

***Regulation of Health Food  
in Australia***

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# CONTENTS

	<i>page</i>
<b>Acknowledgements</b>	
<b>Executive Summary</b>	
<b>Part 1 - Introduction</b>	<b>1</b>
Background	1
Scope of the Research	1
Methodology	1
<b>Part 2 - Regulation of Health Food in Australia</b>	<b>2</b>
Terms and Definitions	2
<i>Health Food</i>	2
<i>Food</i>	2
<i>Therapeutic Good</i>	3
<i>Complementary Medicine</i>	3
Health Claim	4
<b>Part 3 - Country Background</b>	<b>7</b>
Basic Facts	7
<b>Part 4 - Regulatory Framework of Complementary Medicines</b>	<b>8</b>
Legislation and Guidelines	8
Authorities Involved in the Regulation of Complementary Medicines	9
<i>Therapeutic Goods Administration</i>	9
<i>Office of Complementary Medicines</i>	10
<i>Complementary Healthcare Consultative Forum</i>	10
<i>Complementary Medicines Evaluation Committee</i>	11
<i>Therapeutic Goods Advertising Code Council</i>	11
<i>External Reference Panel on Interface Matters</i>	11
<i>Reforms of the Regulatory Framework</i>	12
<b>Part 5 - Control of Complementary Medicines</b>	<b>13</b>
Introduction	13
<i>Registered Complementary Medicines</i>	13
<i>Listed Complementary Medicines</i>	14
Licensing of Manufacturers	14
Pre-Market Assessment	14
Post-Market Vigilance	15
Regulation of Advertisements	15
Infringement of Regulations	16
Sanctions for Non-compliance	16

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<b>Part 6 - Sale and Distribution of Complementary Medicines</b>	<b>18</b>
Sale: Application Procedures	18
<i>Step 1 : Determination of Food/Therapeutic Good</i>	18
<i>Step 2 : Possession of Valid Licences</i>	18
<i>Step 3: Pre-Market Assessment</i>	19
<i>Step 4: Listing or Registration in the Australian Register of Therapeutic Goods</i>	20
Distribution : Distribution Channels	21
Fees and Charges	21
<b>Part 7 - Analysis</b>	<b>23</b>
Drawing Expertise to the Regulatory System	23
Balance Between Safety of Products and Expedition of Processing Applications	23
Balance Between the Need to Improve Market Access for the Products and the Need to Maintain Consumer Confidence in the Safety of the Products	23
Regulation of Complementary Medicines	24
<b>Appendices</b>	<b>25</b>
<b>References</b>	<b>32</b>

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## **EXECUTIVE SUMMARY**

1. In Australia, there are interface products between foods and medicines called complementary medicines. They are in the form of capsules, pills, tablets, powder, etc. and they are allowed to carry health or related claims.
2. There are four main pieces of legislation and guidelines governing the regulation of complementary medicines. They are the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations, the Therapeutic Goods Advertising Code (TGAC) and the Code of Good Manufacturing Practice (GMP).
3. The Therapeutic Goods Act 1989 requires that complementary medicines which are imported or manufactured for supply in Australia must be included in the Australian Register of Therapeutic Goods (ARTG). Complementary medicines may be either 'listed' (low risk) or 'registered' (high risk) in the ARTG depending on their composition and the intended purpose of use.
4. Most complementary medicines are 'listed' goods. Listed goods are evaluated for safety and quality, but not efficacy. Registered goods are evaluated for safety, quality and efficacy.
5. TGAC governs all advertising of complementary medicines which carry therapeutic claims. The Therapeutic Goods Regulations require all advertising of complementary medicines in the mainstream media to go through a system of prior approval. Other non-mainstream media advertising must also comply with TGAC but are not required to be formally approved.
6. Claims for listed goods are limited by the restrictions of TGAC, and manufacturers must hold appropriate evidence to support claims they have made about their products.
7. All complementary medicines supplied in Australia are required to comply with the Code of GMP. The Code of GMP describes the principles and practices that are necessary to follow in order to provide assurance that each complementary medicine product is safe and reliable. Overseas manufacturers are expected to comply with the equivalent standard of GMP as would be required for an Australian manufacturer.
8. All complementary medicines must be submitted to a pre-market assessment before they are made available to the public. They are also subject to post-market vigilance to ensure compliance with the relevant legislation.
9. For manufacturers who want to supply complementary medicines in Australia, they must possess valid licence which certifies compliance with GMP, and go through a pre-market assessment to ensure the products are safe and of standard quality. They must also hold evidence to support claims made about the products and be able to enter the products on the ARTG before the products can be supplied in Australia.
10. Most complementary medicines are widely available through direct marketing, health food stores and supermarkets.

# **REGULATION OF HEALTH FOOD IN AUSTRALIA**

## **PART 1 - INTRODUCTION**

### **1. Background**

1.1 In March 2000, the Panel on Health Services requested the Research and Library Services Division to conduct a research on the regulation of health food in overseas places.

### **2. Scope of the Research**

2.1 The objective of this research is to study the regulation of health food in Australia, Taiwan, the United States and Hong Kong. The scope includes differentiation of health food from conventional food and medicine, the relevant regulation and its enforcement, and the channel through which health food is marketed. This study mainly discusses food products not sold in their conventional forms: they include products sold in the form of capsules, pills, tablets or powder, etc.

2.2 Australia is chosen because there is legislation governing interface products between foods and medicines called complementary medicines. Complementary medicines can be in the form of capsules, pills, tablets or powder, etc. and may carry health claims.

2.3 This research report forms part of the series of reports discussing the regulation of health food. There are four separate research reports on this subject.

### **3. Methodology**

3.1 Information for this research report is obtained from the Internet, government reports and relevant reference materials. Telephone interviews with government officials in Australia were also conducted.

3.2 The average exchange rate in 1999 between HK\$ and AUS\$ was HK\$5.01 = AUS\$1.<sup>1</sup>

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<sup>1</sup> Census and Statistics Department, *Hong Kong Monthly Digest of Statistics*, May 2000.

## **PART 2 - REGULATION OF HEALTH FOOD IN AUSTRALIA**

### **4. Terms and Definitions**

#### Health Food

4.1 In Australia, there is no legal definition of "health food". Products for oral consumption are regulated by the Australian government as either foods or therapeutic goods. The intended use or the principal use of the product is the primary consideration when determining whether the product is a food or a therapeutic good.

#### Food

4.2 The definition of food in Australia can be found in three pieces of legislation:

- (1) the Australia New Zealand Food Authority Act 1991 Section 3A;
- (2) the National Food Authority Act 1991 - No. 118 of 1991 Section 3; and
- (3) the Therapeutic Goods Amendment Act 1996 - No.6 of 1996 Subsection 3(1).

4.3 All these definitions are similar to each other and they generally refer to substances used for human consumption, but do not include a prescribed dose nor therapeutic goods within the meaning of the Therapeutic Goods Act 1989.

4.4 The current Australian food regulations prohibit any attachment of health and related claims to food products unless the claims are specifically prescribed by the Food Standards Code<sup>2</sup> or approved by the Australia New Zealand Food Authority (ANZFA). An exception is the folate/neural tube defects health claim (detailed in paragraph 4.5 below).

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<sup>2</sup> The Food Standards Code is a collection of individual food standards. It is developed by the Australia New Zealand Food Authority and it has the force of law.

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4.5 At the moment, the Australian government is conducting a "pilot to trial" on one health claim known as "The Folate/Neural Tube Defects Health Claim Pilot" to assess the effectiveness of health claims on food labels in improving diets and reducing death and illness rates. This health claim is the first health claim allowed to be put on food labels and it describes a link between increased maternal dietary folate intake and a reduction in the incidence of neural tube defects in new born infants. This health claim is used because ANZFA considers that there is sufficient scientific evidence showing that appropriate levels of folate intake by women prior to and during pregnancy can reduce neural tube defects, including spina bifida, in infants as much as 70%. Foods authorized by ANZFA to carry this health claim are required to meet certain nutritional qualifying criteria. To date, over 100 food products, including fresh foods such as vegetables and fruits and processed foods such as bread and cereals carry the folate claim. The pilot had an original sunset date on 13 February 2001. In July 2000, the pilot sunset date was extended to August 2002.

#### Therapeutic Good

4.6 A therapeutic good is broadly defined in the Therapeutic Goods Act 1989 as a good which can be represented in any form and which is for therapeutic use. It can be a medicine or a medical device. Please see Appendix I for the detailed definition of a therapeutic good.

4.7 Therapeutic goods may carry therapeutic claims. There are three levels of therapeutic claims - high, medium and general. High level claims are the strongest claims such as treating, curing, managing or preventing a disease or disorder, or treating vitamin or mineral deficiency diseases. More evidence is required to support them. Medium level claims are the lesser claims such as health enhancement claims which apply to health enhancement of normal people, such as improving, promoting, enhancing or optimizing body organs or systems. General level claims are the broadest claims such as health maintenance claims which refer to an effect of a product or substance that may have in maintaining health, but it does not include health enhancement or prevention claims. Health maintenance claims may also relate to the normal physiological consequences for good health associated with a product or substance, or to the provision of nutritional support and to the use of the terms "cleansing", "detoxification" and "tonic".

#### Complementary Medicine

4.8 In Australia, there are interface products between foods and therapeutic goods called complementary medicines. Complementary medicines are low risk products which include herbal medicines, traditional medicines, vitamins, special purpose foods, nutritional supplements, homoeopathic and naturopathic products.



4.9 Complementary medicines are either listed (low risk) or registered (high risk) goods in the Australian Register of Therapeutic Goods, depending on their ingredients and claims made. Most complementary medicines are listed. Examples of complementary medicines are fibre or shark cartilage in the form of capsules, tablets or pills.

4.10 The Australian Register of Therapeutic Goods keeps a record of the following:

- (1) therapeutic products which are approved for marketing;
- (2) ingredients contained in each therapeutic product; and
- (3) therapeutic claims made for each product.

At present, there are about 55 000 products in the Australian Register of Therapeutic Goods.

4.11 Section 7 of the Therapeutic Goods Act 1989 provides clarity for products at the food/ therapeutic good interface. A product is a therapeutic good if it claims a therapeutic effect. If a product fits the definition of either a food or a therapeutic good, it is referred to a joint Therapeutic Goods Administration / Australia New Zealand Food Authority committee known as the External Reference Panel on Interface Matters (or ERPIM). The ERPIM recommends to the Parliamentary Secretary for Health and Aged Care whether the product will be regulated as food or as a therapeutic good.

4.12 The presentation of a product can help to determine whether it will be treated as a food or a therapeutic good. For example, a clove of garlic is a food. However, if it is concentrated and marketed in capsule form with claims that it can be used to relieve cold and flu symptoms, it will be treated as a therapeutic good.

## **5. Health Claim**

5.1 Complementary medicines are allowed to make therapeutic claims on their labels and in advertising, but the types of claims allowed to be made are restricted to medium or general level claims only. They are generally claims relating to minor conditions and must carry specific warning statements. Please see Appendix II for more definitions of claims about complementary medicines.

5.2 There are three principles relating to claims made about complementary medicines:

- (1) before claiming an intended use or indication, sponsors must hold adequate evidence to support all claims they make about a product;
- (2) claims must be true, valid and not misleading. They must be consistent with the use as recorded on the Australian Register of Therapeutic Goods in relation to that product; and
- (3) claims should not lead to unsafe or inappropriate use of a product.<sup>3</sup>

5.3 The regulation of products for oral consumption in Australia is summarized in Diagram 1.

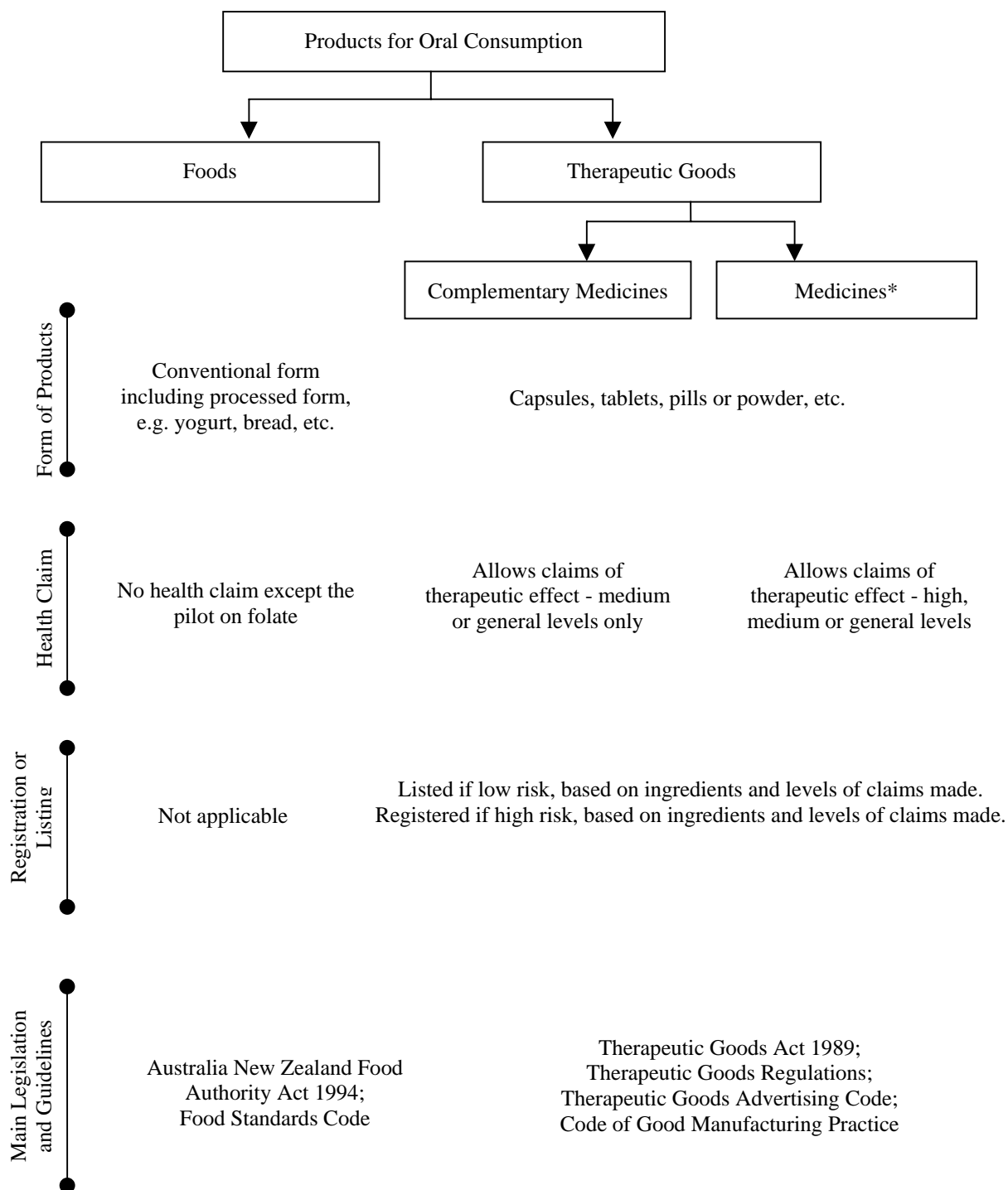
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<sup>3</sup> Therapeutic Goods Administration, *Draft Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods*, April 2000.

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**Diagram 1 - Regulation of Products for Oral Consumption**



\* The regulation of the many categories of medicines is complicated and is not covered in this report. However, it must be pointed out that non-prescription medicines and other types of low risk medicines, which are not necessarily complementary medicines, can be listed and may not make high level therapeutic claims.

## PART 3 - COUNTRY BACKGROUND

### 6. Basic Facts

6.1 As at June 1998, Australia has a population of 18.8 million.<sup>4</sup> The Gross Domestic Products (GDP) of Australia in 1997-1998 amounted to AUS\$564,705 million (or HK\$2,829,172 million).<sup>5</sup>

6.2 According to the Therapeutic Goods Administration as published in its website updated in 1999, Australians spend about AUS\$621 million (or HK\$3,111 million) per year on complementary medicines.<sup>6</sup> Per capita spending on complementary medicines is therefore about AUS\$33 (or HK\$165).

6.3 It is estimated that more than 60% of Australians use complementary medicines at least once a year.<sup>7</sup> The importation of Chinese herbal medicines has been increasing at the rate of 100% per year since 1993.<sup>8</sup>

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<sup>4</sup> Australian Bureau of Statistics, *Australia at a Glance*, January 2000.

<sup>5</sup> Australian Bureau of Statistics, *Australia Now - A Statistical Profile* at <http://www.abs.gov.au/>.

<sup>6</sup> Therapeutic Goods Administration, *Complementary Medicines Fact Sheets*, at <http://www.health.gov.au/tga/docs/html/facts.htm>.

<sup>7</sup> Office of Complementary Medicines, *Complementary Medicines Reform Package: An Overview* at <http://www.health.gov.au/tga/>

<sup>8</sup> Therapeutic Goods Administration, *Information: Office of Complementary Medicines*.

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## **PART 4 - REGULATORY FRAMEWORK OF COMPLEMENTARY MEDICINES**

### **7. Legislation and Guidelines**

7.1 There are four main pieces of legislation and guidelines which govern the regulation of complementary medicines. They are the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations, the Therapeutic Goods Advertising Code and the Code of Good Manufacturing Practice (GMP).

7.2 The Therapeutic Goods Act 1989 requires that, unless otherwise exempt, all therapeutic goods for supply in Australia must be entered in the Australian Register of Therapeutic Goods. They must also comply with GMP and other relevant standards. Goods that are listed in the Australian Register of Therapeutic Goods must be composed only of substances which have been evaluated for safety and quality. Listed products are considered to be low risk and are not required to be evaluated on a case-by-case basis. Registered goods must be evaluated by the Therapeutic Goods Administration of the Australian government on a case-by-case basis, for safety, quality and efficacy. In other words, the difference between listed goods and registered goods is that registered goods have been additionally evaluated for efficacy on a case-by-case basis.

7.3 The Therapeutic Goods Regulations require that all advertising of complementary medicines must comply with the Therapeutic Goods Advertising Code. In some circumstances such as advertising in the mainstream media<sup>9</sup>, manufacturers must seek prior approval of the advertisements from the appropriate authority.

7.4 The Therapeutic Goods Advertising Code was initially a self-regulatory code developed by the former Therapeutic Goods Advertising Code Council. The Code is now the subject of co-regulation between the Therapeutic Goods Administration and key stakeholders (consumers, healthcare professions, advertisers and industry associations, including the Proprietary Medicines Association of Australia<sup>10</sup> and Complementary Healthcare Council of Australia<sup>11</sup>).

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<sup>9</sup> Mainstream media means any magazines or newspapers for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

<sup>10</sup> The Proprietary Medicines Association of Australia represents companies that manufacture or sponsor non-prescription consumer healthcare products.

<sup>11</sup> The Complementary Healthcare Council of Australia is the peak body representing the complementary healthcare industry in Australia.

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7.5 The Therapeutic Goods Advertising Code is a set of principles and guidelines which ensures socially responsible marketing and advertising of therapeutic goods in a way that will promote the appropriate use of these products. All advertisements and generic information provided about complementary medicines directed to consumers must comply with the Therapeutic Goods Advertising Code.

7.6 The Code of GMP describes the principles and practices that are necessary to follow in order to provide assurance that each complementary medicine product is safe and reliable. It comprises requirements relating to premises, equipment, personnel, documentation and quality control. These GMP requirements are enforced through systems of factory audits and mandatory licensing of factories which manufacture complementary medicines.

7.7 All complementary medicines, whether or not they are locally manufactured or imported from overseas countries, are required to comply with the above legislation and to observe the above guidelines.

## **8. Authorities Involved in the Regulation of Complementary Medicines**

### Therapeutic Goods Administration

8.1 The Therapeutic Goods Administration is a division of the Federal Department of Health and Aged Care and is responsible for administering the Therapeutic Goods Act.

8.2 The Therapeutic Goods Administration carries out a range of assessment and monitoring activities to ensure therapeutic goods including complementary medicines available in Australia are of an acceptable standard.

8.3 Overall control of the supply of complementary medicines is exercised through three measures:

- (1) licensing of manufacturers;
- (2) pre-market assessment; and
- (3) post-market vigilance.

### Office of Complementary Medicines

8.4 The Office of Complementary Medicines is created within the Therapeutic Goods Administration. This Office was established in April 1999 as part of a reform package introduced by the Parliamentary Secretary for Health and Aged Care to improve regulation on complementary medicines. It combines the evaluation of and application for complementary medicines under one roof.

Its main responsibilities are:

- (1) consulting and liaising with interest groups to foster co-operation and confidence in the regulatory arrangements for complementary medicines;
- (2) evaluating data in order to make assessments for listed and registered complementary medicines;
- (3) providing support to Complementary Medicines Evaluation Committee and Complementary Healthcare Consultative Forum; and
- (4) providing advice to the Minister and the Therapeutic Goods Administration on the regulation of complementary medicines and associated matters.

### Complementary Healthcare Consultative Forum

8.5 The Complementary Healthcare Consultative Forum was established and chaired by the Parliamentary Secretary for Health and Aged Care. Its establishment also formed part of the reform package launched in 1999. The purpose of the Forum is to facilitate consultation between government and the complementary healthcare sector in order to exchange information on broad policy, regulatory performance and other related issues. The original charter for the Forum was to develop the reform agenda for the regulation of complementary medicines but was later extended to cover the broader complementary healthcare sector.

8.6 The Complementary Healthcare Consultative Forum examines complementary healthcare research, regulation and education as well as industry, consumer and practitioner issues.

8.7 Members of the Forum include representatives of consumer organizations, complementary medicines marketing organizations, industry, complementary medicine practitioners, the Therapeutic Goods Administration and state / territory governments.

### Complementary Medicines Evaluation Committee

8.8 The Complementary Medicines Evaluation Committee (CMEC) became a statutory expert committee under the Therapeutic Goods Amendment Act 1999. It is responsible for making recommendations about complementary medicines and substances for the Australian market.

8.9 The CMEC is made up of 11 members who are appointed by the Parliamentary Secretary for Health and Aged Care. It may call upon an expert advisory panel to ensure more specific advice is available.

### Therapeutic Goods Advertising Code Council

8.10 The Therapeutic Goods Advertising Code Council was established under the Therapeutic Goods Regulations (Amendment) 1997 No. 400. The Council reviews the Therapeutic Goods Advertising Code with the assistance of CMEC to address criticism of existing advertising controls for low risk complementary healthcare products including complementary medicines.

8.11 Members of the Therapeutic Goods Advertising Code Council include representatives of manufacturers, industry, consumer organizations, healthcare professionals, and the Therapeutic Goods Administration.

### External Reference Panel on Interface Matters

8.12 The External Reference Panel on Interface Matters (ERPIM) is an advisory panel to provide advice on interface matters to the Therapeutic Goods Administration and the Australia New Zealand Food Authority. It consists of representatives of the Therapeutic Goods Administration, Australia New Zealand Food Authority, state / territory and New Zealand health authorities, the Australian Quarantine Inspection Service, industry and consumers.

8.13 The function of the ERPIM is to determine whether a product is a 'food' or a 'therapeutic good'. It also speeds up the decision making process and provides greater certainty for industry and regulators.



### Reforms of the Regulatory Framework

8.14 In April 1999, reforms to the regulation of complementary medicines were implemented by the Therapeutic Goods Administration. These include establishing the Office of Complementary Medicines (paragraph 8.4 above), and the Complementary Healthcare Consultative Forum (paragraphs 8.5 to 8.7 above) and also making the Complementary Medicines Evaluation Committee a statutory body (paragraphs 8.8 to 8.9 above). The Therapeutic Goods Advertising Code Council is required to revise related codes to allow sponsors to make a wider range of claims. In this connection, the Therapeutic Goods Administration also streamlined the administrative and technical arrangements for application processing.

## PART 5 - CONTROL OF COMPLEMENTARY MEDICINES

### 9. Introduction

9.1 In Australia, the law requires sponsors of complementary medicines to provide assurances on the safety of substances before products are approved for supply.<sup>12</sup> "Sponsor", in relation to complementary medicines, means a person who exports, imports, manufactures the goods, or arranges for another person to export, import or manufacture the goods for supply (whether in Australia or elsewhere).

#### Registered Complementary Medicines

9.2 Registrable complementary medicines<sup>13</sup> undergo a thorough evaluation of their safety, quality and efficacy in the form in which they are intended for sale. Safety will be based on an assessment of the active ingredients as well as any safety implications relating to the product presentation (e.g. dose size, labelling and manner of use). The validity of label claims is also examined. Product stability is checked; an assessment made of the shelf life and required storage conditions based on validated laboratory data is also required. Manufacturers of registered complementary medicines are required to obtain valid licences before they can supply registered goods in Australia. Efficacy may be assessed by clinical trial data and/or by literature research substantiating the efficacy of the active ingredients in the same or very similar presentations.

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<sup>12</sup> Complementary Medicines Evaluation Committee, *Minutes of the 8<sup>th</sup> Meeting*, 16 September, 1998.

<sup>13</sup> According to the Office of Complementary Medicines, there is no essential difference between a registered complementary medicine and a medicine in Australia. The term "complementary" designates which part of the Therapeutic Goods Administration will evaluate the product and which external expert committee will oversee the process. A registered complementary medicine product undergoes the same evaluation process as other registered, non-prescription medicine product. Moreover, the requirements for the registration of complementary medicines and other registered, non-prescription medicines are essentially the same. The Therapeutic Goods Administration uses the same application form and applies the same standards to them. As registration applications are considered on a case-by-case basis, the Therapeutic Goods Administration is capable of 'tailoring' the evaluation to the medicine under review. Furthermore, the advertising and labelling requirements applying to registered complementary medicines are the same as those applying to other registered, non-prescription medicines.

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### Listed Complementary Medicines

9.3 Similar to the restrictions imposed on the manufacturers of registered complementary medicines, manufacturers of listed complementary medicines are also required to obtain valid licences before they can supply listed goods in Australia. Label claims that can be made about listed complementary medicines are also limited by the Therapeutic Goods Advertising Code to medium and general levels claims only.

9.4 However, sponsors of listed complementary medicines do not have to provide evidence to the Therapeutic Goods Administration of product stability for the duration of the claimed shelf life. Neither are the products required to undergo the same rigour of assessment of their efficacy as the registered products are.

## **10. Licensing of Manufacturers**

10.1 Australian manufacturers of therapeutic goods including complementary medicines must be licensed. Their manufacturing processes must comply with the Code of GMP. The aim of licensing is to protect public health by ensuring that therapeutic goods including complementary medicines meet definable standards of quality assurance and are manufactured in conditions that are clean and free of contaminants.

10.2 Overseas manufacturers of therapeutic goods supplied to Australia must provide documentary evidence that the goods are manufactured to a standard of GMP equivalent to that expected of Australian manufacturers of the same goods.

## **11. Pre-Market Assessment**

11.1 All complementary medicines have to be submitted to a pre-market assessment (please see paragraphs 16.5 to 16.9 for details) before they can be made available to the public. After assessments, they will carry one of two identifying labels: the "Aust R#" or the "Aust L#" labels. "Aust R#" products are registered products which have been evaluated for safety, quality and efficacy. "Aust L#" products are listed products which have been evaluated for safety and quality.

11.2 In general, the pre-market approval process takes 20 days<sup>14</sup> before the product can be marketed.

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<sup>14</sup> Strategic Policy Choices and the Canadian Health Food Association, *A Sector Profile of Canada's Natural Health Products Industry*, 1998, p.62.

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## **12. Post-Market Vigilance**

12.1 In Australia, post-marketing activities include investigating problems which have been reported, laboratory testing of products on the market and monitoring of market activities to ensure compliance with the legislation. However, these activities tend to be problem-driven rather than proactively collecting and testing samples from the market place.

12.2 The Adverse Drug Reactions Advisory Committee receives reports of all suspected adverse reactions to drugs and other medicinal substances, including herbal, traditional or alternative remedies. It is not mandatory to make reports to the Committee and these reports are usually made by competing manufacturers who alert the Committee or the Therapeutic Goods Administration of breaches of regulations.

## **13. Regulation of Advertisements**

13.1 All claims made about complementary medicines must be capable of substantiation. That is, evidence must be held by sponsors which demonstrates the claims are true, valid and not misleading.

13.2 All advertising of complementary medicines which carry therapeutic claims must by law comply with the requirements and standards of the Therapeutic Goods Advertising Code.

13.3 The Therapeutic Goods Regulations require that all advertising for publication or broadcast in the mainstream media must go through a system of prior approval. Other non-mainstream media advertising must also comply with the Therapeutic Goods Advertising Code but are not required to be formally approved.

13.4 The responsibility for the approval of mainstream advertising has been delegated to two different associations -- the Complementary Healthcare Council and the Proprietary Medicines Association of Australia. Please see Appendix III for the approval procedures for advertisements of complementary medicines.

## **14. Infringement of Regulations**

14.1 Complaints about advertisements or generic information about complementary medicines in the mainstream media are considered by the Complaints Resolution Panel of the Therapeutic Goods Advertising Code Council. Complaints about other forms of publication such as indoor posters, catalogues, facts sheets, etc. are considered by different industry panels. Appendix III describes the procedures for handling complaints about advertisements of complementary medicines.

14.2 The Complaints Resolution Panel consists of representatives from government, industry, consumers, advertising agencies and healthcare professionals. It is chaired by a person elected by the Therapeutic Goods Advertising Code Council. It hears complaints about alleged contravention of the therapeutic goods regulations by the advertisements of complementary medicines. The Panel may request a person to withdraw an offending advertisement or publish a retraction. If a person does not comply with such a request, the Panel may make recommendations to the Parliamentary Secretary for Health and Aged Care to withdraw approval for the advertisement, or cancel the registration of the complementary medicine in question.

14.3 As mentioned in paragraph 14.1, each industry panel is able to consider complaints in terms of their respective Codes of Practice. Each panel includes a representative from the Therapeutic Goods Administration as an observer and it can impose a range of sanctions, including corrective advertising and pecuniary fines.

## **15. Sanctions for Non-compliance**

15.1 It is an offence to manufacture, supply, import or export 'counterfeit' therapeutic goods including complementary medicines in Australia. 'Counterfeit' is defined<sup>15</sup> as containing a false representation on the label or in the product presentation, in a document or record relating to the goods or their manufacture or in advertising for the goods. The maximum penalty for a person committing this offence is 5 years imprisonment, a fine of up to 500 penalty units (currently AUS\$55,000 or HK\$275,550) or both imprisonment and a fine. A corporation that commits the offence may be fined up to AUS\$275,000 (or HK\$1.4 million).

15.2 It is also an offence to manufacture, supply, import or export therapeutic goods including complementary medicines which are not registered, listed, approved or exempt under the Therapeutic Goods Act. The maximum penalty for committing this offence is a fine of up to 240 penalty units (currently AUS\$26,400 or HK\$132,264).

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<sup>15</sup> Section 42E of the Therapeutic Goods Amendment Act (No. 2) 2000.

15.3 We have made enquiries about the extent of the infringement of the regulations and the penalties imposed on the infringers. Unfortunately, no information has been provided by the Therapeutic Goods Administration as of the date of publication of this report. According to the Complaints Register compiled by the Complaints Resolution Panel of the Therapeutic Goods Advertising Code Council, the Panel heard 44 complaints about alleged contravention of the therapeutic goods regulations by advertisements of non-prescription medicines and complementary medicines from January 2000 to November 2000. However, there was no breakdown of these complaints by types of products. The following table summarizes the complaints made about the advertisements of **both** non-prescription medicines and complementary medicines.

**Table 1 - Complaints Register, January 2000 to November 2000**

No. of complaints heard by the Complaints Resolution Panel	44
No. of complaints found justified	38
No. of complaints found unjustified	5
No. of complaints whose justification was not yet determined	1
Action taken for justified complaints - withdrawal of advertisements from further publication	27
Action taken for justified complaints - no sanction <sup>1</sup>	11

Remark:

1. No sanction - Usually, if the sponsor provides an undertaking to the Complaints Resolution Panel to obtain approval for future advertising or to withdraw the advertisements in question, no sanction will be imposed.

Source: TGACC, *Complaints Register* at <http://www.tgacc.com.au/complaintsList.cfm>

**PART 6 - SALE AND DISTRIBUTION OF COMPLEMENTARY MEDICINES****16. Sale: Application Procedures**Step 1: Determination of Food/Therapeutic Good

16.1 First, the sponsor (i.e. either manufacturer or importer) has to determine whether the product is a food or a therapeutic good. If he is uncertain, he may refer to the ERPIM for food / therapeutic good determination. He may also refer to Schedules 4 and 5 of the Therapeutic Goods Regulations 1990 to determine whether the product is listable or registrable. Please see Appendix IV for details.

Step 2: Possession of Valid Licences

16.2 The manufacturer of the complementary medicine product must also possess a valid licence which certifies compliance with the Code of GMP. Compliance with the Code of GMP is ascertained by carrying out regular on-site audits which can last from part of a day to four or more days. Each audit involves a detailed examination of the operations and procedures of the factory, and includes a detailed review of batch documentation and quality control testing. Product samples may be taken away for testing by the Therapeutic Goods Administration Laboratories. The audit is concluded with an exit interview during which the manufacturer is provided with a summary of the findings of the audit. This summary is confirmed in writing later by means of an audit report. A written response to this report is expected.

16.3 The licence is issued by the GMP Audit and Licensing Section of the Therapeutic Goods Administration. It is valid for one year and is renewable.

16.4 If an overseas manufacturer is unclear as to what actual documentation is required as acceptable evidence of GMP compliance, he may send his documents to the GMP Audit and Licensing Section of the Therapeutic Goods Administration and request a clearance assessment of the GMP evidence prior to actually submitting an application. This clearance assessment is not mandatory but it will expedite the licensing process. GMP audits of overseas manufacturers are undertaken from time to time by the GMP Audit and Licensing Section, particularly where alternative acceptable evidence of compliance to an equivalent Code of GMP is not available.

16.5 This requirement of possession of valid licences applies to manufacturers only. Importers can submit a pre-market assessment after he has determined whether the product is a food or a therapeutic good.

### Step 3: Pre-Market Assessment

#### *Safety and Quality*

16.6 All complementary medicines have to be submitted to a pre-market assessment before they can be made available to the public.

16.7 If a product contains substances which are already listed in the Australian Register of Therapeutic Goods, the assessment is relatively simple. The product can be assessed by the sponsor himself against the defined standards, i.e. the assessment is a self assessment, and then it will be submitted to a simple 'eligibility review' conducted by the Therapeutic Goods Administration. The following criteria are considered in the 'eligibility review'<sup>16</sup>:

- (1) eligibility of ingredients disclosed in the application; and
- (2) eligibility of therapeutic claims in terms of compliance with the Therapeutic Goods Advertising Code including the presence of mandatory warning statements.

16.8 However, if the product contains substances which are not included in Part 5 of Schedule 4 of the Therapeutic Goods Regulations as being Listed Substances, then the evaluation for safety and quality must be undertaken by the Therapeutic Goods Administration with advice from the Complementary Medicines Evaluation Committee. The sponsor has two options for evaluation:

- (1) that the substances would be evaluated as new *Listable* complementary medicine *substance*; or
- (2) that product would need to be evaluated as a *Registered* complementary medicine *product*.

16.9 Both options involve similar evaluation procedures, that is, the Therapeutic Goods Administration will look at the data supplied by the sponsor to determine the safety and quality of the product. In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used, are all taken into account.

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<sup>16</sup> Therapeutic Goods Administration, *Guidelines on Correcting Errors and Omissions for Medicines Listed in the Australian Register of Therapeutic Goods*, May 1999.

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16.10 According to the Therapeutic Goods Administration, both options for evaluation take between four and 12 months to complete. The difference between these two options is that for the first option, other sponsors of complementary medicines could also use that *substance* provided that they could meet the compositional parameters of that substance as a Listable substance. For the second option, other sponsors of similar, competing products would have to make separate applications to the Therapeutic Goods Administration should they also wish to have their product included in the Australian Register of Therapeutic Goods. In other words, using the first option will save money and time of sponsors who use the same Listable substance.

### *Substantiation of Claims*

16.11 Complementary medicines are allowed to carry medium or general level claims and both of these claims must be supported by scientific evidence or evidence of traditional use. However, for claims based on evidence of traditional use, their wordings are required to be qualified. The Therapeutic Goods Act 1989 requires that sponsors must hold evidence to support claims at the time of listing. Please see Appendix V for the regulatory approach.

16.12 Scientific evidence refers to quantifiable data. Types of quantifiable scientific evidence include clinical trials in humans, epidemiological evidence, animal studies and other evidence of biological activity.

16.13 Evidence based on traditional use refers to documentary evidence that a substance has been used over three or more generations of recorded use for a specific health related or medicinal purpose. Where tradition of use has been recorded as an oral rather than written history, then evidence of such should be obtained from the appropriate practitioner or indigenous groups, who maintain such a history.

### Step 4: Listing or Registration in the Australian Register of Therapeutic Goods

16.14 All complementary medicines must be entered on the Australian Register of Therapeutic Goods before they can be supplied in Australia.

16.15 Sponsors of low risk products which carry general or medium levels claims are required to apply for the listing of the products in the Australian Register of Therapeutic Goods. However, if the sponsors wish to make claims about the *efficacy* of the low risk products, they must apply for the registration (not listing) of the products in the Australian Register of Therapeutic Goods. Registered products are evaluated for safety, quality and efficacy before they are made available for supply in Australia.

16.16 Sponsors can apply to the Therapeutic Goods Administration for the listing or registration of the products after the pre-market assessment. The products can be put on the market for sale provided that the sponsors can obtain a certificate of listing or registration issued by the Therapeutic Goods Administration.

## **17. Distribution: Distribution Channels**

17.1 There is little restriction on the sale of complementary medicines in Australia unless they are "scheduled" which means that they must be sold in a pharmacy and on prescription from a medical doctor. Most complementary medicines are widely available through direct marketing, pharmacies, health food stores and supermarkets.

## **18. Fees and Charges**

18.1 From 1998/1999 onwards, the Australian government decided that the Therapeutic Goods Administration would recover 100% of its operating costs through fees and charges collected from the therapeutic goods industry. There are mainly three kinds of fees and charges, namely, annual charges, evaluation fees and licence fees.

18.2 Each product included in the Australian Register of Therapeutic Goods, whether 'registered' or 'listed', attracts an annual charge. The charge varies according to the product group. For example, 'registered' complementary medicines attract an annual charge of AUS\$465 (or HK\$2,330) while 'listed' complementary medicines attract an annual charge of AUS\$350 (or HK\$1,754).<sup>17</sup>

18.3 Application fee for new listed products entering in the Australian Register of Therapeutic Goods is AUS\$400 (or HK\$2,004) while the processing fee for listed products (for variation to an existing listing) is AUS\$200 (or HK\$1,002).<sup>18</sup>

18.4 Evaluation fees are set to recover fully the operating costs associated with regulating a particular product category. For example, the evaluation fee for a new prescription medicine can be in excess of AUS\$150,000 (or HK\$751,500) whereas the cost for a relatively lower risk complementary medicine is AUS\$270 (or HK\$1,353).<sup>19</sup>

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<sup>17</sup> Therapeutic Goods Administration, *Summary of Increases in Fees and Charges, Effective 1 July 2000*.

<sup>18</sup> Therapeutic Goods Administration, *Summary of Increases in Fees and Charges, Effective 1 July 2000*.

<sup>19</sup> Therapeutic Goods Administration, *TGA Fees and Charges Explanatory Note*, 8 March 2000.

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18.5 The GMP licence application fee is AUS\$540 (or HK\$2,705) and the examination fee of a plant master file<sup>20</sup> is AUS\$5,625 (or HK\$28,181). There is also an annual licence charge which is charged according to the type of the products. For example, for herbal products, the annual licence charge is AUS\$3,500 (or HK\$17,535). Site inspection fee is charged according to the time taken by the auditor. The hourly rate per auditor is AUS\$355 (or HK\$1,779) for local inspection and AUS\$745 (or HK\$3,733) for overseas inspection.<sup>21</sup>

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<sup>20</sup> A plant master file contains information relevant to understand the manufacturing operations of a firm.

<sup>21</sup> Therapeutic Goods Administration, *Summary of Fees and Charge at 1 July 2000*.

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## **PART 7 - ANALYSIS**

### **19. Drawing Expertise to the Regulatory System**

19.1 A critical link in the overall effectiveness of a high quality and responsive regulatory system usually lies in its access to professional expertise. In Australia, the membership of the various authorities involved in the regulation of complementary medicines gives access to a wide range of expertise. For example, members of the Complementary Healthcare Consultative Forum, the Complementary Medicines Evaluation Committee and the Therapeutic Goods Advertising Code Council include healthcare practitioners, professionals, industry representatives and consumers, etc. With this wide range of expertise available in the regulatory system, the government is able to respond quickly to the rapidly growing industry of complementary medicines.

### **20. Balance Between Safety of Products and Expedition of Processing Applications**

20.1 All complementary medicines must be submitted to a pre-market assessment before they can be put for sale. If the complementary medicine products are listed (low risk) products, sponsors are allowed to conduct the pre-market assessment by themselves. This arrangement shortens the processing time of the application for listing in the Australian Register of Therapeutic Goods. However, if the product contains substances which have not been listed in the Australian Register of Therapeutic Goods, the assessment has to be conducted by the Therapeutic Goods Administration. In this way, the Therapeutic Goods Administration can expedite the process but not at the expense of the safety of the products and that of consumers.

### **21. Balance Between the Need to Improve Market Access for the Products and the Need to Maintain Consumer Confidence in the Safety of the Products**

21.1 Traditionally in Australia, the regulation of therapeutic goods has involved extensive evaluation of the safety, quality and efficacy of products before they are approved for supply. About a decade ago, the Australian government created a new category of therapeutic goods called 'Listed' category. Listed goods are low risk goods which have been evaluated for safety and quality. In other words, each substance in each listed complementary medicine must have been evaluated for safety and quality. Individual products do not need to undergo further evaluation for safety providing they are composed of substances which have already been listed in the Australian Register of Therapeutic Goods. The quality of the products is ensured through compliance with GMP.

21.2 Hence, the creation of a 'listed' category of complementary medicines provides timely market access for the industry whilst maintaining a sufficient degree of regulatory control to ensure the safety and quality of products.

## **22. Regulation of Complementary Medicines**

22.1 Rigid control has been placed on the marketing of complementary medicines in Australia. First, the claims which may be made about complementary medicines are restricted to words like "assist" rather than "treat" and indications are limited to minor self-limiting conditions. Secondly, all complementary medicines must carry either the "AUST R#" or "AUST L#" labels which indicate whether or not the efficacy of the products has been proven. This provides useful information to consumers and avoids confusion. Thirdly, the products have to be manufactured by a Therapeutic Goods Administration-licensed manufacturer following recognized principles of GMP. This provides quality assurance to consumers about conditions of the manufacturing site of the products. Lastly, both listed goods and registered goods are subject to the same stringent requirements of safety and quality.

## Appendix I

### Definition of a Therapeutic Good

Given below is the definition of a therapeutic good contained in the Therapeutic Goods Act 1989.

"therapeutic goods" means 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 subparagraph (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 declares 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.

The Therapeutic Goods Act defines *therapeutic use* as follows:

"therapeutic use" means 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.

**Appendix II****Definition of Medium and General Levels Claims Which May Be Made About Complementary Medicines**

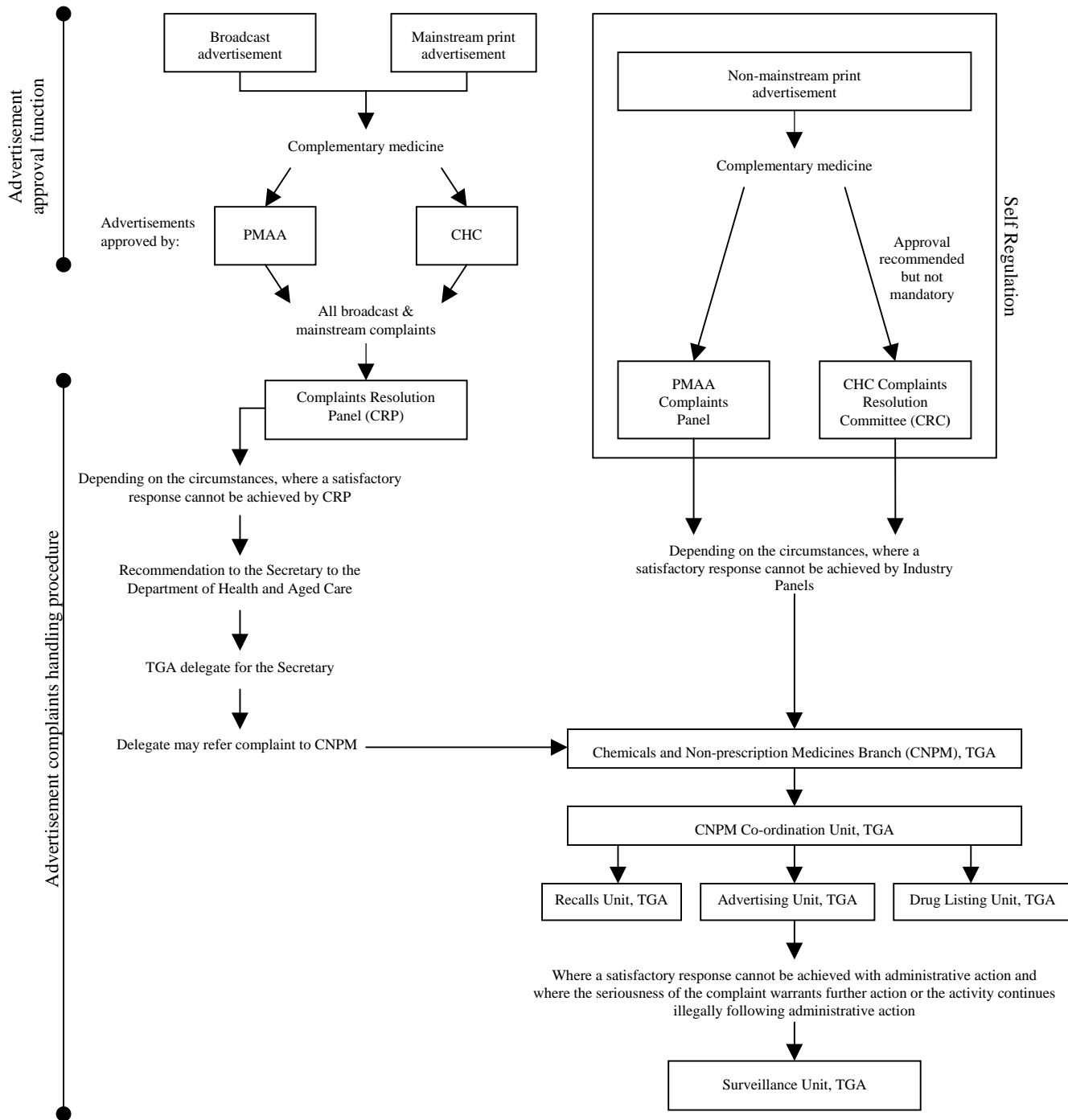
1. Aids / Assists claim -- a claim which describes how a product or substance may aid / assist in the management of a named symptom / disease or disorder.
2. Discrete events claim -- a claim which refers to the ability of a product or substance to reduce the frequency of a discrete event such as migraine.
3. Risk reduction claim -- a claim which relates to reducing the risk of a particular disease, disorder, condition, symptom or ailment.
4. Health enhancement claim -- a health maintenance claim which relates to health enhancement for normal people, such as improving, promoting, enhancing or optimizing (or words to that effect) body organs or systems.
5. Symptom claim -- a claim which relates specifically to the temporary relief of a particular symptom. All symptom claims must be accompanied by the statement "If symptoms persist consult your healthcare practitioner".
6. Claim relating to vitamin or mineral supplementation -- a claim which refers to supplemental intakes of the vitamin or mineral. A vitamin or mineral supplementation claim is only permitted where the recommended daily dose of the product provides at least 25% of the Recommended Dietary Intake (RDI) for that vitamin or mineral. Vitamin and mineral claim of any kind should not refer to the presence of vitamins or minerals unless they are present in the recommended daily dose of the product to at least the level of 10% of the RDI, unless there is evidence to support a therapeutic effect below this level.
7. Health maintenance claim -- a claim which refers to an effect that a product or substance may have in maintaining health (or words to that effect), but not including health enhancement or prevention claims. A health maintenance claim may also relate to the normal physiological consequences for good health associated with a product or substance, or to the provision of nutritional support and to the use of the terms, cleansing, detoxification and tonic.

Source: Therapeutic Goods Administration, *Draft Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods*, April 2000.



**Appendix III**

**The Approval and Complaints Procedures for Advertisements of Complementary Medicines**

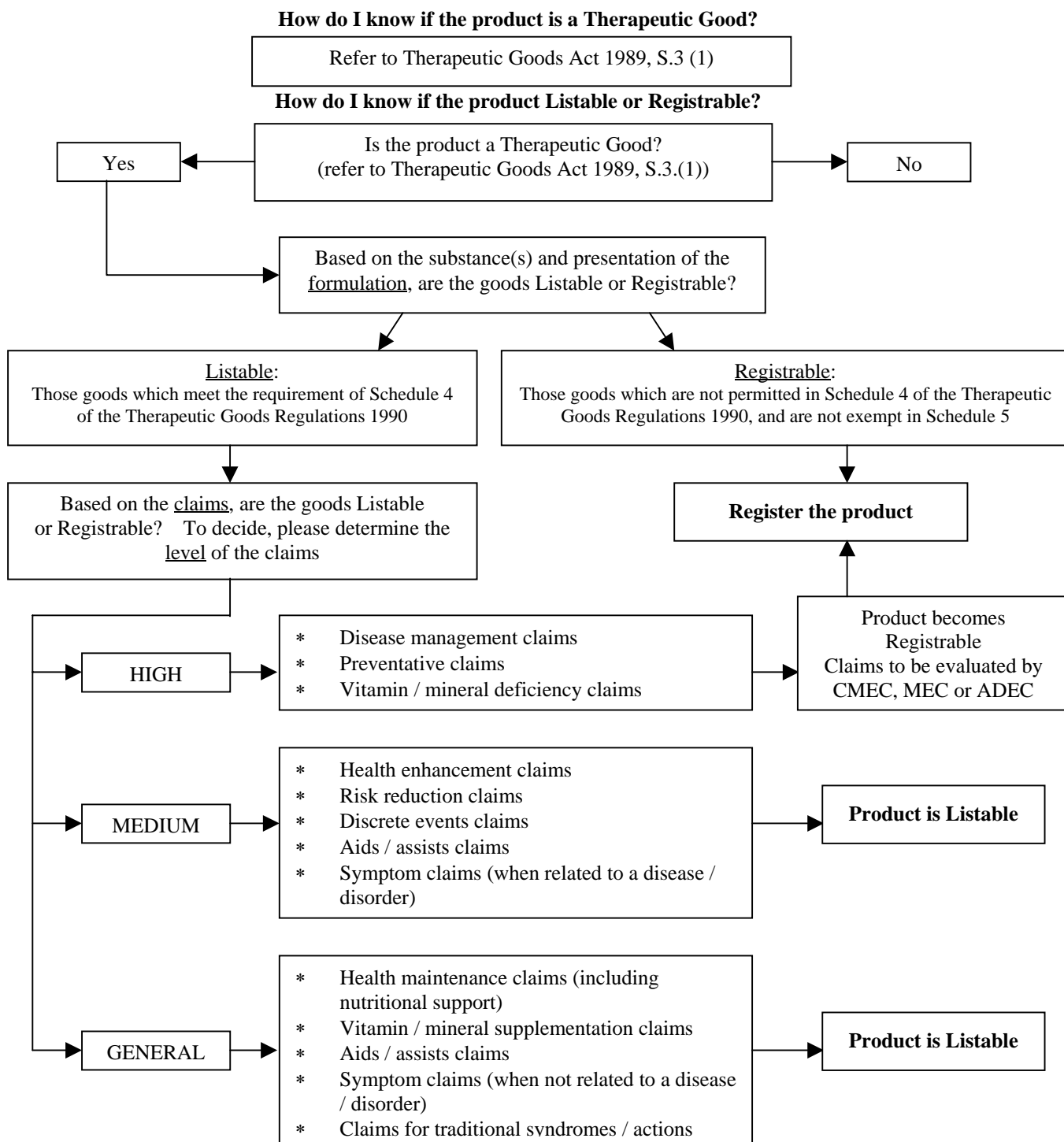


PMAA - Proprietary Medicines Association of Australia  
 CHC - Complementary Healthcare Council  
 TGA - Therapeutic Goods Administration

Source: Tasman Asia Pacific, *Analysis of Market Circumstances Where Industry Self-Regulation Is Likely To Be Most and Least Effective*, May 2000, p.132.

**Appendix IV**

**Determination of a Listable / Registrable Product**



Note: This is a general guide only. Products should be considered on a case by case basis.

CMEC - Complementary Medicines Evaluation Committee; MEC - Medicines Evaluation Committee  
ADEC - Australian Drug Evaluation Committee

Source: TGACC, *FAQ*, at <http://www.tgacc.com.au/flow1.cfm>

## Appendix V

## Levels and Types of Claims and the Evidence Required to Support Them

Level of Claim	Type of Claim	Type of Evidence	Wording of Claim <sup>4</sup>	Evidence Required
Medium	<ul style="list-style-type: none"> <li>♦ Health enhancement<sup>1</sup></li> <li>♦ Reduction of risk of a disease / disorder</li> </ul>	Scientific evidence	Not applicable	Medium level. Sponsor must hold the evidence for listable goods
	<ul style="list-style-type: none"> <li>♦ Reduction in frequency of a discrete event</li> <li>♦ Aids / assists in the management of a named symptom / disease / disorder</li> <li>♦ Relief of symptoms of a named disease or disorder<sup>2</sup></li> </ul>	Evidence of traditional use	This (tradition) medicine has been used for (indication) <sup>5</sup> . This claim is based on traditional use. <sup>6</sup>	Primary evidence: two of the following four sources that demonstrate adequate support for the indications claimed: <ul style="list-style-type: none"> <li>♦ TGA-approved Pharmacopoeia</li> <li>♦ TGA approved Monograph</li> <li>♦ Three independent written histories of use in the classical or traditional medical literature<sup>7</sup></li> <li>♦ Availability through any country's government public dispensaries for the indication claimed</li> </ul>
General	<ul style="list-style-type: none"> <li>♦ Health maintenance, including nutritional support</li> <li>♦ Vitamin or mineral supplementation<sup>3</sup></li> <li>♦ Relief of symptoms (not related to a disease or disorder)<sup>2</sup></li> </ul>	Scientific evidence	Not applicable	General level. Sponsor must hold the evidence for listable goods

Level of Claim	Type of Claim	Type of Evidence	Wording of Claim <sup>4</sup>	Evidence Required
General	<ul style="list-style-type: none"> <li>♦ Health maintenance, including nutritional support</li> <li>♦ Relief of symptoms (not referring to a disease or disorder)<sup>2</sup></li> <li>♦ Claims for traditional syndromes and actions<sup>5</sup></li> </ul>	Evidence of traditional use	This (tradition) medicine has been traditionally used for (indication). <sup>5</sup>	Primary evidence: two of the following four sources that demonstrate adequate support for the indications claimed: <ul style="list-style-type: none"> <li>♦ TGA-approved Pharmacopoeia</li> <li>♦ TGA approved Monograph</li> <li>♦ Three independent written histories of use in the classical or traditional medical literature<sup>7</sup></li> <li>♦ Availability through any country's government public dispensaries for the indication claimed</li> </ul>

## Remarks:

1. Health enhancement claims apply to enhancement of normal health. They do not relate to enhancement of health from a compromised state.
2. All claims relating to symptoms must be accompanied by the advice "If symptoms persist consult your healthcare practitioner".
3. Vitamin or mineral supplementation claims are only permitted where the recommended daily dose of the product provides at least 25% of the Recommended Dietary Intake (RDI) for that vitamin or mineral. Where vitamins or minerals are the subject of other kinds of claims, the dose must be consistent with the evidence to support the claim being made. Claims should not refer to the presence of vitamins or minerals unless they are present in the recommended daily dose of the product to at least the level of 10% of the RDI, unless there is evidence to support a therapeutic effect below this level.
4. Or words to that effect.
5. Terms must be in the original language of the traditional medical culture, e.g. "shen" not "kidney" in traditional Chinese medicines.
6. Where scientific evidence is available to support the entire claim, the words, "This claim is based on traditional use" is optional.
7. In cultures where an oral tradition is clearly documented, evidence of use from an oral tradition would be considered acceptable provided the history of use was authenticated. Modern texts which accurately report the classical or traditional literature may be used to support claims.

Source: Therapeutic Goods Administration, *Draft Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods*, April 2000.

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