



*"sustainable health and enhanced wellness..... naturally"*

**Complementary Healthcare Council of Australia  
Code of Practice for the Marketing of  
Complementary Healthcare and Healthfood Products**

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## Definitions

**Advertisement** 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.

**Advertorial** means advertisements, which link editorial comment with a specific product in such a way that the reader is led to associate the two.

**Council** means the Complementary Healthcare Council of Australia Inc.

**Code Administration Committee (CAC)** is the committee appointed under the provisions of this code to administer the code.

**Committee of Management (COM)** is the management committee of the CHC appointed by the executive committee of the Council.

**Complaint Resolution Committee (CRC)** is the committee appointed under the provisions of this code to handle complaints made concerning breaches of provisions of this code.

**Food** is defined under the Model Food Act as:

- a) Any substance or thing of a kind used, or represented as being use, for human consumption whether it is live, raw, prepared or partly prepared), or
- b) Any substance or thing of a kind used, or represented as being for, use as an ingredient or additive in a substance or thing referred to in paragraph (a), or
- c) Any substance used in preparing a substance or thing referred to in paragraph (a) - other than a substance used in preparing a living thing - if it comes into direct contact with the substance or thing referred to in that paragraph, such as a processing aid, or
- d) Chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum, or
- e) Any substance or thing declared to be a food under a declaration in force under section 3B of the *Australian New Zealand Food Authority Act 1991* of the Commonwealth (and prescribed by the regulations for the purposes of this paragraph), whether or not the substance, thing or chewing gum is in a condition fit for human consumption.

However, food does not include a therapeutic good within the meaning of the Therapeutic Goods Act 1989 of the Commonwealth. To avoid doubt, food may include live animals and plants.

**Industry** means the complementary healthcare and health food industry.

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

**Mediation** is a voluntary and confidential conference, facilitated by mediators independent of any party, where all participants have agreed to attend and to co-operate in good faith to resolve the dispute between them.

**National Executive Committee (NEC)** means the committee that is elected by each division for ratification by the membership at the annual general meeting of the Complementary Healthcare Council of Australia Inc.

**Practitioner** means a practitioner accredited by an association listed in Schedule 1 of the Therapeutic Goods Regulations.

**Product** means a complementary healthcare or healthfood product.

**Schedule 1** refers to Schedule 1 of the Therapeutic Goods Regulations.

**Specified media** in relation to an advertisement or generic information means:

Mainstream media within the meaning of section 42B of the Act  
Cinematograph films, or

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Displays about goods, including posters in shopping malls (except inside an individual shop)  
In or on public transport  
On billboards

**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.

**Therapeutic Goods** are defined by the Therapeutic Goods Act 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 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 for which there is a prescribed standard in the Australia New Zealand Food Standards code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or
- f) Goods, which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

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

Use in or in connection with:

- a) Preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- b) Influencing, inhibiting or modifying a physiological process in persons or animals; or
- c) Testing the susceptibility of persons or animals 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 or animals.

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## Acronyms

ACCC	Australian Competition & Consumer Commission
ADMA	Australian Direct Marketing Association
ANZFA	Australia New Zealand Food Authority
ARTG	Australian Register of Therapeutic Goods
ASM	Advertising Services Manager
CAC	Code Administration Committee
CHP	Complementary healthcare product
COM	Committee of Management
CRC	Complaints Resolution Committee
DSAA	Direct Selling Association of Australia
CHC	Complementary Healthcare Council of Australia Inc
NEC	National Executive Committee
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code

## Background and Introduction

The Complementary Healthcare Council of Australia Inc (CHC) is a national industry body founded in 1998 following the amalgamation of the Nutritional Foods Association of Australia (NFAA) and Australian Council for Responsible Nutrition (ACRN) and incorporated under the ACT Associations Incorporation Act in October 1998.

### Membership

CHC membership includes raw material suppliers, manufacturers, wholesalers, distributors, importers and retailers of complementary healthcare products and health foods, (including mail order traders and multi level marketing organisations), consultants, practitioner associations, practitioners and consumers.

### Philosophy

The Council seeks to promote the industry's interests by encouraging and advancing optimum community health through increasing awareness of the role played by the appropriate use of complementary healthcare and health food products to improve health and prevent sickness.

### Activities

CHC activities include policy development; information gathering, assessment and dissemination; regulatory affairs and government liaison; issuing relevant publications; organising trade and consumer promotions and trade shows; providing education and training seminars, and facilitating industry self-regulation.

### Self Regulation

Self-regulation within the industry commenced in 1984 with the introduction of a Code of Ethics and Advertising Guidelines. The CHC's policy setting and direction is vested in its NEC, elected by the relevant divisions and ratified by the membership, COM (appointed by the NEC), and a committee structure. CHC management and the execution of policy are coordinated by its national secretariat in Canberra.

### Code of Practice

This owes its origin to the determination of the CHC's members to further secure and maintain high standards of marketing and promotion. Members have enshrined this philosophy in the industry's evolving vision and value statements, as follows:

### Vision

The complementary healthcare industry is committed to the enhancement of the health and well being of all Australians. We believe in freedom of choice and the right of consumers to factual information.

### Values

The complementary healthcare industry is committed to:

- Advancing public health
- Working with the Government to ensure an appropriate regulatory framework
- Being the contact point for all stakeholders in matters relating to natural healthcare and complementary medicines

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CHC members accept that the maintenance of high standards plays a paramount role in the marketing of the industry's products and will take all practical steps to ensure fair and honest dealings within the market.

### **The Code's Objective**

The CHC's prime objective in developing this code is to develop and recommend acceptable principles and practices that deal fairly with relationships between the:

- Supplier and consumer
- Supplier and retailer
- Supplier and natural health care professional
- Retailer and the consumer

but do not compromise safety or public benefit or the right of a particular consumer to make an informed judgment or purchasing decision.

The approach is predicated on the capacity of respective audiences to understand messages and discriminate between what is empirical and what is promotional or puffery. What distinguishes this code from imposed regulations is that members agree to support it and not treat its provisions as obstacles to be circumvented by legal ingenuity.

### **Purpose of the Code**

- 1.1 This code has been developed by the Complementary Healthcare Council of Australia Inc which has among its members: suppliers, manufacturers, raw material suppliers, importers, distributors, agents or marketers, retailers (including mail order traders and multi level marketers) and natural health care professionals who actively market (purchase or obtain for resale) complementary healthcare and health food products.
- 1.2 Adherence is a mandatory requirement of CHC membership as a condition of doing business.
- 1.3 Council members submit to this code in all aspects because they acknowledge an obligation to ensure that their dealings are consistent with the highest standards of integrity; that product claims are honest, intelligible, substantial, and conform to canons of good taste, and comply with relevant Commonwealth, State and Territory legislation.
- 1.4 Non CHC-members are invited and encouraged to accept and abide by this code.
- 1.5 For the purposes of this code it is considered that sponsors generally supply to one or more of the following three distinct marketing audiences:
  - Natural health care professionals
  - Retailers
  - The general public
- 1.6 The above three activities are supplemented by:
  - Mail order merchandising direct from sponsor to the general public
  - Multi-level marketing from the principal sponsor company through distributors and agents to the consumer
  - Marketing by the retailer to the general public
- 1.7 Specifically, the purpose of the code is to assist members to ensure that:
  - They possess a thorough knowledge and due regard for their customers' requirements by responsibly informing them about health and nutrition products that are available and the importance of them to their well being

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- All information is presented in an accurate, honest and balanced way
  - Such information is communicated in a way which advances the responsible and rational use of complementary healthcare and health food products, but does not encourage salesmanship at the expense of respect for customer welfare and needs
  - The highest standards of professionalism are employed in dealings and relationships, and
  - they are aware that commercially significant sanctions will apply for those found to be in breach.

#### **4. General Principles**

**Scope:** These general provisions apply to the marketing of all products irrespective of the specific target audience.

##### **4.1 Conduct**

- 4.1.1 Members should not engage in any unfair or unconscionable conduct or commercial practice.
- 4.1.2 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.
- 4.1.3 Members shall comply at all times with the provisions of such other codes that are from time to time developed and/or endorsed by the CHC.
- 4.1.4 Members will guard against marketing products in a way that might encourage inappropriate use in children.
- 4.1.5 Members will at no time make statements that may lead consumers to forego appropriate medical advice or the advice of a health care professional.
- 4.1.6 Members within a manufacturing or supplier company will appoint a responsible person within the organisation to ensure that these code provisions are followed diligently. The CHC will be notified of the details of this person and these will be included in a register. The member nominee will also bring to the attention of the member any information received about possible adverse reactions to any product or ingredients contained therein and also maintain a record of consumer complaints, including adverse reactions.
- 4.1.7 Members shall ensure that all appropriate personnel within their organisations and outside service organisations and consultants shall be aware of the requirements of this code and the responsibilities attendant to it.
- 4.1.8 Members will cooperate with the CHC in the investigation of problems and/or complaints that may from time to time arise under the provisions of the code.

##### **4.2 Advertising and Promotion**

###### **General**

- 4.2.1 Advertising and promotional material must be clearly distinguishable as such.
- 4.2.2 All material must clearly identify the source of that material by detailing the advertiser's name, address, telephone / facsimile number.
- 4.2.3 Advertising and promotional material (including graphics and other visual representations) must not mislead or contain exaggerated claims (direct or implied) and must conform to generally accepted standards of good taste and recognise the standing of the recipient.
- 4.2.4 Literature references, information, findings or conclusions from independent research, surveys or scientific studies must be assessed and presented in a balanced, objective, honest and accurate manner.

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- 4.2.5 All descriptions, claims and comparisons that relate to any objectively ascertainable facts must be capable of substantiation.
  - 4.2.6 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.
  - 4.2.7 Unqualified superlatives must not be used.
  - 4.2.8 Claims must not imply that a product or an active ingredient is unique or has some special merit, quality or property unless this can be substantiated.
  - 4.2.9 A product may not use the word *new* for more than one year following general introduction. To justify such a description the advertiser must be able to demonstrate the existence of real novelty in effect or formulation or presentation or brand name (provided that the same advertiser under a different brand name has not previously sold the product).
  - 4.2.10 No advertisement shall denigrate or attack unfairly any other products, goods or services or other sectors of the industry.
  - 4.2.11 Advertising and 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.
  - 4.2.12 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.
  - 4.2.13 No advertisement shall rest on claims that a product does not contain an ingredient commonly used in competitive products in such a way as to give the impression that the ingredient is generally unsafe or harmful.
  - 4.2.14 Care should be taken in the use of the word *natural* or a similar term used unqualified to describe a product or its ingredients.

*Made or derived from natural sources* may be a more appropriate description. In advertisements for products, which combine ingredients from natural sources with synthetic active and/or non-active ingredients, the term *natural* must be used only in reference to those constituents to which it applies.

### **4.3 Recommendations and Testimonials**

- 4.3.1 Testimonials should represent the user's genuine views. If a testimonial is shortened, care should be taken that the original meaning is not changed in any way.
- 4.3.2 Any material in testimonials, which is contrary to this code, must not be used.
- 4.3.3 The writers of testimonials may not be identified as members of any health care profession.
- 4.3.4 Testimonials for therapeutic goods can be used only in relation to the indication for which the product has been accepted for inclusion in the ARTG.

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## **5. Marketing of Products to the Public Including Retailers**

**Scope:** This section sets out principles governing marketing activities to the public, including retailers.

### **5.1 Underlying Principles**

- 5.1.1 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.
- 5.1.2 All retailers at present are considered in the same manner as members of the general public under advertising provisions within therapeutic goods legislation and regulation.
- 5.1.3 No advertisement shall encourage directly or indirectly the indiscriminate, unnecessary or excessive use of the product in question, and shall not encourage salesmanship at the expense of respect for customer welfare and needs.

### **5.2 Shelf Talkers**

- 5.2.1 Claims included in shelf talkers must be consistent with those included in the ARTG in relation to that product.
- 5.2.2 Shelf talkers that include a statement of purpose must carry the appropriate required warning statements.

### **5.3 In store Advice to Consumers**

- 5.3.1 In store advice and information is encouraged but the following parameters should be observed:
- The advice or information shall not be diagnostic in nature
  - It shall be confined to [general health and nutrition] issues
  - It shall *not* involve sale of practitioner only products, and
  - It shall be consistent with respect to a customer's legitimate needs and welfare.

### **5.4 Practitioner Only Products**

- 5.4.1 Products labeled practitioner-only or practitioner dispensing only shall not be supplied for sale over the counter without a formal consultation.
- 5.4.2 Such products may be sold or dispensed only by a natural health care professional.

### **5.5 Direct Sellers**

- 5.5.1 In the event that a salesperson, distributor or representative offering a company's products for sale should engage in any improper course of conduct pertaining to a sales presentation of its goods or services, the company shall promptly investigate the complaint and shall take such action as it may find appropriate and necessary to redress the problem and to put in place systems that will prevent the problem recurring.
- 5.5.2 A Company will be considered responsible for breaches of any relevant legislation by their salespersons, distributors or representatives where the company has authorised supported or condoned the practice. The company is required to establish appropriate procedures to ensure that its salespersons, distributors or representatives comply with all relevant legislation.
- 5.5.3 Companies shall not use the independent contractor status of salespersons, distributors or representatives supplying their products under its trademark or trade name as a defence against alleged breaches of any relevant legislation, but they shall not be prevented from raising such a defence under any other circumstances.

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## 5.6 Direct Marketers

- 5.6.1 A direct marketer shall not make misleading or deceptive claims about an offer delivered through direct marketing whether by words, omission, illustration or any other means. A direct marketer shall not make false or misleading claims with respect to the price or quality of goods or services.
- 5.6.2 A Company will be considered responsible for breaches of any relevant legislation by their employees, agents or subcontractors where the company has authorised supported or condoned the practice. Its employees, agents or subcontractors shall consider a Company responsible for breaches of legislation, even if it had no knowledge of the offending practice. The company is required to establish appropriate procedures to ensure that its employees, agents or subcontractors comply with all relevant legislation.
- 5.6.3 In the event that an *employee, agent or subcontractor* offering a company's products for sale should engage in any improper course of conduct pertaining to the sales presentation of its goods or services, the company shall promptly investigate the complaint and shall take such action as it may find appropriate and necessary to redress the problem and to put in place systems that will prevent the problem recurring.

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## 6. Advertising Products to the General Public

**Scope:** This section sets out principles governing advertising products to the public including retailers.

### 6.1 Provisions

6.1.1 These provisions apply to material such as leaflets, brochures, catalogues, web site and Internet; shelf talkers, newsletters, magazine and journal advertising, point of sale material, videos, direct mail letters, lectures, seminars etc not considered *mainstream media*. These provisions are in addition to the *general principles* at Section 4.

### 6.2 Advertising Rules

- 6.2.1 Advertisements for products must be truthful and not misleading and be socially responsible.
- 6.2.2 Advertisements for CHPs must comply with the Therapeutic Goods Advertising Code (TGAC).
- 6.2.3 A CHP may be advertised only for those indications included in the ARTG in relation to that product.
- 6.2.4 The CHC advertising services manager must approve advertisements for CHPs in specified media other than broadcast media.
- 6.2.5 Advertisements for CHPs in broadcast media must be approved by the advertising services manager of the Australian Self Medication Industry.
- 6.2.6 No advertisement shall denigrate other forms of medicine or pharmaceutical drugs.
- 6.2.7 Claims of *no side effects* for a CHP product require written permission from the Secretary, Commonwealth Department of Health and Family Services.
- 6.2.8 Advertising of CHPs shall contain the relevant mandatory statements as set out in provisions of the TGAC.
- 6.2.9 Advertisements shall be clearly distinguishable from editorial material.
- 6.2.10 Advertisements should not be placed (or accepted) on the basis that they will be in juxtaposition to editorial matter in such a way as to suggest that the product is suitable for conditions for which the product would not be permitted to be recommended in an advertisement, or for which it has not been accepted.
- 6.2.11 No advertisement shall contain any offer to diagnose, prescribe or treat with therapeutic products by correspondence.
- 6.2.12 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.
- 6.2.13 No advertisement should in any way tend to discourage the reader from seeking the advice of a qualified health care professional.
- 6.2.14 No advertisement shall employ any words, phrases or illustrations that claim or imply the cure of any ailment, illness or disease as distinct from the relief of its symptoms.
- 6.2.15 Advertisements suggesting that the use of a product should be for routine or prolonged use are acceptable only if such use is capable of reasonable justification.

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### 6.3 Advertorials

6.3.1 Advertorials are permissible provided the content of the editorial complies with the advertising provisions. In general, there are two categories of publications:

- Those published independently of a particular sponsor and containing advertisements for a variety of sponsors' products; and
- Those published by or on behalf of a particular sponsor for the primary purpose of promoting the use or supply of that sponsor's products. Such a publication may be a single page, a pamphlet, Internet or a magazine, etc.

6.3.2 In relation to the *first category* of publication, editorial comment is regarded as an advertisement (*advertorial*) for a product if a product name, label, advertisement or product specific information, for the ingredients mentioned in the *editorial* content appears on the same page, or on the page immediately preceding or the page immediately proceeding the *editorial* content.

6.3.3 In relation to the *second category*, the publication is regarded, in its entirety as an advertisement.

### 6.4 Web Site Advertising

6.4.1 Advertisements on company web sites must comply with the advertising requirements as detailed in the Internet Guidelines at *Attachment 3*.

6.4.2 Claims for branded product on web sites must be in compliance with those that are included in the ARTG in relation to that product.

### 6.5 Provisions for Advertising Foods

6.5.1 Advertisements for food shall comply with the provisions specified in Standard A1 (19) of the Australian Food Standards Code and are as follows:

- a) Save where otherwise expressly prescribed by this code, any label on or attached to a package containing or any advertisement for food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import.
- b) Any label on or attached to a package containing or an advertisement for a food shall not include the word *health* or any word or words of similar import as a part of or in conjunction with the name of the food.
- c) Save where otherwise expressly prescribed by this code, any label on or attached to a package containing or any advertisement for food shall not contain any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person.
- d) Save where otherwise expressly prescribed by this code, the label on or attached to a package containing or any advertisement for food shall not contain the name of or a reference to any disease or physiological condition.

### 6.6 Books

6.6.1 If an advertisement for a product also mentions or offers the sale of a book the following rules must be observed.

6.6.2 The overall intent of the advertisement must not seek to circumvent the provisions of this Code or the Therapeutic Goods Advertising Code.

6.6.3 The book cannot make a claim for a branded product if that claim is not included in the ARTG for that product.

6.6.4 If a book is published by or on behalf of the advertiser then it will be treated as an extension of the advertisement and subject to the same rules.

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- 6.6.5 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.
  - 6.6.6 If an independently published book is mentioned but not offered for sale the advertisement should not give the impression that there is any medical claim being made that would not normally be permitted.

## **6.7 Journal References**

- 6.7.1 The title of an article referenced in an advertisement must not contravene the code or section 22(5) of the Therapeutic Goods Act, and name of the journal should appear, even if the name of the journal includes a prohibited representation.

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## 7. Marketing of Complementary Healthcare Products for Registered Indications to Practitioners

**Scope:** This section of the Code sets out principles governing marketing activities by advertisers to practitioners. These provisions are in addition to the *general principles* at Section 4.

### 7.1 Underlying Principles

7.1.1 Practitioners possess an understanding and knowledge of the beneficial properties of the product and the ability to distill such information from any advertising or promotion excesses.

7.1.2 These provisions deal specifically with the advertising, promotion and supply of product for registered indications.

7.1.3 Products must be included in the ARTG for the registered indications, which are advertised to practitioners. [*Listed* products for *practitioner-only* purposes may not be advertised or supplied with *proscribed* claims.]

7.1.4 Products are so located that they are inaccessible by the general public or unauthorised personnel.

### 7.2 General Provisions

7.2.1 Products with **registerable** claims (i.e. *restricted* or [*prohibited*] *representations* in terms of the Therapeutic Goods Advertising Code) included in the ARTG as registered goods (other than certain homeopathic goods) are *practitioner-only* and shall be supplied and advertised only to qualified practitioners.

- Products labeled as *practitioner-only* are products which do not have a statement of purpose and must at all times be labeled and dispensed by the practitioner

7.2.2 Sponsors shall not supply *practitioner-only* products to retail outlets unless the following is observed:

- Such products are supplied to the qualified practitioner's own account, kept separately and supplied by the retailer in accordance with clear instructions received from the practitioner
- Where the retail outlet is the collection centre for the practitioner's patients, the product must conform to State/Territory labeling requirements
- The retail outlet has a separate closed consulting area furnished as a consulting room for use by the practitioner
- The supply, payment and stock control are the sole responsibility of the practitioner and adequate records are kept.

7.2.3 The products are not to be publicly displayed or routinely retailed over-the-counter.

### 7.3 Advertising and Promotion

7.3.1 Advertisements and promotional material from sponsor to practitioner are exempted from the provisions of the TGAC unless such material supplied by the sponsor is to be used as product support information (e.g. video, audiotape, leaflet or brochure) supplied by the practitioner to the patient.

7.3.2 Information and claims must be capable of substantiation. Such substantiation must be provided without delay upon receipt of a request.

7.3.3 Such information and claims must not exceed those included in the ARTG in relation to that product as required under Section 22 (5) of the Act.

7.3.4 Promotion at professional trade displays, seminars and forums (of *practitioner-only* products) must only be directed at qualified health care professionals.

7.3.5 Activities advertised as educational or scientific should not be used for product promotion.

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## **8. Administration of the Code of Practice**

### **8.1 Code Administration Committee**

8.1.1 This code is to be administered by the Code Administration Committee (CAC), which will be made up of:

- The Executive Director of the Complementary Healthcare Council of Australia Inc or his / her nominee
- Three members of the CHC (selected by NEC), one of whom must have technical expertise, and the other two being a supplier and a retailer member. Each position may have an alternate to attend meetings in the absence of the member
- A practitioner approved by the NEC
- An observer from the Therapeutic Goods Administration;
- A member with extensive experience in administration of food law at State level approved by the NEC
- A consumer representative approved by the NEC
- A representative of the Australian Direct Marketing Association approved by the NEC
- A representative of the Direct Selling Association of Australia approved by the NEC
- An observer from the Australian Competition & Consumer Commission, and
- An observer from the Essential Oils Traders [Focus Group] on invitation from the Committee.

Such persons should have:

- An ability to be well informed and objective
- An unbiased appreciation of the philosophy of complementary medicine
- An ability to analyse issues and to judge their effects on consumers and different sectors of the community
- An ability to exercise sound and balanced judgments
- An ability to present an argument rationally and convincingly and to negotiate and make appropriate compromises to achieve an acceptable outcome
- Relevant community and business experience in technical and professional skills where appropriate
- A close interest in and commitment to examining the issues of concern in administering this code, and
- Involvement or links with relevant user/consumer/community public interest groups.

8.1.2 A committee member shall hold office for a period of two years and shall be eligible for reappointment.

8.1.3 A quorum shall consist of the Chair, one manufacturer, one representative from both the ACA and the TGA, one practitioner and the Executive Director or his/her alternate.

8.1.4 The CAC shall meet at least twice each year.

8.1.5 The tasks of the CAC are:

- To overview the effective operation and administration of the complaints handling procedures and CRC
- To develop policy for the coordinated promotion of the code
- To publish an annual report on the operation of the code

- 
- To conduct a regular review of complaints and issues raised with the industry concerning marketing and promotion practices
  - To collate statistical data of complaints, in aggregate, so that the code's Annual report provides a comprehensive view of the industry response to complaint handling
  - To determine the policy and procedures to promote the code's application throughout the market and its recognition by consumers, and
  - To prepare at least annually an operating budget for the Code which will cover its cost of operation and promotion

## **8.2 Advertising Approval**

- 8.2.1 All advertisements for CHPs in specified media are required by law to be approved by the CHC advertising services manager.
- 8.2.2 Members are encouraged to seek clearance for all other advertising material through the pre-clearance service established under the CHC Code of Practice.

## **8.3 Complaints Resolution**

- 8.3.1 The Code Administration Committee will sit as a Complaints Resolution Committee at two-monthly intervals or more frequently as required. The purpose of the CRC is to self regulate the industry by assessing complaints on products and advertisements from Government, industry, consumers and other bodies and to take appropriate action to remedy the situation.
- 8.3.2 In assessing whether a breach of the code has occurred, the CRC shall take into account whether the advertising or promotion would mislead the relevant target audience.

## **8.4 Complaint Handling Procedures**

- 8.4.1 All complaints whether concerning members or non-members will be dealt with expeditiously.
- 8.4.2 Complaints received from whatever source should be recorded and full details documented as per the guidelines for complaints.
- 8.4.3 The CHC will acknowledge the complaint in writing to the parties and allow the advertiser the opportunity to provide an explanation prior to the CRC's consideration of the complaint.
- 8.4.4 Where a complaint about a CHP involves risk to public safety or a CHP that has not been included in the ARTG, the CHC executive director of the CHC, or his/her delegate, will refer the matter immediately to the Surveillance Unit of the Therapeutic Goods Administration for further action, as it deems appropriate.
- 8.4.5 After considering all information provided where the complaint may constitute a breach of this code, the complaint should be referred to the CRC.
- 8.4.6 Upon determination of the alleged breach, the executive director, or his/her delegate, shall notify all relevant parties of the decision of the CRC and appeal provisions.
- 8.4.7 Complaints referred as part of a monitoring process will be referred to the CRC for consideration and determination of appropriate action.

## **8.5 Sanctions**

- 8.5.1 One or more of the following sanctions may be applied by the CRC where breaches of the Code have been established:
- a) A requirement to give an undertaking in writing to discontinue any practice which has been determined to constitute a breach of the code
  - b) A requirement to recall and destroy any offending material

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- c) In less serious cases, a requirement to have the offending material amended at the next print run
  - d) A requirement to have future advertising and promotion material pre-cleared
  - e) Repeat offenders may be required to appear before the CRC
  - f) A requirement to lodge a bond of at least \$1500 for 12 months to be released provided no further similar or major offences are recorded against the company in that period, together with an administration fee up to \$250
  - g) Forfeiture of a lodged bond
  - h) Fines that reflect the damage done by the breach or negate the commercial advantage gained by the offending material
  - i) Suspension or exclusion from membership as stipulated in the rules of the CHC (subject to ratification by the NEC)
  - j) In the case of supply of therapeutic goods which are not included in the ARTG, reference of the matter to the TGA Surveillance Unit; and/or
  - k) Suspension or exclusion from participation in any advisory and/or policy defining body of the CHC

## **8.6 Compliance**

8.6.1 Should a sponsor refuse to comply with the sanction imposed by the CRC or refuse to have a complaint heard by that committee, then the CHC executive director may either:

- Direct the publication in the next edition of the CHC's newsletter details of the breach and the CHC's consequent requirements for remedial action
- In the case of refusal by the offending member to undertake the required remedial action, direct the publication in the trade press of the member's breach and the CHC's requirements for remedial action
- In the case of therapeutic goods, refer the matter to the TGA for appropriate action
- In the case of foods refer the matter to the relevant state food regulatory agency
- Refer the matter to the ACCC
- Institute legal proceedings on behalf of the CHC

## **8.7 Policy on Convicted Members**

8.7.1 The policy applies to CHC members convicted under Australian law.

8.7.2 The CHC does not condone deliberate non-compliance with any relevant Australian law. Such action may bring the industry, the CHC and its members into disrepute, or disadvantage the consumer or other organisations in the marketplace.

8.7.3 Upon conviction at law, the CHC will review the matter and the outcome at the next occurring meeting of the CRC.

8.7.4 The CRC will consider pertinent issues including:

- The intent of the offender
- The culpability
- Actual damage
- Potential for damage
- Remorse demonstrated
- Rectification undertaken, and

- 
- The range of applicable sanctions, including a co-regulatory approach with the relevant Government authority, recognising that any sanctions imposed by the CHC relate to potential damage to the industry, and not to the breaches of law for which a sentence has already been imposed

and make a recommendation to the NEC on the appropriate course of action.

- 8.7.5 The NEC will determine the appropriate action and cause this to be published in full detail in the CHC's newsletter and/or other media as deemed appropriate to the matter.
- 8.7.6 The NEC will determine the reasonable costs of the sanction applied and require these to be paid by the offending member. A fine may be imposed for damage to the industry in the range of \$2,500 to \$20,000.

## **8.8 Appeal Provisions**

- 8.8.1 There will be access to these appeal code provisions should any party to a CRC decision feel aggrieved and wish the decision reviewed.
- 8.8.2 An appeal attracts a \$250 administration fee, which shall be waived in the case of an appeal by a consumer.
- 8.8.3 An appeal against a decision of the CRC shall be in writing and directed to the NEC within 14 days of formal notification of the decision.
- 8.8.4 The NEC may consider the appeal, or establish an expert panel to consider the appeal.
- 8.8.5 The expert panel shall include the Chair of the CRC (or nominee), one technical expert, one industry representative, one practitioner and a TGA representative as appropriate, and as approved by the NEC.
- 8.8.6 The NEC or the expert panel, after meeting to examine the complaint and providing the appellant an opportunity to present views either personally or in writing, may:
- a) Uphold the appeal
  - b) Reject the appeal
  - c) Amend the CRC decision
  - d) Defer a decision pending provision of further information, or
  - e) Refer the matter to a Trade Practices Lawyer for adjudication.
- 8.8.7 The NEC will advise the appellant of the outcome of the appeal after it has endorsed the decision of the expert panel, or taken its own decision. The NEC decision is final.

## **8.9 Publicising the Code**

- 8.9.1 The Code Administration Committee shall widely publicise the code's existence and the administration rules (and any alterations thereto) to the industry, the general public and other relevant audiences.

## **8.10 Records and Reporting**

- 8.10.1 The Code Administration Committee shall keep appropriate data. Such data shall include:
- The number of complaints lodged and by whom
  - The number found to be in breach of the code and why
  - Details of the action taken
  - The number found not to be in breach of the code and why
  - Time taken to deal with complaints

- 
- How many items were monitored within each category, and
  - How many monitored were found to be in breach and why and action taken

### **8.11 Reporting Procedures**

8.11.1 The Code Administration Committee shall report to the NEC at least annually on the operation of its activities including the number of complaints, type of complaints and whether the complaints were substantiated. The CAC shall produce an annual report on the code and its administration and distribute it widely to interested parties.

### **8.12 Review and Evaluation of the Code and Administration Rules**

8.12.1 The code and its administration will be reviewed and evaluated by the NEC each 12 months or as required.

8.12.2 Comments shall be sought from interested parties on the review and evaluation of the Code and on proposed amendments.

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## **9. Mediation**

### **9.1 General Provisions**

- 9.1.1 The NEC may invite members, or non-members, who are in dispute to participate in mediation. The NEC will appoint a mediator or mediation panel to assist the parties to discuss, negotiate and achieve a solution.
- 9.1.2 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.
- 9.1.3 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. NEC will monitor progress in implementation of the agreement.

### **9.2 Mediation Panel**

- 9.2.1 Where the parties to a dispute agree that mediation may be preferable to litigation in resolving a dispute, the NEC will engage a mediator or establish a mediation panel to facilitate the process. The panel will normally comprise NEC members, including where practicable, the CHC executive director.

### **9.3 Mediator**

- 9.3.1 Where the NEC agrees to engage a mediator, the mediator will be responsible for arranging and conducting mediation and reporting to the NEC on progress.

### **9.4 Mediation Session**

- 9.4.1 The CHC secretariat will arrange the mediation session in consultation with the parties and panel members.

### **9.5 Documentation**

- 9.5.1 Relevant documentation will be circulated to the Parties and Mediator or Panel Members one week before the scheduled mediation.

### **9.6 Costs**

- 9.6.1 The NEC may seek from the parties a contribution to the costs incurred by the CHC in arranging a mediation session e.g. room hire, mediator or secretariat travel. NEC panel members and the parties will normally meet their own expenses in participating in mediation.

**Guideline for the Tamper-Evident Packaging of Medicine, Complementary  
Healthcare Products and Medical Devices**

**22<sup>nd</sup> December 2000  
Edition 1**

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**Edition 1**

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## 1. INTRODUCTION

This guideline has been developed by the Australian Self-Medication Industry (ASMI) in consultation with the Australian Pharmaceutical Manufacturers Association (APMA), the Complementary Healthcare Council of Australia (CHC), the Medical Industry Association of Australia (MIAA), Consumers Health Forum (CHF), the Therapeutic Goods Administration and the State and Territory Health Departments.

It has been based on the guideline developed by and imposed as a condition of membership of the ASMI since the early 1980s. The development and subsequent revisions were based largely on the US requirements. In this revision, the US, UK, Canada and New Zealand have been consulted and as a result, the Guideline reflects world's best practice.

It is believed that compliance with this guideline is in the interests of the community, the industry and individual companies alike.

In order to maximise the effectiveness of tamper-evident packaging, the industry is committed to educating consumers, healthcare professionals and retailers about the importance of identifying that tamper-evident packaging features are present and intact as part of normal purchasing and use practices.

An Industry Guidelines Committee (IGC) has been formed to:

- maintain the currency of TEP Guideline with appropriate reference to international best practice;
- assess new forms of tamper-evident packaging for inclusion into the Guideline;
- coordinate annual reviews as set out in section 6.2;
- review the Guideline following three-year implementation period prior to the introduction of legislation;
- coordinate/advise on the evaluation of consumer recognition and understanding of labeling statements; and
- periodically review products exempted from the Guideline.

## 2. DEFINITIONS/CONCEPTS

Tamper-Evident Packaging (TEP):

*Packaging having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible or audible evidence to consumers that tampering has occurred.*<sup>1</sup>

Tamper-evident packaging may involve immediate-container/carton systems or any combination thereof. It is intended to provide a visual indication of package integrity when handled in a reasonable manner during manufacture, distribution and retail supply. The visual indication is required to be accompanied by appropriate precautionary label statements to describe the tamper-evident feature(s) to the consumer and to warn that the absence of or damage to such feature(s) at the time of purchase is an indication of possible tampering with the product.

"Tamper proof" (as distinct from tamper-evident packaging) is not possible and, therefore, any suggestion that a package is tamper proof, is considered to be deliberately misleading.

## 3. SCOPE

The guideline has been developed for the Australian Medicines Industry, including Complementary Healthcare Products and the Medical Devices, Industries.

This guideline comes into effect on 1 January 2001. For the next three years compliance will be voluntary (see Clause 6.2 on auditing for compliance). It is envisaged that after three years, compliance will become mandatory under therapeutic goods legislation.

Tamper-evident packaging is to be applied to:

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<sup>1</sup> This definition is derived from the US FDA definition for Tamper-resistant packaging.

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### **3.1 Non-Prescription and Complementary Healthcare Products**

All non-prescription and complementary healthcare products that may be administered transdermally, ingested orally or come in contact with mucous membranes (other than dentrifices, lozenges, essential oils and preparations in aerosol containers).

### **3.2 Prescription Medicines**

In recognition of the secure supply chain for prescription products and their restricted availability to consumers, being stored in the dispensary and only supplied on prescription, prescription medicines are not required to be packaged in tamper-evident packaging. However, many prescription medicines are currently packaged in acceptable tamper-evident packaging as described in Section 4. If sponsors choose to use TEP for their prescription products, they should use an acceptable form of packaging as described in this guideline.

### **3.3 Medical Devices**

Most medical devices are supplied directly to healthcare providers. In recognition of the secure supply chain for medical devices supplied to healthcare providers and their restricted availability to patients, being stored either in controlled rooms with restricted access or departments where their supply is controlled, medical devices are not required to be packaged in tamper-evident packaging as described in Section 4. Should sponsors choose to use TEP for their medical devices, they should use an acceptable form of packaging that will meet the Essential Principles relating to product safety outlined in the Medical Devices Regulations, anticipated to come into effect in mid 2001. The Essential Principles require, among other things, that a medical device must be designed, manufactured and packed in such a way as to ensure any risks associated with contaminants and infection are minimised having regard to the intended purpose of the device.

Products such as contact lens, cleaning solutions, eye lubricants and artificial tears that can be purchased by consumers and that come into direct contact with the eye, are required to be packaged in tamper-evident packaging as described in Section 4.

### **3.4 Two-Piece Hard Gelatin Capsule Products**

Many products that are available on the Australian market are presented as two-piece hard gelatin capsules.

Two-piece hard gelatin capsules are specifically dealt with here because, of the product tampering incidents around the world, many have occurred in two piece hard gelatin capsules and this dosage form is now considered to be vulnerable to tampering attempts.

In response, some manufacturers have employed technology to seal the capsule so that it is not easily taken apart. This type of sealing has become mandatory in the US.

The approach of the Australian industry is to recognise the vulnerability of this dosage form and to set out specific tamper evident packaging requirements but not to mandate the use of capsule sealing technology which is a costly and prohibitive burden and is not considered to have the desired effect. It is considered that the way to maximise the effectiveness of tamper evident packaging features is through education of consumers and healthcare professionals to enhance consumers' ability to identify the features and to use them as part of their purchasing and medication use regimes rather than through increasing the number of physical barriers.

Tamper evident packaging requirements for:

### **3.5 Unsealed Two-Piece Hard Gelatin Capsules**

A minimum of two tamper evident packaging features and corresponding statements on the label or consumer medicine information (CMI).

### **3.6 Sealed Two-Piece Hard Gelatin Capsules**

A minimum of one tamper evident packaging feature and a corresponding statement on the label or consumer medicine information (CMI).

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## **4. ACCEPTABLE TAMPER-EVIDENT FEATURES**

The packaging technologies listed below are considered to meet the requirements for TEP provided that they are properly designed and appropriately used.

Whilst these classes of packaging are acceptable, they should not be seen to be exclusive of other packaging types or to preclude technological innovation.

Tamper-evident packaging must not be regarded as replacing or obviating the need for Child Resistant Closures wherever the law requires such closures.

In selecting/developing tamper-evident packaging, manufacturers are urged to give serious consideration to the needs of arthritic or manually impaired persons.

### **4.1 Film Wrappers**

A transparent film with distinctive design is wrapped securely around the entire product container. The film must be cut or torn to remove the product. The wrapper must have an identifying characteristic (e.g. a pattern, name, registered trade mark, logo, or picture) that cannot be readily duplicated.

Tinted wrappers are not acceptable as an identifying characteristic because of the possibility that their material may be available to the public.

A reasonably tight "fit" of the film around the container must be achieved, e.g. by a heat shrink type process. Sealing of a film wrapper with overlapping end flaps is acceptable only if the ends cannot be opened and resealed without leaving visible evidence of tampering.

The use of cellophane with overlapping end flaps is not acceptable because of the possibility that the ends can be opened and resealed without leaving visible evidence that tampering has occurred.

### **4.2 Blister or Strip Packs**

Dosage units (for example, capsules or tablets) are individually sealed in plastic or foil. The individual compartment must be torn or broken to obtain the product. The backing materials cannot be readily separated from the blisters or easily replaced without leaving evidence of tampering.

### **4.3 Bubble Packs**

The product and container are sealed in plastic and mounted in or on a display card. The plastic must be torn or broken to remove the product. The backing material cannot be readily separated from the bubble or easily replaced without leaving evidence of tampering.

### **4.4 Heat Shrink Bands or Wrappers**

Bands or wrappers with a distinctive design (e.g., a pattern, name, registered trade mark, logo, or picture) are shrunk by heat to seal the union of the cap and container.

The seal must be cut or torn to remove the product. The band or wrapper cannot easily be worked off and reapplied without visible damage to the band. Use of a perforated tear strip can enhance tamper evidence.

Cellulose wet shrink seals are not acceptable as the knowledge of how to remove and reapply these seals without evidence of tampering is widespread.

### **4.5 Foil, Paper, or Plastic Pouches**

The product is enclosed in an individual pouch that must be torn or broken to obtain the product. The pouch should have a distinctive design (e.g., a pattern, name, registered trademark, logo, or picture).

The end seals of the pouches cannot be separated and resealed without showing visible evidence of entry.

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For sterile medical devices, packaging is designed so that it cannot be opened without obviously damaging the unit pack or seal of the unit pack, which is non-resealable and carries a label statement “Sterile if in unopened undamaged pack” or words or symbols to that effect. This type of packaging is considered to be tamper-evident without additional labeling requirements.

Direct printing of the label on the container is preferred to using a label that could be removed and substituted.

#### **4.6 Bottle Mouth Inner Seals**

Paper, thermal plastic, polystyrene foam (except those applied with pressure-sensitive adhesive), plastic film, foil, or combinations thereof, with a distinctive design (e.g., a pattern, name, registered trademark, logo or picture) is sealed to the mouth of a container under the cap. The seal must be torn or broken to open the container and remove the product.

Seals applied by heat induction to containers appear to offer a higher degree of tamper evidence than those that depend on an adhesive to create the bond.

#### **4.7 Tape Seals**

Paper or foil with a distinctive design is sealed over all carton flaps or a bottle cap. The seal must be torn or broken to remove the product.

Tape seals are acceptable only if they contain a unique feature that makes it apparent if the seals have been removed and reapplied, e.g., a permanent adhesive.

#### **4.8 Breakable Caps**

The container is sealed by a plastic or metal cap that either breaks away completely when removed from the container or leaves part of the cap attached to the container. The cap, or a portion thereof, must be broken in order to open the container and remove the product. The cap cannot be reapplied in its original state.

#### **4.9 Sealed Metal Tubes or Plastic Blind-end Heat Sealed Tubes**

Both ends of the tube are sealed. The mouth or blind-end must be punctured to obtain the product.

A tube with a crimped end is acceptable if the crimped end cannot be breached by unfolding and refolding without showing visible evidence of tampering.

Direct printing of the label on the container is preferred to using a label that could be removed and substituted.

#### **4.10 Aerosol Containers**

Pressurised aerosol containers are believed to be inherently tamper-resistant because of their particular design. However it is recommended that a secure overcap be used.

Direct printing of the label on the container (e.g., lithographing), is preferred to using a paper label which could be removed and substituted.

#### **4.11 Cans (Both All-Metal and Composite)**

The top and bottom of a composite must be joined to the can walls in such a manner that they cannot be pulled apart and reassembled without visible evidence of entry. Rather than attaching a separate label, direct printing of the label onto the can (e.g., lithographing) is preferred.

#### **4.12 Cardboard Cartons**

Cardboard Cartons specifically designed to ensure that in order to obtain the product, the carton seal must be cut or torn to remove the product and must not be able to be easily worked open and resealed without obvious damage to the carton. The carton must be non-resealable without showing visible evidence of entry.

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#### **4.13 In-Built Tamper-Evident Controls**

Products such as In-Vitro Diagnostics (IVDs), which are supplied direct to the public, may have built in controls which demonstrate clearly that the product is unacceptable by showing a test-method failure, avoiding the potential for false results. Products incorporating such controls, which must be obvious to the user from the packaging information / instructions when trying to assess the test results, are considered as having Tamper-evident controls, and for the purposes of this Guideline are considered to comply with the requirements without needing additional packaging or labeling.

### **5. UNACCEPTABLE TAMPER-EVIDENT FEATURES**

#### **5.1 Sealed Cartons**

Sealed paperboard cartons as currently available in the marketplace (e.g., cartons sealed by gluing the end flaps together) are unacceptable. However, future technological advances may provide sealed paperboard packages that meet the intent of the TEP requirements.

5.2 Paper, thermal plastic, polystyrene foam bottle seals applied with pressure-sensitive adhesive do not offer adequate evidence of tampering.

5.3 Cellulose wet shrink seals are not acceptable as the knowledge of how to remove and reapply these seals without evidence of tampering is widespread.

5.4 Tape seals that do not carry a feature that makes it apparent if the seals have been removed and reapplied, e.g., a permanent adhesive are unacceptable.

### **6. APPLICATION**

#### **6.1 Validation**

Validation against the relevant description and to ensure that the tamper-evident feature performs as designed is required. The test should be appropriate to, and challenge, the particular tamper-evident feature. The notes in Appendix 1 may be helpful.

Recognizing the variability of packaging components, routine testing on a batch-by-batch basis is recommended to ensure that the tamper-evident packaging system is appropriately applied and complies with specifications. These tests should form part of the routine quality control (QC) specifications.

Written validation and verification (QC) records must be maintained.

#### **6.2 Annual review**

During the first three years of operation of this whole-of-industry guideline, the Industry Guideline Committee will coordinate an annual design review of product packaging to facilitate and measure industry's progress towards compliance with the Guideline. Non-compliant companies will be notified of the remaining time in which to bring products into compliance. Following the three-year implementation period, it is anticipated that the requirement to comply with the Guideline will be enforceable under the therapeutic goods legislation.

#### **6.3 Changes to acceptable systems**

If a system becomes unacceptable, the guideline will be reissued and become effective immediately for new products and within an agreed time frame for existing products.

On introduction of a new system, the guideline will be reissued and become effective immediately.

### **7. LABELING**

A fundamental requirement for any tamper-evident packaging system is the provision of appropriate advice to the intending consumer as to the nature of the specific tamper-evident characteristic and the ability of the consumer to then identify the relevant packaging features.

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That advice must be displayed in a prominent place on the primary pack. The Consumer Medicine Information (CMI) leaflet that is provided at the point of purchase for some products may also help to communicate the TEP messages. For products with a container and primary pack, label advice must also be provided on the container, describing TEP features of the container (the only exceptions are blister packs and small containers). Alternatively, the container must bear a statement alerting the consumer that the container should be inside a carton (or other primary pack) at the time of purchase.

Each package should contain a statement that is prominently placed so that consumers are alerted to the specific tamper-evident feature of the package. The statement is required to be so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing. Sample statements in current use are provided in Appendix 2. These statements have not been tested against performance principles. Coordination if such testing will be the responsibility of the Industry Guideline Committee.

If the tamper-evident feature chosen is one that uses an identification characteristic, that characteristic is required to be referred to in the Statement.

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## APPENDIX A

### NOTES FOR GUIDANCE ON TESTING OF TAMPER-EVIDENT PACKAGING FEATURES

The following notes are designed to assist members undertaking routine validation and verification of TEP closures.

It should be noted that the Guideline provides acceptable design characteristics that depend on the correct conjunction of component, equipment and routine application for their performance to specification.

The Guideline is formulated in general terms and cannot address all potential situations. The onus remains with the company to ensure that the TEP feature performs as designed.

Some factors that may be considered in relation to validation are:

- line settings
- effect of temperature
- grades of plastic
- torque
- supplier certification

Some issues that may be considered in relation to the validation process itself are:

- the degree of challenge in respect to tolerances
- time intervals
- acceptable levels of failure
- sample size

**Primary validation** should be fully documented and take place at product pack development stage.

**Verification (QC)** of the functionality of the tamper evident features of the packaging should be fully documented and take place:

- prior to use of the packaging in the manufacturing process, and
- on the finished product prior to release for sale.

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## APPENDIX B

### SAMPLE LABEL STATEMENTS

The following statements are examples of those currently used in the Australian market to describe tamper-evident packaging features or drawn from overseas labelling recommendations. In deviating from these statements, it is recommended that sponsors employ performance-based labelling principles and ensure that revised statements deliver at least equivalent consumer understanding that is demonstrated through testing with consumers.

Tamper-Evident Feature	Suggested Wording
Film Wrappers	<ul style="list-style-type: none"><li>Do not use if film wrapper is damaged or missing</li></ul>
Blister or Strip Packs	<ul style="list-style-type: none"><li>Do not use if blister seal is broken</li><li>Do not use if blister backing is damaged</li></ul>
Bubble Packs	<ul style="list-style-type: none"><li>Do not use if blister seal is broken</li></ul>
Heat Shrink Bands or Wrappers	<ul style="list-style-type: none"><li>Do not use if seal (around cap/under lid, etc.) is broken or missing</li><li>Do not use if tape (band) around cap is damaged</li><li>Band around cap must be present to ensure package security</li><li>The seal over/around the cap is your assurance that the package has not been opened</li><li>For your protection, this bottle has an imprinted seal around the neck</li></ul>
Foil, Paper, or Plastic Pouches	<ul style="list-style-type: none"><li>Do not use if pouch is torn</li></ul>
Bottle Mouth Inner Seals	<ul style="list-style-type: none"><li>Do not use if inner foil liner is missing or broken</li><li>Bottle sealed under cap for your protection</li></ul>
Tape Seals	<ul style="list-style-type: none"><li>Now with tamper-evident carton seal</li><li>Tape over carton flaps must be unbroken</li><li>Use only if carton seal is unbroken</li><li>Do not use if seals over carton ends are missing or broken</li></ul>
Breakable Caps	<ul style="list-style-type: none"><li>Now with tamper-evident cap seal</li><li>Bottle has been opened if cap is separated</li><li>Use only if cap seal is unbroken</li><li>The seal on the cap is your assurance that the package has not been opened</li><li>Do not use if cap seal is broken</li></ul>
Sealed Metal Tubes or Plastic Blind-end Heat Sealed Tubes	<ul style="list-style-type: none"><li>Do not use if foil seal at mouth of tube is broken</li><li>Do not use if sealed tip is cut</li></ul>
Cans (Both All-Metal and Composite)	<ul style="list-style-type: none"><li>Do not use if can is damaged</li></ul>
In-Built Tamper-Evident Controls	<ul style="list-style-type: none"><li>Sterile if in unopened undamaged pack</li></ul>

# **CHC Internet Guideline for Complementary Healthcare Products**

**April 2001**

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## Australian Internet Guideline for Complementary Healthcare Products

### Purpose of the Guideline

This guideline provides a basic framework to assist in the presentation on the Internet of branded advertising, generic information, *bona fide* news and educational material for complementary healthcare products (CHPs). It applies to websites under the Australian regulatory system, namely websites belonging to companies from within Australia or where consumers are referred to an Australian address for supply of goods.

### Definitions

"Branded advertising" means advertising *directly linked* to a specific, named product, for example, Company A's Garlic 500 Capsules.

"Non-branded advertising" means advertising *not directly linked* to a specific, named product.

"Directly linked" means information on the same web page.

"Not directly linked" means any information separated by at least one *hyperlink*.

"Hyperlink", for the purpose of this guideline, means a clickable navigation aid to take the reader from one page on the Internet to another. Hyperlinks can take the reader from one page on a company website to another page on the same company website or to a page on another company's website. Some hyperlinks can take the reader to another part of the same webpage; however, for the purpose of this guideline this will not be considered a hyperlink.

"Generic information" means any information about therapeutic goods with respect to the composition, properties or other characteristics but does not include *branded advertising* (as defined above) or *bona fide* news.

"Indications" means the specific therapeutic uses for a good as on the ARTG record (refer to the Therapeutic Goods Act 1989 S 3 (1))

"Therapeutic claims" means advertising claims based on the therapeutic indications.

"ARTG" means the Australian Register of Therapeutic Goods

"TGAC" means the Therapeutic Goods Advertising Code

### General principles

A website is an interconnected entity, and is analogous to a magazine with the individual pages on the website being comparable to the pages of a magazine. Sites will have a mixture of branded and non-branded information. All information, whether branded or non-branded, must comply with the following three principles:

- a. All content must comply with Australian trade practices and competition legislation and be socially responsible.
- b. All content must be true, valid, and not misleading, and contain only correct and balanced statements that the sponsor has already verified.
- c. Sponsors must be able to substantiate both express and implied claims.

In addition, all branded advertisements and directly linked information must also comply with the following provisions:

- d. All therapeutic claims must be consistent with the product indications on the ARTG and comply with S 22(5) of the Therapeutic Goods Act.
- e. All therapeutic claims must comply with the TGAC, including the use of relevant warning statements.

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### **Types of information on websites**

The decision tree will assist with classifying information sponsors wish to publish on their websites. Therapeutic information on a website can be considered branded or non-branded, and these are treated differently with respect to compliance with the TGAC. This division depends upon the relationship of the material to placement of branded product information. Unless "non-branded" information is at least one hyperlink away from branded advertising it is considered branded and must comply with the provisions of the TGAC and S 22(5) of the Therapeutic Goods Act. This does not apply where the non-branded information does not concern an ingredient present in the branded product.

**a. Branded (product-specific) advertising includes:**

- Claims consistent with indications as on the ARTG
- Other marketing claims
- Information on substances that is directly linked to branded product(s)

**b. Non-branded information includes:**

- Generic information on topics such as substances, ailments, healthy lifestyle habits, providing that it is not directly linked to branded product.
- *Bona fide* health news and educational information

**Other useful information**

- Provide consumers with easily accessible, accurate information about your identity and physical location, and about the goods and services you offer online.
- It may be useful to provide consumers with contact details and relevant codes of practice of any self-regulatory scheme or business association of which you are a member.
- For information about the Therapeutic Goods Advertising Code consult the Therapeutic Goods Advertising Code Council (TGACC) website: [www.tgacc.com.au](http://www.tgacc.com.au)
- For information about the Trade Practices consult the Australian Competition & Consumer Commission (ACCC) website: [www.accc.gov.au](http://www.accc.gov.au)
- For information about the supply and sale of CHP's in Australia consult the Therapeutic Goods Administration (TGA) website: [www.health.gov.au/tga](http://www.health.gov.au/tga)

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