



**Marketing & Supply Code of Practice:
Complementary Medicines**

Edition 2, Version 2, November 2015

Version History

Version	Description of Change	Contributors	Effective Date
Marketing & Supply Code of Practice: Complementary Medicines Edition 2, Version 2	Name change for organisation Addition of sections: General Principles – Conduct of CMA Members; Conduct of CM Retailers; Sanctions Multiple minor amendments	CMA Board of Directors Marketing Code Governance Committee Complaints Resolution & Monitoring Committee	November 2015
Edition 2, Version 1 Marketing & Supply Code of Practice: Complementary Medicines & Health Food Products	New Code High level principles updated in line with the recommendations of the Working Group on Promotion of Therapeutic Products	CHC Board of Directors Practitioner Medicine Technical Committee External Stakeholder Consultation	September 2013
Edition 1 CHC Code of Practice for the Marketing of Complementary Healthcare Products	Multiple versions		1995 - 2013

Title: CMA Marketing & Supply Code of Practice: Complementary Medicines

Publication date: November 2015

Review date: November 2017

Edition: Two

Published by: Complementary Medicines Australia

PO Box 450

Mawson, ACT 2606

Australia

Telephone: 02 6260 4022

Facsimile: 02 6260 4122

E-mail: cma@cmaustralia.org.au

Website: www.cmaustralia.org.au

The contents of this document are subject to the provisions of the *Copyright Act 1968* as amended from time to time.

Contents

Version History.....	2
Contents	
1 Introduction.....	5
2 High Level Principles Underpinning this Code.....	6
3 Objectives.....	7
4 Scope.....	8
5 General Principles – Conduct of CMA Members.....	10
6 General Principles for the Marketing of Complementary Medicines.....	11
7 Provisions for Advertising Foods.....	14
8 Marketing to Consumers and non-Healthcare Professional Retailers.....	15
9 Conduct of Complementary Medicines Retailers.....	17
10 Marketing to Healthcare Professionals.....	19
11 Marketing and Supply of Practitioner Only Products.....	23
12 Complaints Handling.....	25
13 Sanctions and Enforcement Action.....	29
14 Appeal Procedures.....	32
15 Monitoring of Promotional Materials and Promotional Spend.....	34
16 Administration.....	35
17 Functions of the Marketing Code Governance Committee.....	36
18 Code Monitoring.....	37
19 Review and Amendments.....	39
20 Publicising the Code.....	40
21 Disclaimer.....	41
Appendix 1 Definitions.....	42
Appendix 2 References.....	47
Appendix 3 Resources.....	48

1 Introduction

- 1.1** Complementary Medicines Australia (CMA) is an independent, non-government body and Australia's only peak organisation representing the whole of the complementary medicine and healthcare products industry.
- 1.2** CMA members agree to adhere to the Code's provisions which, in some instances, may prescribe a standard of conduct that is higher than that specified in the legislation. Our members subscribe to the tenet that ethical business practices are an integral component of a sustainable industry. Consumers are able to recognise member companies that adhere with this philosophy by their use of the CMA Logo.
- 1.3** A sustainable complementary medicines industry relies on every company involved voluntarily complying with the provisions of this Code.
- 1.4** The Australian complementary medicines industry promotes the concept of preventative health and wellbeing via the provision of high quality, low-risk products that are self-selected by consumers or prescribed by healthcare professionals.
- 1.5** Complementary medicines are included under the quality use of therapeutic products, which is based on genuine consumer health needs and supported by the ethical conduct of all parties. The quality use of therapeutic products means: selecting diagnostic and treatment options wisely based on the best available evidence and the consumer's needs; choosing suitable therapeutic products if this is considered necessary and using therapeutic products safely and effectively.
- 1.6** This Code may be referred to using the abbreviated title of the *CMA Code of Practice*.

2 High Level Principles Underpinning this Code

- 2.1** Therapeutic products companies should have as their primary objective the maintenance of the trust and confidence of all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant community. Companies will do this by:
- 2.1.1 adhering to the ethical promotion of therapeutic products;
 - 2.1.2 providing products that conform to the highest relevant standards of safety, efficacy and quality as established by the TGA;
 - 2.1.3 maintaining trust and confidence in the industry through transparency and accountability;
 - 2.1.4 respecting ethical requirements and Codes of Conduct which apply to healthcare professionals;
 - 2.1.5 upholding not just the letter of the Code but also the spirit of the Code;
 - 2.1.6 having in place a comprehensive process to monitor behaviour and deal with complaints;
 - 2.1.7 remedying behaviour if found to be in breach of the Code.
- 2.2** CMA is committed to collaborating with relevant stakeholders in code creation, revision, education, monitoring and compliance.
- 2.3** Promotional activities shall be ethical and consistent with the objectives of Quality Use of Medicines. Such promotional activities should be able to withstand public scrutiny and should not discredit, or be likely to discredit, the Industry, CMA or members.

3 Objectives

- 3.1 To define the principles and fundamental requirements CMA members agree to uphold in their business practices, recognising that the conduct of an individual member can reflect upon both the industry and the Association's membership.
- 3.2 To define guidelines to be followed by members to minimise their risk of breaching the *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods Advertising Code 2007* (all as amended from time to time) as well as Australian Consumer Law and all other relevant legislation, legislative instruments, government guidelines or standards (existing from time to time).
- 3.3 To enhance consumer confidence in the quality and safety of complementary medicines by ensuring members:
 - 3.3.1 possess a thorough knowledge and due regard for their customers' requirements by responsibly informing them about health and nutrition products that are available and their importance to wellbeing;
 - 3.3.2 present information in an accurate and balanced way that advances the responsible and rational use of complementary medicines, but does not encourage salesmanship at the expense of customer welfare and needs;
 - 3.3.3 employ the highest standards of professionalism in dealings and relationships; and
 - 3.3.4 are aware that sanctions will apply for those found to be in breach of this Code.

4 Scope

- 4.1** The aim of this Code is to describe suitable standards of commercial conduct generally and of marketing and promotional practices in particular.
- 4.2** The provisions, requirements and principles described in this Code apply to manufacturers, raw material suppliers, healthcare professionals, retailers (including direct marketing and direct selling agents), and all other parties involved with the marketing, advertising, supply or distribution of complementary medicines.
- 4.3** Adherence to the provisions, requirements and principles described within this Code are a condition of membership of CMA. Personnel employed by members need to be aware of the requirements of this Code and the responsibilities inherent in membership of CMA.
- 4.4** In support of industry self-regulation, and to strengthen the likely outcome of a level playing field for self-regulatory codes, CMA encourages all non-members to adopt and follow the principles described within this Code. CMA expects non-members will abide by the Code's processes if a complaint is received, with refusal resulting in the complaint being referred to the relevant government authority.
- 4.5** CMA will ensure that all members and non-members receive fair and equitable treatment under this Code.



Part A

Provisions of the Code

5 General Principles – Conduct of CMA Members

Scope: This section applies to all CMA members. Non-members are encouraged to adopt and follow the principles described within this Code.

- 5.1** Members shall not engage in any unfair or unconscionable conduct or commercial practice.
- 5.2** Members shall at all times ensure that they are familiar with, and comply with, the relevant provisions of Commonwealth and/or State/Territory legislation which relate to the industry's functions and operations.
- 5.3** Members shall comply at all times with the provisions of such other codes that are from time to time developed and/or endorsed by CMA.
- 5.4** Members will at no time make statements that may lead consumers to forego appropriate medical advice or the advice of a healthcare professional.
- 5.5** Members will ensure that all appropriate personnel within their organisations, and relevant outside service organisations and consultants shall be aware of the requirements of this code and the responsibilities attendant to it.
- 5.6** Members will cooperate with CMA in a timely manner in the investigation of problems and/or complaints that may from time to time arise under the provisions of the code.

6 General Principles for the Marketing of Complementary Medicines

Scope: This section applies to all promotional materials. This includes materials that may be directed to either consumers or healthcare professionals.

6.1 Claims - *Substantiation*

- 6.1.1 Claims must be capable of substantiation. Any information used to substantiate a therapeutic or promotional claim must include sufficient detail and be of adequate quality to substantiate the validity of the claim.
- 6.1.2 Quotations from medical literature or from personal communications must accurately reflect the meaning of the author and/or outcomes of the study.
- 6.1.3 If qualifying statements are used with a therapeutic or promotional claim, they should be linked to the relevant claim with an asterisk or similar identifier and be of sufficient prominence to provide adequate balance to the primary claim.
- 6.1.4 Claims must not imply that a product or a substance is unique or has some special merit, quality or property unless this can be substantiated.
- 6.1.5 To justify the use of the word *new* the advertiser must be able to demonstrate the existence of real novelty in effect or formulation or presentation or brand name and this description may only be used for a period of 12 months.
- 6.1.6 Slogans, which because of brevity or for any other reason are capable of misinterpretation, shall be used only in association with copy that clearly indicates their correct meaning.
- 6.1.7 Claims around the words natural, naturally-derived, organic, environmental and sustainable or similar must be verified.

6.2 Promotional Claims - *Editorials / Advertorials*

- 6.2.1 Advertorials directed to consumers are required to comply with all advertising legislation.
- 6.2.2 Advertisements/advertorials should not be placed in a publication so that they are close to genuine editorial matter that would suggest indications of use not listed on the ARTG for the advertised product. If there has been valuable consideration for 'editorial matter', this may also be considered an advertisement and be required to meet the full requirements of advertising legislation.

6.3 Promotional Claims - *Reporting Research*

- 6.3.1 Literature references, information, findings or conclusions from independent research, surveys, or scientific or clinical studies must be relevant, and assessed and presented in a balanced, objective and accurate manner.
- 6.3.2 The title of an article referenced in an advertisement must not contravene this Code or section 22(5) of the *Therapeutic Goods Act 1989*.

6.4 Promotional Claims - *Comparative Statements*

- 6.4.1 Points of comparison should be based on facts which have been substantiated and reflect the full body of evidence or experience at the time of publishing. . Refer also to Sections 4(2)(c) and 4(5) of the TGAC for advertising directed to consumers.
- 6.4.2 Comparisons should be balanced, fair and compare like with like. All comparative statements should be designed so that on any reasonable interpretation, consumers would not be misled either about the product being advertised or about any product with which it may be compared.
- 6.4.3 No advertisement shall denigrate or attack unfairly any other products, class of products, goods or services or other sectors of the industry.
- 6.4.4 Advertisements may state that a product does not contain an ingredient commonly used in competitive products in a manner that promotes consumer choice. These representations must not, however, give the impression overall that the ingredient is unsafe or harmful.

6.5 Promotional Claims - *Imitation*

- 6.5.1 Advertisements in any media should not be designed to resemble editorial matter unless clearly identified as an advertisement or advertorial.
- 6.5.2 Promotional material should not imitate the devices, copy, slogans or general layout adopted by other advertisers in a way that is likely to mislead or confuse.

6.6 Promotional Claims - *Competitions*

- 6.6.1 The conduct of competitions shall comply in all respects with relevant Commonwealth and State regulations.
- 6.6.2 The nature of any competition must comply with the relevant provisions of the Code and must comply with the TGAC if included in an advertisement for therapeutic goods directed to consumers, or the competition itself meets the definition of 'advertisement'.
- 6.6.3 No competition should encourage, or be likely to encourage, inappropriate or excessive use.

6.7 Company Media through internet and social media

The CMA supports the right of companies to use the internet as a means of providing accurate and reliable information on products for the benefit of healthcare professionals and the wider community.

- 6.7.1 Internet and social media pages designed specifically for healthcare professionals must be log-in and password protected to prevent access by consumers. This includes but is not limited to product technical information and forums.
- 6.7.2 Where references to other information sources or internet sites are made, companies must take all reasonable steps to ensure that these information sources and sites are appropriate and will enhance appropriate use of the product. It should be made clear when the reader is leaving the site or being directed to a site that the company has not developed.

6.7.3 It is appropriate for companies to link their websites to this Code of Practice on the CMA website. Such a linkage must not be used to imply that the CMA endorses any part of the content of the company's site but to provide information on the Code of Practice and the standard it sets.

6.8 Trade Displays

6.8.1 All promotional materials used at trade displays must be consistent with the relevant provisions of this Code, and if directed at consumers the TGAC, where those promotional materials meet the definition of an advertisement promoting the use or supply of therapeutic goods.

6.8.2 Sampling to the general public must comply with the relevant State & Territory legislation.

6.8.3 Gifts or offers provided by a company to encourage consumers or healthcare professionals to visit a trade display must comply with this Code.

7 Provisions for Advertising Foods

- 7.1** Advertisements for foods shall comply with the relevant Food Standards. Under Food Standard 1.2.7 some foods are permitted to make health claims and members should refer to the Standard for the approved foods and claims.
- 7.2** The Therapeutic Goods Administration's (TGA's) Food Medicine Interface Guidance Tool contains seven questions to help determine whether a particular product is likely to be a therapeutic good or a food. The tool is designed to take into consideration the relevant definitions in the *Therapeutic Goods Act*. Members should refer to the Food Medicine Interface Guidance Tool, which is available on the TGA website.

8 Marketing to Consumers and non-Healthcare Professional Retailers

Scope: This section applies to all advertising materials directed to the general public, i.e. those who are not healthcare professionals, including *mainstream media* and *below-the line* materials, internet and broadcast media. These provisions are in addition to the *general principles* at Section 6.

8.1 Underlying Principles

- 8.1.1 It is recognised and understood that the general public may possess limited technical and scientific knowledge, and may rely on statements and claims made in advertising and promotional material to form judgments on the performance expected of a product.
- 8.1.2 Advertisements for complementary medicine products must comply with the *Therapeutic Goods Advertising Code 2007* (TGAC).

8.2 Advertising Rules

- 8.2.1 No advertisement shall contain any offer to diagnose, prescribe or treat with therapeutic products by correspondence.
- 8.2.2 No advertisement should in any way tend to induce fear or unjustified concern that the reader is suffering, or without using the product being advertised, may suffer or suffer more severely, from any illness, ailment or disease. TGAC Sections 4(2)(d) and (e) apply.
- 8.2.3 No advertisement should in any way tend to discourage the reader from seeking the advice of a qualified healthcare professional.

8.3 Internet and Social Media

- 8.3.1 Consumer comments and testimonials linked in any way to a company's website or social media page must be monitored and removed, within a reasonable time period, from the company website if not compliant with this Code and the TGAC.
- 8.3.2 A company that publishes a link to a third party site is responsible for monitoring the linked site to ensure compliance to the relevant codes and legislation, unless the viewer is advised that they are leaving the company controlled site or controlled content.

8.4 Shelf Talkers

- 8.4.1 Therapeutic claims included in shelf talkers must be consistent with the indications that are included in the ARTG in relation to each product.
- 8.4.2 When a shelf talker meets the definition of an advertisement it must comply in full with the TGAC, including carrying the appropriate required warning statements.

8.5 Books

- 8.5.1 If an advertisement for a product also mentions or offers the sale of a book the overall intent of the advertisement must not be to circumvent the provisions of this Code or the *Therapeutic Goods Advertising Code 2007* (as amended from time to time).

- 8.5.2 If a book is published by or on behalf of the advertiser, and makes a claim for a branded product, then it will be treated as an extension of the advertisement and subject to the same rules;
- 8.5.3 If the book is published independently and is offered to the reader there must be a cover price and there can be no inference in the advertisement itself that the book might contain information of a medical nature not permitted in the advertisement.

9 Conduct of Complementary Medicines Retailers

Scope: This section of the Code sets out principles governing the role of complementary medicines retailers. These provisions are in addition to the general principles in sections 5 and 6. As members with the most day-to-day contact with consumers, the importance of the role of the retailer should not be underestimated. As such, a high level of professionalism, the necessary skills and knowledge and an ethical approach to business practices are needed by retail members to ensure and enhance the reputation of complementary medicines retailing. Any retail non-member involved within the complementary medicines industry is invited to accept and observe this Code.

9.1 Purpose and Objectives of this Section

- 9.1.1 This section is intended to establish the basic principles and practices that deal fairly with relationships between retail members and customers, as well as relationships between retail members and other stakeholders within the complementary medicines industry.
- 9.1.2 In line with CMA vision and values, this Code reflects complementary medicines retailers' commitment to the enhancement of public health and wellbeing. In an increasingly competitive environment, the welfare of the customer remains paramount.
- 9.1.3 This Code may not be construed in any way that is deemed to contradict statutory law, nor does it remove the obligation upon members to conduct their business in accordance with said law.

9.2 Provisions

- 9.2.1 In store advice and information is encouraged but should not be diagnostic in nature and be consistent with respect to a customer's legitimate needs and welfare.
- 9.2.2 Retailers will accurately communicate the potential benefits, risks and/or consequences associated with the goods, services and programs that they provide.
- 9.2.3 Retailers will be truthful about their qualifications and the limitations of their education, expertise and experience in providing goods and services consistent with their respective level of professional competence.
- 9.2.4 Retailers will only engage in treatment, diagnosis, or prescribing if lawfully licenced to do so. If applicable, CMA retailers will maintain, improve, and expand professional competence through continued study and education, memberships, and involvement in public health issues.
- 9.2.5 Retailers will cooperate to whatever extent they are able with CMA to educate consumers in the safe and proper use of complementary medicines.
- 9.2.6 Retailers will ensure they comply with all relevant Commonwealth, State and Territory legislation, including but not limited to the *Competition and Consumer Act 2010*, *Customs Act 1901* and *Quarantine Act 1908*.
- 9.2.7 Employees of a retailer will be encouraged to openly communicate any expectations of job-related assignments that conflict with their professional ethics.
- 9.2.8 All complementary medicines sold in Australia, unless specifically exempt, must be listed or registered with the Therapeutic Goods Administration (TGA). It is the responsibility of the retailer to work with reputable suppliers as this will help ensure that the products being sold have been listed or registered on the Australian Register of Therapeutic Goods (ARTG).

- 9.2.9 Practitioner-only complementary medicine products must not be publicly accessible or supplied for sale over the counter without authorisation from a Healthcare Professional.
- 9.2.10 Use of the CMA logo should be for approved uses only, as outlined in the document *Policy and Procedures for the use of the CMA Member Logo*.
- 9.2.11 The CMA logo must not appear to endorse any individual product or brand of products.

10 Marketing to Healthcare Professionals

Scope: This section of the Code sets out principles governing marketing activities by advertisers to Healthcare Professionals. These provisions are in addition to the *general principles* in sections 5 and 6.

10.1 Underlying Principles

- 10.1.1 All information, claims and graphical representations provided to healthcare professionals must be current, accurate, balanced and must not mislead, either directly, by implication or by omission.
- 10.1.2 Promotional and educational materials directed to healthcare professionals may discuss contraindications and safety if these are able to be substantiated.
- 10.1.3 Companies should ensure that relationships with healthcare professionals do not bring the industry into disrepute or reduce public confidence in the industry.
- 10.1.4 Companies should act in a manner that does not compromise or appear to compromise patient care and the quality use of medicines.

10.2 Communication with Media aimed at Healthcare Professionals

- 10.2.1 A company may issue a media release to the healthcare professional media for a number of purposes, including but not limited to: announcing a new product, new dosing, or new formulation, or alerting healthcare professionals to the results of significant new research.
- 10.2.2 Companies have an obligation to confirm that the media is directed to healthcare professionals only and that access by consumers is restricted.
- 10.2.3 Upon request, companies may provide educational material to medical journalists in the same manner as provided to healthcare professionals.
- 10.2.4 No sponsorship should be conditional upon any obligation by the journalist to report on a company's product(s). Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a journalist.

10.3 Management of Company Representatives

Conduct

- 10.3.1 Company representatives should at all times maintain a high standard of ethical conduct and professionalism in the discharge of their duties.
- 10.3.2 Company representatives must not employ any deception to gain an appointment with a healthcare professional.

Training

- 10.3.3 Companies have a duty to ensure that company representatives and other relevant employees are fully trained and informed of their responsibilities under this Code and all relevant laws, guidelines and other codes.

10.3.4 Company representatives should possess sufficient knowledge to present information on the company's products in a current, accurate and balanced manner.

10.4 Product Samples

10.4.1 The distribution of samples must be carried out in a reasonable manner and be compliant with individual State and Territory legislation, as applicable.

10.4.2 Records must be kept in compliance with individual State and Territory legislation, as applicable.

10.5 Gifts and Offers

10.5.1 No gift, benefit in kind or pecuniary advantage shall be offered or given to healthcare professionals or to administrative staff as inducement to recommend, prescribe, dispense or administer a Company's product(s).

10.5.2 This section prohibits the provision of gifts and offers to healthcare professionals unless they meet the requirements of:

- company-branded items of stationery;
- educational material directed to healthcare professionals or patients;
- sponsorship to attend an educational event;
- appropriate hospitality at an educational event;
- trade related activity.

Brand name reminders

10.5.3 Given that complementary medicines may be marketed directly to consumers, brand name reminders may be used within the following parameters:

- a) The nature of any brand name reminder or its packaging must not have the capacity to be confused with a therapeutic good.
- b) An individual brand name reminder should be of token value and should not bring discredit to the industry.

10.6 Educational Events

10.6.1 The primary purpose of an educational meeting must be the enhancement of healthcare and /or the quality use of complementary healthcare products.

10.6.2 Company involvement in educational events must have the objective of providing current, accurate and balanced healthcare education in an ethical and professional manner. When organising or sponsoring educational events, it is also important to ensure an appropriate balance between the duration of educational content and any hospitality provided to delegates.

10.6.3 The conduct of company representatives at educational events must also be able to withstand public and professional scrutiny and be socially responsible.

10.6.4 The identity of the company/s sponsoring the event should be clearly communicated in all materials relevant to the educational event.

- 10.6.5 The choice of venue must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. The venue should not be chosen for its leisure, sporting or recreational facilities.
- 10.6.6 Delegates at educational events must not be paid for their attendance unless they have an additional role at the event such as presenting or acting as MC.
- 10.6.7 Meals or beverages offered by companies to healthcare professionals must be secondary to the educational content. Meals and beverages must be appropriate for the educational content and duration of the meeting and should not be excessive.

10.7 Sponsorship of healthcare professionals to attend educational events

- 10.7.1 Direct travel costs or part thereof may be provided to delegates of the meeting if justified by the educational content or the origin of the delegates.
- 10.7.2 A reasonable level of accommodation expenses may be provided to delegates at a company educational meeting if justified by the time and duration of the meeting or the origin of the delegates.
- 10.7.3 Any accommodation provided to a sponsored healthcare professional must be reasonable and appropriate for the time and duration of the meeting and origin of the healthcare professional.
- 10.7.4 A company must not subsidise or pay for the hospitality, travel or other expenses of any relative or associate of a sponsored healthcare professional who does not have a genuine need for attending an educational event.

10.8 Sponsorship of third party educational conferences

- 10.8.1 Companies may sponsor educational events that are organised by a society, college, university or other healthcare professional organisation, and may sponsor 'in-institution' educational events held within a healthcare professional workplace.
- 10.8.2 Financial sponsorship of an educational event should be paid to the healthcare professional organisation, and not paid directly to an individual healthcare professional.
- 10.8.3 The third party organising the educational meeting should independently determine the educational content, select the speakers and invite the attendees. Companies should undertake a review of the educational value prior to agreeing to sponsor the event.
- 10.8.4 The sponsoring company may propose a speaker for the educational meeting, but the final choice of speakers should be determined by the healthcare professional organisation or nominated faculty.

10.9 Research and Education Grants

- 10.9.1 A company may provide a grant or financial support provided that the support is made only to a healthcare professional practice, institution or health related organisation for education, research, or for activities that improve the use of complementary medicine products, and/or to improve health outcomes.
- 10.9.2 The provision of financial support to stakeholders for the purposes of research and/or education must not be conditional upon or provided in the expectation of the stakeholder recommending or supplying therapeutic goods.

10.9.3 Publication of research results must identify the researcher and the financial sponsor of the research.

10.10 Market Research with Healthcare Professionals

10.10.1 Promotion should not be represented as market research or research of any type. The purpose of these activities should be to collect data and not a means to promote company product(s).

10.10.2 Market research studies must be clearly identified as such when the initial approach is made to participants.

10.10.3 Any payment (whether cash or kind) should not exceed a level commensurate with the time involved.

10.11 Consulting arrangements with healthcare professionals

10.11.1 Companies may seek the services of suitably qualified and experienced healthcare professionals to provide a service, advice and/or guidance on a range of matters. Any remuneration for services rendered should not exceed that which is commensurate with the services supplied. A company may provide reasonable travel, accommodation or hospitality to consultants in association with the consulting services.

10.12 Pharmaceutical Benefits Scheme (PBS)

10.12.1 Should a complementary medicine be listed on the Pharmaceutical Benefit Scheme (PBS), all promotional material directed at healthcare professionals must include a clear and prominent statement drawing attention to the PBS listing and restrictions.

11 Marketing and Supply of Practitioner Only Products

Scope: This section of the Code sets out principles governing marketing and supply activities by advertisers of practitioner only complementary medicine products to healthcare professionals.

CMA has published the *Guideline for the Sale and Supply of Practitioner Only Products*, which documents industry-endorsed best practice for the sale and supply of these products. The Guideline should be read in conjunction with this section of the Code.

11.1 Underlying Principles

- 11.1.1 These provisions deal specifically with the advertising, promotion and supply of practitioner only complementary medicine products.
- 11.1.2 Practitioner only complementary medicine products may be included in the ARTG as either Listed or Registered products.
- 11.1.3 Practitioner Only Products in retail outlets should not be directly accessible by the general public.
- 11.1.4 Sponsors should only supply Practitioner Only Products to a retail outlet where a Healthcare Professional is prescribing and dispensing onsite. Practitioner Only Products may be marketed to healthcare students for educational purposes.



Part B

Administration of the Code

12 Complaints Handling

Establishment and Procedures of the Complaints Resolution and Monitoring Committee (CRMC)

- 12.1** Complaints relating to alleged breaches of this Code will be heard by a complaints resolution and monitoring committee (CRMC), with membership as approved by the CMA Board, which:
- 12.1.1 will provide for a Chair that the committee elects by a majority vote of the members of the committee and holds the initial term of two (2) years;
 - 12.1.2 will include a CMA Secretariat staff member (acting as Secretary to the committee);
 - 12.1.3 will consist of:
 - a) the CMA Chief Executive Officer or their representative;
 - b) a maximum of six (6) members of the CMA, three of whom must have technical expertise and one being a retailer member;
 - c) a complementary healthcare Practitioner;
 - d) a Consumer representative; and may also include:
 - e) a member with extensive experience in administration of food law at State level;
 - f) an observer from the Therapeutic Goods Administration (with regulatory experience in the advertising and supply of CMs) on invitation from the Committee;
 - g) an observer from a special interest group on invitation from the Committee;
 - 12.1.4 will provide for committee members to be entitled to hold office for two (2) years and thereafter to be eligible for reappointment;
 - 12.1.5 will provide for each position to have an alternate to attend meetings in the absence of the member;
 - 12.1.6 will meet as required.
- 12.2** The CMA Board may from time to time appoint one or more experts to assist the CRMC in its deliberations. Experts and observers will not have voting rights.
- 12.3** A quorum consists of the Chair and four (4) other members of the CRMC.
- 12.4** Complaints handling procedures shall include not less than the following:
- 12.4.1 the CRMC will not consider a complaint while its substance is the subject of pending Court proceedings;
 - 12.4.2 a party to a complaint must notify the Chair of the CRMC immediately upon becoming aware of any Court proceedings concerning the substance of the complaint;

- 12.4.3 the Secretary of the CRMC must acknowledge a complaint, whether concerning a Member or a non-member, in writing, within ten (10) working days of its receipt and allow the respondent the opportunity to provide an explanation prior to the CRMC's consideration of the complaint.
- 12.4.4 Anonymous complaints will be accepted by the Secretary of the CRMC and progressed through the complaints process.
- 12.4.5 Where a complaint about a complementary medicine product involves risk to public safety or a complementary medicine product that has not been exempt from being included in the ARTG, the CMA Chief Executive Officer, or his/her delegate, will refer the matter immediately to the Therapeutic Goods Administration for further action, as it deems appropriate.
- 12.4.6 A complaint may be referred to any other agency, as appropriate.
- 12.4.7 After considering all information provided where the complaint may constitute a breach of this Code, the Secretariat shall refer the complaint to the CRMC.
- 12.4.8 Upon determination of the alleged breach, the Chief Executive Officer, or his/her delegate, shall notify all relevant parties of the decision of the CRMC and appeal provisions.
- 12.4.9 Complaints referred as part of a monitoring process will be referred to the CRMC for consideration and determination of appropriate action.
- 12.5** With respect to a complaint:
- 12.5.1 the party wishing to complain will be encouraged by the Secretary of the CRMC (but not required) before lodging a complaint to seek to resolve the issue with the Member or non-Member whose behaviour has given rise to the complaint (the respondent); and
- 12.5.2 the complainant may request that their name be withheld so as to protect the privacy of the complainant and avoid any possible disincentive to making a complaint.
- 12.6** In relation to the procedure for making a complaint, the following shall apply:
- 12.6.1 The complaint and supporting material must be in writing and forwarded to the Secretary of the CRMC, and should state, amongst other things:
- a) the nature of the conduct being complained of;
 - b) the provision(s) of this Code alleged to have been breached and the reasons for asserting the breach has occurred; and
 - c) where relevant, provide supporting traditional, scientific or other technical data to support the complaint.

Consideration of the Complaint

- 12.7** The Secretary of the CRMC must forward a copy of the complaint to the Chief Executive Officer (or equivalent) of the respondent within ten (10) working days of receiving the complaint and request a response, in writing, to the Secretary of the CRMC within a further fifteen (15) working days.
- 12.8** Members of the CRMC with a conflict of interest must leave the meeting and this exit plus re-entry to the meeting must be recorded in the minutes of the meeting. A quorum must still exist for the complaint to be considered.

12.9 The CRMC may inform itself of any other matter by:

12.9.1 seeking further information from the complainant or respondent;

12.9.2 consulting such persons as it thinks fit; and

12.9.3 referring to publicly available information,

Provided that:

- (a) any person consulted by the CRMC is bound to maintain confidentiality under a written non-disclosure agreement;
- (b) matters not raised in the original complaint are forwarded to the Respondent with an opportunity to respond within ten (10) working days; and
- (c) the parties are provided with a record of all information obtained pursuant to this clause and are afforded a period of ten (10) working days within which to respond.

12.10 The CRMC must consider a complaint on the basis of all material properly before it and subject to any contrary provisions set out in this Code. The CRMC will deal with all complaints in accordance with amongst other things, the standards set out in Australian Standards ISO 10002-2006 (Customer Satisfaction – Guidelines for complaints handling in organisations).

12.11 If the CRMC considers that a breach of this Code has occurred, it must determine the appropriate sanction.

12.12 The CRMC must provide a written notice of its decision to the complainant and the respondent within fifteen (15) working days of the CRMC making its decision together with its reasons and any sanctions. The notice must include details of appeal procedures.

12.13 A complainant may withdraw a complaint at any time, in which event the respondent must be informed in writing by the Secretary of the CRMC and the complaints handling procedure terminated.

12.14 The CRMC may determine not to hear a complaint, if it is satisfied that:

12.14.1 the complaint is trivial, vexatious, misconceived or lacking in substance/ supporting material; or

12.14.2 the complaint has previously been dealt with by the CRMC or another authority; or

12.14.3 the complaint can be more effectively or more conveniently dealt with by another authority, and refers the complaint to that other authority.

12.15 If the complaint is not heard pursuant to clause 12.14 the Secretary to the CRMC must inform the complainant and the respondent in writing, detailing the reasons.

12.16 Termination of the complaints handling procedure pursuant to this clause will not prevent the CRMC from referring to the CMA Board for its consideration any action or conduct on the part of a Member, which in its opinion may be likely to bring the complementary healthcare industry into disrepute.

Mediation

12.17 The CMA Board may invite members or non-members who are in dispute, to participate in mediation. Where the parties agree that mediation may be preferable to litigation in resolving a dispute, the CMA Board will engage a mediator or establish a mediation panel to facilitate the process. The panel will normally comprise non-conflicted CMA Board members, including where practicable, the CMA Chief Executive Officer.

12.18 All negotiations during mediation are non-binding and confidential. The parties must be present in person at mediation. It is not expected that the parties will be legally represented at mediation.

12.19 Any agreement reached as a result of mediation will be in writing and signed by the parties and the chair of the mediation panel or mediator. The agreement remains confidential to the parties and the mediation panel and/or the mediator, unless the parties agree it be made public. The CMA Chief Executive Officer will monitor progress in implementation of the agreement.

12.20 Where the CMA Board agrees to engage a mediator, the mediator will be responsible for arranging and conducting mediation and reporting to the Board with regard to progress. The mediator will be available to help the parties come to a final decision based on the discussions. Mediation is not legally binding.

12.21 The CMA secretariat will arrange the mediation session in consultation with the parties and panel members.

12.22 Relevant documentation will be circulated to the parties and mediator or panel members one week before the scheduled mediation.

12.23 The CMA Board will seek from the parties an equal contribution to the costs incurred by the CMA in arranging a mediation session e.g. room hire, mediator, CMA Board and secretariat travel. The parties will meet their own expenses when participating in mediation.

13 Sanctions and Enforcement Action

13.1 Where a breach of this Code has been established, before determining any sanction, the CRMC must first classify the severity of the breach with reference to the classification set out below.

Severity of Breach	Potential Implications
Minor Breach	<ul style="list-style-type: none"> ○ No safety implications to consumers ○ No effect on how consumers or healthcare professionals view the product or its competitors
Moderate Breach	<ul style="list-style-type: none"> ○ No safety implications to consumers ○ Will impact on the perceptions of the consumer or healthcare professionals regarding the product or competitor product
Severe Breach	<ul style="list-style-type: none"> ○ Safety implications posed to consumers ○ Major adverse impact on the complementary healthcare industry in Australia <ul style="list-style-type: none"> ○ will have a major impact on how consumers or healthcare professionals view the product or competitor products
Repeat Breach	<ul style="list-style-type: none"> ○ When the same or a similar breach is repeated in the promotion of either a particular product, or any product of a company, which had been found to be in breach of the Code within the preceding 24 months ○ Safety implications ○ Major adverse impact on the complementary healthcare industry in Australia

13.2 Where the CRMC finds that a Member has breached this Code, the CRMC may apply one or more of the following sanctions outlined below. **Note that only examples are given** and these examples may not cover the complete scope of sanctions that may be applied by the CRMC.

Minor or Breach	<ul style="list-style-type: none"> ○ Warning issued; ○ Member to take immediate action to discontinue/modify the practice in breach of Code (confirmed in writing to CRMC that remedial action has occurred within ten (10) working days of receipt of notification); ○ Requirement to have the offending material amended at the next print run and to destroy any offending material remaining in the Member's possession.
-----------------	---

	<ul style="list-style-type: none"> ○ Fine of up to \$20,000 plus GST ○ Member to provide written undertaking to comply with the Code in future, acknowledging consequences of future breach; ○ Referral to other relevant agency.
Moderate Breach	<ul style="list-style-type: none"> ○ Warning issued; ○ Member to take immediate action to discontinue/modify the practice in breach of Code (confirmed in writing to CRMC that remedial action has occurred within ten (10) working days of receipt of notification); ○ Requirement to have the offending material amended at the next print run and to destroy any offending material remaining in the Member's possession. ○ Fine of up to \$50,000 plus GST ○ Member to provide written undertaking to comply with the Code in future, acknowledging consequences of future breach; ○ Referral to other relevant agency.
Severe Breach	<ul style="list-style-type: none"> ○ Member to provide written undertaking to comply with the Code in future, acknowledging consequence of future breach; ○ Requirement to recall and destroy all offending material; ○ Requirement to have future advertising and promotion material pre-cleared by an ASM at the expense of the advertiser/sponsor for a specified period; ○ Repeat offenders may be required to appear before the CRMC; ○ In the case of supply of therapeutic goods which are not included in the ARTG, reference of the matter to the TGA; ○ In the case of supply of a food, reference of the matter to the relevant State Authority; ○ Suspension (for such time as determined by the CMA Board) and exclusion from CMA activities if a CMA member e.g. committee participation; ○ Refer to ACCC for misleading and deceptive conduct; ○ Fine of up to \$150,000 plus GST; ○ TGA notification; ○ Referral to other relevant agency.
Repeat Severe Breach	<ul style="list-style-type: none"> ○ Instant removal of CMA membership (where applicable). The company may re-apply for CMA membership once compliance to the Code requirements are demonstrated to the satisfaction of the CRMC and CMA Board; ○ Requirement to recall and destroy all offending material; ○ Refer to ACCC for misleading and deceptive conduct; ○ TGA notification and referral;

	<ul style="list-style-type: none">○ Fine of up to \$300,000 plus GST;○ Publishing of complaint and sanction on the CMA website.○ Referral to other relevant agency.
--	---

13.3 If the CRMC resolves that a complaint from a Member is frivolous or vexatious, the CRMC may request the complainant to show cause why it should not pay to the Secretary of the CRMC, costs and any out-of-pocket expenses associated with the complaint for abuse of this Code.

13.4 If the CRMC resolves that a breach of this Code warrants the suspension or the expulsion of any member from CMA, it must make a recommendation to the CMA Board. The CMA Board must deal with the recommendation under the provisions of the CMA Constitution.

13.5 In the event that the CRMC requires a member to cease conduct and the member wishes to appeal the decision, the CRMC decision will stand and must be complied with, pending the outcome of the appeal.

13.6 Should a respondent fail to comply with an order or directive of the CRMC the CMA may:

13.6.1 refer the complaint to the TGA (or other relevant authority); and/or

13.6.2 refer to the CMA Board for disciplinary action under the Constitution.

Publishing of Complaints

13.7 The CMA shall publish the outcomes of every upheld complaint received by the CRMC on the CMA website as and when the complaints are finalised. The website publication will be removed after 12 months.

13.7.1 When a Complaint or appeal is not upheld, the published information must be limited to the date, the name of the respondent, and a statement that the complaint or appeal was not upheld. When a complaint or appeal is partially upheld, only that portion of the complaint that is upheld will be published.

13.7.2 The details published shall include:

- the name of the product including ARTG ID, as required;
- parties identified in the complaint;
- the nature of the complaint;
- upheld breaches of this Code, TGAC and/or Therapeutic Goods Act 1989;
- the sanctions, if any, imposed by the CRMC;
- if the complaint is treated as withdrawn by the CRMC, the reasons for treating the complaint as such.

13.7.3 The details published shall not include any confidential information where good reason is provided by either party.

13.7.4 The complainant's name will not be published without permission.

14 Appeal Procedures

Establishment of the Advertising Appeals Committee

- 14.1** An Advertising Appeals Committee (AAC) is to be established by the CMA Board and will comprise not less than the following:
- 14.1.1 an independent Chair, preferably a qualified lawyer;
 - 14.1.2 a Secretary to the AAC provided by the CMA (**'Appeals Secretary'**);
 - 14.1.3 four other members drawn from a panel established by the CMA who **did not sit** on the CRMC which heard the complaint being appealed against, being:
 - a) one technical expert;
 - b) one industry representative who is a member of the CMA Board; and
 - c) one complementary healthcare Practitioner;
 - d) an observer from the TGA.
- 14.2** The appellant will be provided with the opportunity to pay for and nominate a further independent representative on the AAC, with this individual to be agreed by the Chair of the AAC.
- 14.3** Prior to selection of members of the AAC, the CMA Board must establish that a proposed member has no conflict of interest with a party subject to an appeal. No panellist may sit on AAC if he or she has a conflict of interest or perceived conflict of interest in the subject matter or with a party, before the AAC.
- 14.4** The quorum for the AAC is the Chair and three (3) other members.
- 14.5** The AAC must make decisions by a majority of its members.
- 14.6** The AAC will consider:
- 14.6.1 the material that was considered by the CRMC in the matter;
 - 14.6.2 the appeal papers and any response from the respondent to the appeal; and
 - 14.6.3 any additional material which the AAC reasonably believes will assist in its deliberations.
- 14.7** The Appeals Secretary must provide a copy of any additional material before the AAC to each party no later than ten (10) working days before the date of the appeal hearing.
- 14.8** A party is entitled to attend the meeting or be heard by the AAC in person on prior arrangement with the Appeals Secretary.

- 14.9** The findings of the AAC are final and binding on the parties. The Appeals Secretary must provide the outcome of the deliberations of the AAC to each party, no later than ten (10) working days after the AAC reaches its decision.
- 14.10** The deliberations of the AAC are confidential and must not be disclosed by a party to the appeal or by a member of the AAC.

The Appeal Procedures

- 14.11** A member who has been found to be in breach of this Code and/or a complainant who has been penalised or fined under clause 12.3 for a frivolous or vexatious complaint or abuse of this Code (the Appellant) may lodge an appeal against the findings and any imposed sanctions.
- 14.12** The Appellant must lodge notice of intention to appeal in writing with the Appeals Secretary within ten (10) working days of receiving advice of the CRMC decision and/or sanctions. The Appellant then has a further ten (10) working days in which to lodge material in support of an Appeal with six (6) copies (one (1) for each member of the AAC and one (1) for the Appeals Secretary).
- 14.13** The Appeals Secretary must provide a copy of the written Appeal to the Secretary of the CRMC for the CRMC's information and any action it may deem necessary to take. The Appeals Secretary must provide a copy of the response from the Secretary of the CRMC to the Appellant within ten (10) working days of receiving it.
- 14.14** The AAC, after meeting to examine the Appeal and providing the Appellant and the Secretary of the CRMC an opportunity to present their cases either in person or in writing, may:
- a) uphold the Appeal;
 - b) reject the Appeal;
 - c) amend the CRMC decision; or
 - d) defer a decision pending provision of further information.
- 14.15** The Appellant may be required to lodge a bond. If unsuccessful in appeal, the Appellant must reimburse CMA for its costs including out-of-pocket expenses, legal costs and reasonable expenses associated with the determination of the Appeal, unless the AAC determines otherwise. Alternatively, the AAC may require such costs to be shared by the parties in proportions determined by the AAC.

15 Monitoring of Promotional Materials and Promotional Spend

- 15.1** To support compliance with this Code the CRMC may proactively monitor selected promotional materials produced by members, on an ongoing basis.
- 15.2** The aims of monitoring are:
- 15.2.1 to encourage compliance with this Code;
 - 15.2.2 to provide advice on compliance issues where necessary;
 - 15.2.3 to obtain and publish statistical data, and identify possible trends in marketing activities; and
 - 15.2.4 to provide information for potential future amendments to this Code.
- 15.3** The CRMC may review any form of promotional material that is not subject to the pre-approval process.
- 15.3.1 Specific types of promotional materials may be selected on a random basis.
 - 15.3.2 The CRMC will determine annually the subject matter to be reviewed during the next twelve (12) months.
- 15.4** CRMC members will advise the committee when there is a conflict of interest associated either with the product class, products, or companies subject to review. The Committee will determine the appropriate action following this disclosure.
- 15.5** The CRMC may request member companies to provide any further information concerning the promotional materials under review.
- 15.6** If, following review of material, the CRMC considers that there has been a moderate, severe, or repeat breach of this Code, the material may be treated as a complaint.
- 15.7** Where monitoring is conducted during the financial year, the CRMC may publish an annual report on the CMA website, which will include a minimum of the following:
- a) the types of materials reviewed;
 - b) the number of items reviewed;
 - c) the number and type of problems found;
 - d) the number of submissions subsequently treated as a complaint.

16 Administration

Establishment and Procedures of Marketing Code Governance Committee

- 16.1** This Code is administered by a Committee (the Marketing Code Governance Committee (MCGC) which is appointed by and responsible to the Board of CMA.
- 16.2** The MCGC shall be comprised of:
- 16.2.1 the Chief Executive Officer of the CMA or their nominee;
 - 16.2.2 the Chair of the CRMC;
 - 16.2.3 one consumer representative;
 - 16.2.4 one complementary health professional representative; and a
 - 16.2.5 minimum of four (4) members of the CMA.
- 16.3** The MCGC shall meet on an “as needs basis” and at a minimum not less than once per year for annual review.
- 16.4** The MCGC must operate in accordance with the following procedures:
- 16.4.1 All MCGC members appointed by the CMA Board shall have an initial term of two (2) years. Thereafter, each such member of the MCGC may stand for re-appointment by the CMA Board in company with any other candidates identified by the CMA Board, for a further term of two (2) years. Not more than one-half of all members of the MCGC should resign in the same year wherever practicable.
 - 16.4.2 The CMA may from time to time second one or more experts to assist the MCGC in its deliberations. Experts and advisors will not have voting rights.
 - 16.4.3 A quorum consists of the Chair and three (3) other members of the MCGC.
 - 16.4.4 Where decisions of the MCGC are not unanimous, a decision shall be made by a majority vote of its members, with the Chair having a casting vote.

17 Functions of the Marketing Code Governance Committee

- 17.1** The MCGC is responsible for the review and evaluation of this Code as well as its administration. To fulfil these functions, the MCGC will, amongst other things:
- 17.1.1 conduct regular three-yearly external reviews of the Code to ensure it continues to reflect community, industry and regulatory standards and values;
 - 17.1.2 consult with key stakeholders;
 - 17.1.3 publish amendments to this Code;
 - 17.1.4 collate statistical data of complaints received and their outcomes;
 - 17.1.5 produce an annual report;
- 17.2** develop, review and renew (where necessary), a set of performance indicators, both quantitative and qualitative, (as the case requires), which will enable ongoing monitoring of the success of this Code in meeting its objectives. The performance indicators will be drafted in such a manner as to enable a third party not otherwise engaged in the administration of this Code, to easily identify the extent to which the objectives of this Code have been met;
- 17.3** develop policy for the coordinated promotion of the Code throughout the market and its recognition by consumers;
- 17.4** to prepare at least annually an operating budget for the Code that will cover its cost of operation and promotion.

18 Code Monitoring

- 18.1** The MCGC will meet no less than once a year and otherwise as and when required to develop strategies to be implemented necessary to:
- 18.1.1 monitor the take up of the CMA Code by non-members (ie: companies agreeing to comply) as a proportion of all companies to whom the code would be applicable;
 - 18.1.2 continue to monitor serious and/or systemic breaches of this Code as they are identified;
 - 18.1.3 take the appropriate remedial action to deal with such serious and systemic breaches of this Code as soon as reasonably possible; and
 - 18.1.4 put in place such preventative measures to evidence that the CMA is undertaking to prevent the continuation of such serious or systemic breaches of this Code as and when required.
- 18.2** The MCGC shall otherwise monitor this Code for compliance through the following additional methods and procedures:
- 18.2.1 a proactive review of all complaints and breaches of this Code received by the CMA will be undertaken no less than one (1) time a year and otherwise as required from time to time.
 - 18.2.2 the methods and procedures for monitoring compliance with this Code, from time to time, shall include a detailed review and consideration of no less than the following:
 - a) an analysis of all data on complaints received by the CMA during the periods monitored;
 - b) comparison with complaints analysis carried out during prior periods of monitoring; and
 - c) identification of any trends, in types of complaints and/or organisations or industry sectors.
- 18.3** Following the collection and analysis of the data referred to in clause 18.2, the MCGC shall identify, document and take all necessary steps to put into effect:
- 18.3.1 all such immediate and longer term remedial action considered necessary to deal with any current and existing problems identified; and
 - 18.3.2 all such preventative action considered necessary or desirable to prevent further breaches of this Code, whether systemic or not.
- 18.4** The MCGC will also audit on a general basis the activities of the CRMC, including but not less than:
- 18.4.1 the number and nature of sanctions imposed; and
 - 18.4.2 the number of successful appeals, if any, to decisions of the CRMC.
- 18.5** In monitoring the performance of this Code, the MCGC shall produce an annual report that includes:
- 18.5.1 the total number of complaints received during the year;
 - 18.5.2 the number of complaints received during the year regarding members and non-members;

- 18.5.3 the total number of breaches, including the specific provisions of the Code breached and any repeat breaches;
- 18.5.4 the enforcement action or sanction(s) taken; and the level of compliance with the requested enforcement action or sanctions;
- 18.5.5 any further quantitative and qualitative analysis of the performance of this Code against the performance indicators set by the MCGC; and
- 18.5.6 a written interpretation of these results in such a way that a person who is not a member of the MCGC can understand the extent to which the code has met its objectives.

19 Review and Amendments

- 19.1** This Code shall be externally reviewed once every three (3) years or more frequently if so determined by the MCGC.
- 19.2** The internal review process will be managed by the MCGC. The MCGC, in conducting the internal review, may seek comment or submissions from members and other relevant stakeholders.
- 19.3** External reviews may be conducted by:
- 19.3.1 an independent, appropriately qualified and experienced consultant; or
 - 19.3.2 a panel of independent, appropriately qualified and experienced persons.
- 19.4** Both the internal and external review process should consider not less than the following issues:
- 19.4.1 Is there a high level of Industry awareness of this Code?
 - 19.4.2 Is there a high level of stakeholder awareness of this Code?
 - 19.4.3 Has the number of complaints on issues this Code is designed to address, been reduced?
 - 19.4.4 Is this Code meeting its stated objectives?
 - 19.4.5 Are the complaints handling mechanisms highly visible?
 - 19.4.6 Are the response times reasonable?
 - 19.4.7 Are this Code's compliance mechanisms effective?
- 19.5** Amendments to this Code must be approved by the CMA Board.
- 19.6** Amendments resulting from any internal and external review of this Code must be adequately publicised so that all stakeholders are aware of those amendments.

20 Publicising the Code

- 20.1** The MCGC will identify and recommend to the CMA the optimal means for the CMA to promote this Code to its members, the complementary healthcare industry, and other relevant stakeholders and participants in the industry.
- 20.2** The MCGC will undertake a publicity campaign upon the commencement of this Code and every time more than a minor change is made and in any case, at least once every three (3) years.
- 20.3** The CMA will ensure this Code is available on its website at all times and must encourage members to reference and provide links to this Code on their own websites.
- 20.4** The CMA will encourage members to otherwise promote this Code on a regular basis.
- 20.5** The MCGC will ensure the regular provision of education regarding the interpretation and application of this Code to members, healthcare practitioners, other professionals, regulators and other relevant stakeholders and participants in the complementary healthcare industry.

21 Disclaimer

- 21.1** This Code is not intended to provide nor shall it be construed as legal advice.
- 21.2** Where there is any conflict or inconsistency between the provisions of this Code and any Commonwealth, State or Territory legislation or instruments, that legislation or instrument will take precedence over this Code.
- 21.3** The CMA and all committees established under this Code will at all times seek to exercise their powers and functions hereunder in a fair, impartial and objective manner for the benefit of no particular member, but rather for the overall greater good and benefit of the complementary healthcare industry and the wider community generally.
- 21.4** The rules of conduct and the standards of good practice imposed upon members by this Code are fair and reasonable and are otherwise necessary for this Code to achieve its objectives.
- 21.5** The powers granted to CMA and the committees established under this Code, particularly but without limitation as they are related to **“Complaints Handling”**, **“Sanctions and Enforcement Action”** and **“Appeal Procedures”**, are fair and reasonable and otherwise necessary for this Code to achieve its objective.
- 21.6** All members are deemed to have released CMA, its servants, agents, consultants and all committees established by CMA under this Code from all claims, demands, actions, suits or proceedings which a member might otherwise have brought or have been entitled to bring against all or any of the released parties, for or in relation to any act or omission taken by one or more of them, in the exercise of their functions or duties under this Code, **PROVIDED, HOWEVER, THAT** any such act or omission has not been taken or made in bad faith, maliciously or in a recklessly negligent manner.

Appendix 1 Definitions

- 1.1 *Advertisement/Promotion*** includes any statement, pictorial representation or design however made that is intended whether directly or indirectly to promote the use or supply of the goods. This includes direct to consumer advertising.
- 1.2 *Advertising Services Manager*** – exercise the delegation on behalf of the CHC, which is a delegate of the Secretary of the Department of Health and Ageing, and given the power to approve or refuse to approve therapeutic goods advertising appearing in specified media, which includes: newspapers, magazines, cinema, outdoor display, television and radio. Outdoor display includes displays about goods appearing in shopping malls (except inside individual shops), in or on public transport and on billboards.
- 1.3 *Advertorial*** means an advertisement which links editorial comment with a specific product in such a way that the reader is led to associate the two, regardless of whether identified as an advertisement or not.
- 1.4 *Approval*** for all advertisements for therapeutic goods appearing in specified media must be finalised prior to publication or broadcast (reviewed and accepted by an Advertising Services Manager). Advertisements appearing in specified media (other than television and radio advertisements) must prominently display an approval number in the bottom right hand corner of the advertisement, stand-alone.
- Advertisements only appearing on the internet or in below the line media do not require approval. However, below-the-line and internet consumer advertisements must still comply with the Therapeutic Goods Advertising Code (TGAC) and other relevant provisions in the Act and Regulations.
- 1.5 *Below the Line*** advertising is comprised of materials such as leaflets, brochures, catalogues, shelf talkers, newsletters, practitioner magazine and journal advertising, point of sale material, videos, direct mail letters, lectures, seminars, technical manuals and product manuals etc not considered to be *mainstream media*. It does not include broadcast media or internet advertising.
- 1.6 *Board*** means the committee elected by the membership of the annual general meeting of Complementary Medicines Australia to govern the organisation.
- 1.7 *Brand Name Reminder*** means such items of low monetary value that are intended to remind healthcare professionals of the existence of a product.
- 1.8 *Broadcast Media*** in relation to an advertisement or generic information means the information is disseminated electronically in a visible or audible form or a combination of such forms. Exceptions are the internet and broadcasts only available to healthcare professionals.
- 1.9 *Claim*** is a description of the specific therapeutic purpose of a product, is an advertising statement about a product and needs to be seen in the broader advertising context. The link between an indication and a claim is through Section 22(5) of the *Therapeutic Goods Act 1989*, which requires that sponsors may only make claims that are consistent with the indications for the product recorded on the ARTG.
- 1.10 *CMA*** means Complementary Medicines Australia.
- 1.11 *Company*** means all entities supplying complementary medicines in Australia. This may include a Direct Selling Organisation.

1.12 Complementary Medicines are defined in the *Therapeutic Goods Regulations 1990* as a therapeutic good consisting principally of one or more designated active ingredients mentioned in Schedule 14 of the Regulations, each of which has a clearly established identity and traditional use.

Regulated in Australia as medicines under the *Therapeutic Goods Act 1989*, complementary medicines include vitamins, mineral and nutritional supplements, homeopathic, aromatherapy products and herbal medicines (unless specifically exempt). The term 'complementary medicines' also comprises traditional medicines, including traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines. Traditional and long-term use is taken into account in establishing safety as a medicine.

1.13 Educational Material means any representation or literature that is intended to provide information about a medical condition or therapy and does not contain specific promotional claims. Examples of educational material include:

- Technical manuals
- CPE (continuing professional education) materials and course notes.

1.14 Ethical Promotion includes:

- promotion only of therapeutic products that are legally available in Australia and then only where permitted under therapeutic goods legislation;
- claims made that are reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They do not include misleading or unverifiable statements or omissions likely to induce unjustifiable use of product or give rise to undue risks;
- comparison of products is factual, fair, and capable of substantiation; and
- promotional activities do not, directly or indirectly, involve misleading, deceptive, unfair or unconscionable conduct, or make inappropriate inducements.

1.15 Evidence used in product promotion should reflect the levels required as outlined in the TGA's Guidelines on the Evidence Required to Support Indications for Listed Complementary Medicines – July 2014.

1.16 Generic information in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic goods, but does not include:

- (a) an advertisement about the goods; or
- (b) generic information included in an advertisement about the goods; or
- (c) bona fide news.

1.17 Healthcare Professional includes a person that meets the description of a healthcare professional in subsection 42AA(1) (2) (3) of the *Therapeutic Goods Act 1989*.

1.18 Mainstream Print Media means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

1.19 Marketing is the sum of commercial processes involved in promoting, selling and distributing a product or service.

1.20 Member means any Ordinary, Corporate, Associate or Life Member, including its employees, that is a member of Complementary Medicines Australia, as defined in its Constitution. Non-members are encouraged to adopt and follow the principles described within this Code.

- 1.21** **Misrepresentation** a false claim of possessing certain positive attributes or of not possessing certain negative attributes.
- 1.22** **Practitioner-Only Product** means a complementary medicine that may be listed or registered on the Australian Register of Therapeutic Goods (ARTG).. It must not be directly publicly accessible or supplied for sale over the counter without a script or authorisation by a healthcare professional.
- 1.23** **Product** means a complementary medicine or healthcare product.
- 1.24** **Product Guide (for consumers, including retailers)** – a Sponsor’s document (hard copy or electronic medium) that provides a list of company specific products with relevant information around ingredients, such as indications, dosage and storage information, etc. Considered to be an advertisement and therefore bound by the *Therapeutic Goods Advertising Code 2007*.
- 1.25** **(The) Regulations** - The *Therapeutic Goods Regulations 1990*, as amended from time to time.
- 1.26** **Puffery** refers to an exaggeration or statement that no reasonable person would take as factual. Puffing generally is defined as “exaggerated, vague, or loosely optimistic statements about a company that are deemed so immaterial and unworthy of reliance that they cannot serve as the basis for liability. The difference between a statement of fact and mere puffery rests in the specificity or generality of the claim." It is worth noting that puffery is not exempt from compliance with advertising legislation.
- 1.27** **Recall**, in respect to a request by the Complaints Resolution and Monitoring Committee, refers to an expectation for all advertising materials found to be in breach of the Code to be returned to the advertiser for destruction. The level of the recall will be specified in the request.
- 1.28** **Retailers (or retail outlets)** are businesses that sell goods directly to the consumer (as opposed to a wholesaler or supplier that normally sell their goods to another business). Retailers can include large businesses, chain stores, independent stores, direct sellers and direct marketers.
- 1.29** **Schedule 1** refers to Schedule 1 of the *Therapeutic Goods Regulations 1990*. It contains a list of national Associations of Complementary Healthcare Professionals.
- 1.30** **Social Media** (such as Facebook, YouTube, Myspace, blogs, and Twitter) is an umbrella term that defines the various activities that integrate technology, social interaction, and the creation of content.
- 1.31** **Specified Media** in relation to an advertisement or generic information, means:
- a) mainstream media within the meaning of s. 42B of the Act; or
 - b) broadcast media, within the meaning of s. 42B of the Act; or
 - c) cinematograph films; or
 - d) displays about goods, including posters:
 - i. in shopping malls (except inside individual shops);
 - ii. in or on public transport; and
 - iii. on billboards.
- 1.32** **Sponsor** is defined in the Therapeutic Goods Act as:
- a) A person who exports or arranges the export of the (therapeutic) goods from Australia; or
 - b) A person who imports or arranges the import of the (therapeutic) goods into Australia; or

- c) A person who, in Australia, manufactures the (therapeutic) goods, or arranges for another person to manufacture the (therapeutic) goods, for supply (whether in Australia or elsewhere);

But does not include a person who:

- d) Exports, imports or manufactures the goods; or
- e) Arranges the exportation, importation or manufacture of the goods on behalf of another person who; at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying out business in, Australia.

1.33 **Technical Manual** is a document containing technical, scientific or education information. A technical manual is produced exclusively for healthcare professionals and is not distributed or available to consumers, and must not refer to or have a direct link to a company product guide or a company branded product.

1.34 **Therapeutic Goods** are defined by the *Therapeutic Goods Act 1989* as goods:

- a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - i) for therapeutic use; or
 - ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
 - iii) for use as a container or part of a container for goods of the kind referred to in sub paragraph (i) or (ii); or
- b) Included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a), (ii) or (iii);

and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

- c) goods declared not to be therapeutic goods under an order in force under section 7; or
- d) goods in respect of which such an order is in force, being an order that declared the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
- e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*); or
- f) goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

1.35 **Therapeutic Use** is defined by the *Therapeutic Goods Act 1989* as meaning:

Use in or in connection with:

- a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons;
- b) influencing, inhibiting or modifying a physiological process in persons; or
- c) testing the susceptibility of persons to a disease or ailment; or
- d) influencing, controlling or preventing conception in persons; or

- e) testing for pregnancy in persons; or
- f) the replacement or modification of parts of the anatomy in persons.

1.36 **Traditional Use** means well documented, or otherwise established, according to the accumulated experience of many traditional healthcare practitioners over an extended period, and accords with well-established procedures of preparation, application and dosage.

1.37 **Unconscionable Conduct** is described by the courts as:

- a) serious misconduct or something clearly unfair or unreasonable
- b) conduct which shows no regard for conscience
- c) conduct which is irreconcilable with what is right or reasonable.

1.38 **Withdraw**, in respect to a Complaints Resolution and Monitoring Committee request, refers to an expectation of no further use or dissemination of the advertising material found to be in breach of the code.

Appendix 2 References

AS 3806-2006 *Australian Standard™ Compliance Programs*

<http://www.saiglobal.com/shop/script/Details.asp?docn=AS073377296XAT>

Australian Competition & Consumer Commission (ACCC) *Guidelines for Developing Effective Voluntary Industry Codes of Conduct*, February 2005

<http://www.accc.gov.au/content/index.phtml/itemId/658186>

Australian Competition & Consumer Commission (ACCC) *Guide to unconscionable conduct*, May 2008

<http://www.accc.gov.au/content/index.phtml/itemId/596950>

Australian Regulatory Guidelines for Complementary Medicines

<https://www.tga.gov.au/book/introduction-argcm>

Medicines Australia *Code of Conduct* Edition 17

<http://www.medicinesaustralia.com.au/pages/page251.asp>

Therapeutic Goods Act 1989

<http://www.comlaw.gov.au/comlaw/management.nsf/lookupindexpagesbyid/IP200401372?OpenDocument>

Therapeutic Goods Regulations 1990

<http://www.comlaw.gov.au/comlaw/management.nsf/lookupindexpagesbyid/IP200400127?OpenDocument>

Therapeutic Goods Advertising Code 2007

<http://www.tgacc.com.au/codeList.cfm>

Working Group on Promotion of Therapeutic Products Report to Parliamentary Secretary Catherine King

<http://tinyurl.com/6u8cqnd>

Appendix 3 Resources

Department of Health & Ageing, Regulatory Policy & Governance Division – Codes of Conduct Advisory Group
<http://www.health.gov.au/internet/main/publishing.nsf/Content/RPGD-Promotion-of-Therapeutic-Goods-Codes-of-conduct-advisory-group>

Complaints Resolution Panel – Recent Panel Determinations
www.tgacrp.com.au/index.cfm?pageID=21

Complementary Medicines Australia Website
www.cmaustralia.org.au

FSANZ Website
www.foodstandards.gov.au

NSW Food Authority
www.foodauthority.nsw.gov.au

NICNAS Cosmetic Guidelines
www.nicnas.gov.au

Therapeutic Goods Administration
<http://www.tga.gov.au>

Therapeutic Goods Administration Food Medicine Interface Guidance Tool
<https://www.tga.gov.au/food-medicine-interface-guidance-tool-fmig>

Therapeutic Goods Advertising Code 2007
www.comlaw.gov.au

ACCC information on misleading & deceptive conduct:
<http://www.accc.gov.au/content/index.phtml/itemId/815335>

CMA Guidelines for the Sale and Supply of Practitioner Only Products
www.cmaustralia.org.au/Regulatory/Guidelines