that is or may be a cartel provision, unless the Commission is satisfied in all the circumstances:*

*(a) that the provision has resulted, or is likely to result, in a benefit to the public; and*

*(b) that the benefit outweighs or would outweigh the detriment to the public constituted by any lessening of competition that has resulted, or is likely to result, from giving effect to the provision.*

*S.90(6) The Commission shall not make a determination granting an authorisation under subsection 88(1), (5) or (8) in respect of a provision (not being a provision that is or may be an exclusionary provision) of a proposed contract, arrangement or understanding, in respect of a proposed covenant, or in respect of proposed conduct (other than conduct to which subsection 47(6) or (7) applies), unless it is satisfied in all the circumstances that the provision of the proposed contract, arrangement or understanding, the proposed covenant, or the proposed conduct, as the case may be, would result, or be likely to result, in a benefit to the public and that that benefit would outweigh the detriment to the public constituted by any lessening of competition that would result, or be likely to result, if:*

*(a) the proposed contract or arrangement were made, or the proposed understanding were arrived at, and the provision concerned were given effect to;*

*(b) the proposed covenant were given, and were complied with; or*

*(c) the proposed conduct were engaged in;*

*as the case may be.*

Section 90(7) imposes a similar test in relation to existing contracts, arrangements or understandings. Section 90(8) deals with exclusionary provisions and third line forcing thus:

*The Commission shall not:*

*(a) make a determination granting:*

*(i) an authorisation under subsection 88(1) in respect of a provision of a proposed contract, arrangement or understanding that is or may be an exclusionary provision; or*

*...*

*unless it is satisfied in all the circumstances that the proposed provision or the proposed conduct would result, or be likely to result, in such a benefit to the public that the proposed contract or arrangement should be allowed to be made, the proposed understanding should be allowed to be arrived at, or the proposed conduct should be allowed to take place, as the case may be...*

# 7. Relevant market

The first step in assessing the effect of the conduct for which authorisation is sought is to define the relevant market(s) affected by the conduct.

GMiA has noted the ACCC's definition of the relevant market in the recent Medicines Australia (MA) authorisation[2]:

> *The ACCC does not accept that all prescription medicines are substitutable for one another and considers that there are likely to be individual product markets for the different types of drugs. However, the ACCC does not consider that a precise definition of the market is necessary for the assessment of Medicines Australia's Code. The ACCC notes that the Code regulates the activities surrounding the promotion of prescription products on an industry-wide basis across all classes of prescription medicines.*

The GMiA believes that for the purposes of considering the Code the relevant market is the market in Australia for the supply of generic medicines.

**Comparison of GMiA and MA operating principles**

Australia's National Medicines Policy (NMP) has the overall aim of ensuring that medicine's use products both optimal health outcomes and economic benefits for Australians and Australia.

The NMP seeks to achieve this aim through four central objectives. As a key partner in the NMP, the pharmaceutical industry must play its role in supporting these objectives:

1. Timely access to the medicines that Australians need, at a cost individuals & the community can afford;
2. Medicines meeting appropriate standards of quality, safety and efficacy;
3. Quality use of medicines; and
4. Maintaining a responsible and viable medicines industry.

Consequently, the promotion and advertising of medicines must be undertaken within this frame work.

[2] *Medicines Australia Limited - Revocation and Substitution - A91150 & A91155 & A91156 & A91183 & A91184* – dated 3 December 2009 – paragraph 5.6 - **http://www.accc.gov.au/content/trimFile.phtml?trimFileName=D09+191610.pdf&trimFileTitle=D09+191610.pdf&trimFileFromVersionId=905117**

While all objectives are relevant to the members of GMiA, generic medicines have a particular and important role in ensuring that Australians have timely access to affordable medicines, and that the Pharmaceutical Benefits Scheme remains sustainable.

Much of the focus of GMiA member promotional activity therefore highlights how selection of our products can contribute to medicine cost and affordability, rather than promoting an individual medicine within the quality use of medicines (QUM) framework.

Our focus, target audience and competitive environment is therefore very different to members of the MA organisation, which primarily seeks to establish the comparative safety & efficacy of a new medicines within the existing treatment pathway, to maximize health outcomes.

| Characteristic | GMiA member | MA member |
|---|---|---|
| **Decision influence point** | Decision to dispense a brand of medicine (cost & affordability) | Decision to prescribe an individual medicine (comparative safety & efficacy) |
| **Primary Customer** | Pharmacist | Medical Practitioner |
| **Promotional Focus** | The company & its product range | An individual medicine (therapeutic claim) |
| **Product classification** | Prescription, OTC and unscheduled medicines | Prescription medicines |
| **Competitive environment** | Multi-brand competitive market determined by price | Exclusive market guaranteed by patent |
| **Consumer involvement in product selection** | Decides which brand | No involvement in brand selection |

- For each individual medicine sold, GMiA members have multiple competitors selling a product that is by legislation, equivalent quality and therapeutic performance characteristics. There is no product exclusivity guaranteed by patent.
- For each individual medicine sold, MA members have no direct competitors. They have exclusivity guaranteed by patent.
- The primary goal of GMiA members is to convince the pharmacist to dispense a particular brand of a medicine, after the decision to prescribe a particular therapeutic agent has been made by the prescriber.
- The primary goal of MA members is to convince the prescriber to prescribe their patent protected product rather than an alternative therapeutic agent for a particular illness or condition.
- The primary selling point for a GMiA member is the price of their brand of medicine, in comparison to other equivalent brands.

- The primary selling point for a MA member is the safety and efficacy of their medicine, in comparison to other therapeutic choices.
- The consumer has very little involvement in the medical practitioner's decision to prescribe a particular therapeutic agent.
- The consumer may choose which brand of a therapeutic agent the pharmacist dispenses.
- GMiA members supply medicines across the supply channel; from open schedule in retail stores, through pharmacy only to prescription medicines.
- MA members generally supply only prescription only medicines.

# 8. Counterfactual

The GMiA understands that the ACCC will apply the 'future with-and-without test' to identify and weigh the public benefits and public detriments generated by the Code.

The appropriate approach to applying this test has been identified by the Tribunal as follows[3]:

(i) *If the claimed public benefits are unlikely to exist without the proposal they can be described as benefits flowing from the proposal.*

(ii) *If the claimed public benefits exist, in part, in a future without the proposal the weight accorded to them may be reduced appropriately.*

(iii) *If, in a future without the proposal, there are public detriments which are removed or mitigated in the future with the proposal that may be considered as an element of the claimed public benefit flowing from the proposal.*

GMiA submits that in the absence of the Code there would be:

- no voluntary mechanism within the generic medicines industry sector for industry members to enforce the standards of conduct set out in Code;
- no requirement for the adoption of internal compliance procedures by Members which complied with the relevant Australian standard;
- no guidelines binding on Members in relation to the sponsorship of Educational Events;
- no external regulatory system in place to constrain the conferring of benefits on Healthcare Professionals by Members;
- no mechanism for the imposition of sanctions on Members for breaching the Code; and
- no independent review function in relation to Educational Events and the marketing and promotional material of Members.

[3] *Ibid.*, para. 119.

# 9. Public benefit

GMiA notes the Tribunal's comments on the meaning of the term public benefit:

> *The words "public benefit" which lie at the heart of the authorisation process encompass "... the widest possible conception of public benefit... anything of value to the community generally, any contribution to the aims pursued by the society, including as one of its principal elements (in the context of trade practices legislation) the achievement of the economic goals of efficiency and progress" : Re Queensland Co-operative Milling Association Ltd; Re Defiance Holdings Ltd (1976) 8 ALR 481 at 510; 25 FLR 169 at 182-183 (Re QCMA)...*[4]

GMiA submits that the Code will deliver the following public benefits:

- an obligation on Members to follow clearly defined Educational Event guidelines and to report regularly on their compliance with these guidelines;
- a mechanism for the review of Educational Event reports by an independent reviewer;
- a mechanism for vetting Member's marketing and promotional material by an independent reviewer;
- the establishment of an independent Code Complaint Committee with the power to examine and apply sanctions in relation to inappropriate activities by Members;
- a system of co-regulation whereby the CCC can impose sanctions on Members for breaches of the TP Act, TG Act, and other relevant guidelines and codes;
- new reporting requirements on the financial sponsorship arrangements between Members and prescribing Healthcare Professionals;
- a requirement that Members train their employees, contractors and agents about the Code and other relevant laws, guidelines and codes; and
- the implementation by Members of an internal complaints handling system, based on the relevant Australian Standard.

GMiA submits that each of the above features of the Code constitutes a significant public benefit.

***Event reporting***

Under the Code there is a commitment to report and publish, on the GMiA website, educational events provided to prescribing healthcare professionals by Members. GMiA has voluntarily introduced this initiative as the Tribunal and ACCC have previously found such educational event reporting to be a public benefit.

[4] *Op. cit.*, para. 107

***Co-regulation system***

GMiA submits that the system of co-regulation which will be established by the Code also delivers significant public benefits. As a result of the Code, Members may be sanctioned by the CCC for alleged contraventions of the Code, the TP Act and TG Act and other relevant guidelines and codes.

The added enforcement provided by the Code in relation to the TGA and the TG Act is a public benefit. As stated by the Tribunal:

> *A voluntary industry code may provide an additional informal low cost complaint and enforcement mechanism covering both the conduct formally addressed by the statutory system and analogous or related conduct which the statutory system does not reach because of legal boundaries or resource limitations. Even if the voluntary enforcement mechanism has gaps and deficiencies the additional coverage it provides may be identified as a public benefit by reason of its capacity to lessen the detriment associated with conduct within the letter or policy of the statutory theme. The relationship between statutory regulation and complementary voluntary codes in such cases is sometimes referred to as "co-regulation".*[5]
>
> *..there are transaction costs associated with the investigations and other administrative and judicial processes necessary for the enforcement of statutory regulation. Those costs and limits on the resources available to government agencies limit the extent of enforcement coverage.*[6]

The fact that the CCC will be able to consider and impose sanctions on Members for conduct which may contravene provisions of the TP Act and TG Act will result in a public benefit. The Code will achieve this public benefit by effectively reducing the costs which investigatory agencies such as the ACCC and TGA would have to expend in investigating and resolving such conduct.

***Training***

The obligation on Members to provide training to their employees, contractors and agents on the Code, and other relevant laws, guidelines and codes delvers a public benefit. This training obligation will increase knowledge about, and compliance with, both the Code and other relevant standards.

Absent the Code there would be no obligation on Members to provide extensive and regular training to their employees, contractors and agents on their obligations under the TP Act and TG Act.

***Internal Complaints Handling Systems***

The implementation by Members of an internal complaints handling system, based on the relevant Australian Standard, delivers a significant public benefit. Such systems have been designed with the express purpose of providing appropriate and timely responses to consumer complaints.

[5] *Ibid.*, para. 119.
[6] *Ibid.*, para. 342.

Absent the Code there would be no obligation on Members to establish an internal complaints handling system based on the relevant Australian Standard.

***External Complaints Handling Systems***

The Code establishes an external and independent complaints handling system, providing Consumers, Healthcare Professionals and other Stakeholders with an effective method to redress complaints against a Member with regard to breaches of the Code.

Absent the Code there would be no obligation on Members to establish an external complaints handling system.

# 10. Public detriment

GMiA notes the Tribunal's comments on the meaning of the term public detriment:

> *Sections 90(6) and 90(7) of the TP Act require consideration of the risk of "detriment to the public", a concept extending to "... any impairment to the community generally, any harm or damage to the aims pursued by the society including as one of its principal elements the achievement of the goal of economic efficiency...": Re 7-Eleven Stores Pty Ltd (1994) 16 ATPR 41-357 at 42,683....*[7]

GMiA submits that there is minimal public detriment arising from the Code.

The main form of public detriment which arises from the Code relates to the potentially anticompetitive effect of the CCC Educational Event guidelines. It could be argued that placing various restrictions on the way in which Educational Events are conducted will lessen competition between Members for attendance at their Educational Events. In a competitive market, pharmaceutical companies would seek to attract attendees to their Educational Events by providing not only valuable educational content but also additional non-educational benefits, such as entertainment.

Even though the Code will effectively ban such "competition" between Members, it is doing so to eliminate an even greater public detriment. As stated by the Tribunal:

> *In our opinion there is a significant detriment associated with the unrestricted development of non-arms length relationships between pharmaceutical companies and healthcare professionals and particularly those relationships which involve the receipt of benefits by healthcare professionals. The detriment lies in the effect that such conduct may have upon the prescribing practices of healthcare professionals directly influenced by it or by the views of professional opinion leaders who have links to particular companies. If the prescribing practices of healthcare professionals are influenced directly or indirectly by sympathies for particular products because of benefits derived from or links to the manufacturer or distributor of those products, patient care may be compromised. Patients in need of treatment will not necessarily be provided with that which is best for them. In an indirect sense there is also an anti-competitive detriment to the extent that key decisions in the relevant market may be affected by factors extraneous to the quality of the product and its cost.*[8]

Another potential anticompetitive detriment may arise from the operation of the CCC which will involve Member representatives participating in decisions to impose sanctions against Members, including financial sanctions. The main concern which arises in this context, is that a Member representative sitting participating in CCC determination may seek to impose a sanction against another Member for inappropriate reasons, such as to gain a commercial advantage.

[7] *Ibid.*, para. 108.
[8] *Ibid.*, para.. 315.

In this regard, GMiA submits that the composition of the CCC, particularly the large number of independent members, will prevent inappropriate decisions being made. The appeal mechanism will also provide a Member with an opportunity to challenge a decision which may have been made for an inappropriate reason.

The GMiA submits that the Code does not result in any other potential public detriments.

# 11. Balance of Public Benefit and Detriment

GMiA submits that the public benefits delivered by the Code are significant, while the public detriment arising from the operation of the Code is minimal.

The Code delivers a significant number of public benefits. Furthermore, these public benefits would not occur in the absence of the Code.

The possible anticompetitive detriments arising from the Code are either minimal or unlikely to occur.

The possibility that the powers of the CCC may be misused by a Member for commercial advantage is made highly unlikely due to the composition of the CCC.

# 12. Length of Authorisation

GMiA believes that five years is an appropriate period for the authorisation. By the end of the five-year period there will be sufficient data available about (1) complaints, (2) the referrals made by the independent reviewer and (3) the decisions made by the CCC to make a meaningful assessment of the effectiveness of the Code.

GMiA

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# Code of Practice

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# 1. Table of Contents

# 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:

i. 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 signatories to and contractually 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.

**5.2** The Code may also serve as guidance for the suppliers of Generic Medicines that are not Members of GMiA. Suppliers of Generic Members 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.

# 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, contractor, agent or representative 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, except in exceptional circumstances;
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.

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 CHS on their respective websites.

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. a representative from the GMiA Board,
vi. a representative from a member company with marketing expertise,
vii. a representative from a member company with legal expertise, and
viii. a representative from a member company with scientific expertise.

12.1.14 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.

12.1.15 Membership of the CCC will be for a period of two (2) years, with members eligible for re-appointment at the end of this term.

12.1.16 The CCC will convene as required to consider complaints and referrals from the Independent Reviewer. The CCC will endeavour to convene within forty (40) business days of receiving information about a complaint from the GMiA Secretariat or a referral from the Independent Reviewer.

12.1.17 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.

12.1.18 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.

12.1.19 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.

12.1.20 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.

12.1.21 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.

12.1.22 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.

12.1.23 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.

12.1.24 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.

12.1.25 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.

12.1.26 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.

12.1.27 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.

12.1.28 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.

12.1.29 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.

12.1.30 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 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 touse 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 distributed to interested parties including Government, peak bodies of Healthcare Professional, peak bodies of Consumer groups and the ACCC.

16.3 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.