
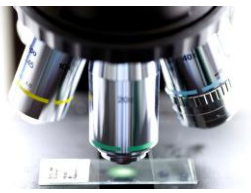


Complementary Healthcare Council of Australia

Response to the Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public

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Contents

PREFACE

Complementary medicines and natural healthcare products are vitamins, minerals and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. Complementary medicines also comprise traditional medicines, including Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines.

Complementary medicines are generally available for use in self-selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health.[1]

The supply of complementary medicines and complementary healthcare products comprises an important and integral component of health care delivery to the community by providing an extensive range of products available for self-selection and for dispensing by Health Professionals. Not surprisingly, half the adult population of Australia purchase a complementary medicine product at least every quarter.[2]

THE COMPLEMENTARY MEDICINES INDUSTRY PEAK BODY

The Complementary Healthcare Council of Australia (CHC) is the peak industry body for the complementary medicines industry. The CHC is unique in representing the entire supply chain from: manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. The CHC is committed to a high growth and sustainable complementary medicines industry. We promote industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality, contributing to improved population health outcomes. We are the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicine industry.

The CHC develops and manages a marketing code of conduct to which its members agree, and to which non-members are encouraged, to comply. This includes operating to the highest regulatory and ethical standards when sourcing, manufacturing and marketing complementary medicines.

THE COMPLEMENTARY MEDICINES INDUSTRY

The complementary medicines industry comprises entities that range in size from multinationals through to smaller regional-based businesses. All industry stakeholders share a desire for complementary medicines to be an essential component of consumer healthcare.

Complementary medicine companies in Australia generate around $2 billion in annual revenues. The industry employs around 5,000 people in highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at $US 83 billion annually[3].

Australian companies export around $200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and the America's, and continues to grow at higher rates than domestic consumption.[4]

1. Source TGA, http://www.tga.gov.au/industry/Complementary Medicine-basics-regulation-overview.htm
2. My Opinions Research, May 2011
3. The Australian National Audit Office, *Performance Audit Report No. 3 2011-2012*, Therapeutic Goods Regulation: Complementary Medicines, pp13.
4. CHC Industry Audit, May 2011.

SUMMARY OF CONCERNS WITH REGARD TO REGULATORY REFORMS

The CHC promotes appropriate industry regulation and advancement to ensure consumers have access to Complementary Medicines of the highest quality. Unfortunately, the current environment of escalating regulatory burden is removing the 'light –touch' regulatory approach that is applicable to these low-risk products. Even now, the regulatory environment causes significant financial impact, particularly on small and medium sized enterprises (SMEs) that are being progressively forced out of the industry. This is in spite of the current Government's promise to improve the competitiveness, innovation and sustainability of Australian SMEs.

The biggest concern of the CHC is that Complementary Medicines do not fit within the current or proposed regulatory system. Many of the criticisms with the current system arise because complementary medicines do not fit within a model designed primarily to accommodate OTC and prescription medicines.

THE CURRENT SYSTEM FOR REGULATION OF ADVERTISING

The *CHC Advertising Reform Position Statement 2009* detailed Industry concerns with the current system for regulation of Advertising as below.

Industry concerns with the existing regulatory framework for advertising:

- Difficulty in communicating bone fide news (due to lack of clarity regarding its definition);
- The inability to provide vital health information to consumers (ie: valid interactions with medical drugs and contraindications in specific diseases).

Industry concerns with the pre-approval system for advertising:

- The pre-approval system is complex and involves two different delegated authorities depending on the type of media in which the product is to be advertised;
- The use of different delegated authorities for different media for advertisements of the same product creates an environment conducive to inconsistency in decision making;
- There is no current provision of pre-evaluation assistance to advertisers or industry.

Industry concerns with the current process for handling of advertising complaints:

- Complaint handling for complementary medicines involves a number of different delegated authorities (CRC, CRP, ASMICP) and therefore has the clear potential for inconsistency in decision making;
- Time taken for handling complaints by some authorities can be two to twelve months (as per complaints decisions published on the CRP website), industry considers this to be too long;
- Complaints about the efficacy of a complementary medicine ingredient are being upheld, however these are considered to be more issues with the listing system than complaints about the advertising of a product per se;
- There is a lack of an appropriate appeal mechanism in order to have decisions of the Complaints Resolution Panel reviewed.

CHC and ASMI in 2012 formally established a joint Advertising Reference Group and commenced a process to inform an agreed industry position on definitions and substantiation of evidence criteria for marketing claims. The rationale for this was to provide sufficient guidance to industry (as agreed by industry) to minimise non-compliance with the *Therapeutic Goods Advertising Code 2007 (*Advertising Code*)*.[5] This document was submitted to the TGA in January 2013. No outcomes have yet been advised. We are aware

5. CHC Issues Paper on the Substantiation of Claims to Comply with the Therapeutic Goods Advertising Code, January 2013, http://www.chc.org.au/Submissions

that a plan to address these issues has commenced, and Industry looks forward to receiving notification on the progress.

UNDERPINNING THE ADVERTISING CODE DIRECTLY IN THE THERAPEUTIC GOODS ACT

Underpinning the Advertising Code directly in the Therapeutic Goods Act is premature at this time as the TGA's Advertising Reforms are yet to be finalised, current requirements are being made subject to new interpretations by Delegates but have yet to be formally notified to industry.

> *The amendments will make it clear that these advertising requirements include not only relevant advertising provisions in the act itself but also those contained in the therapeutic goods advertising code, which is made by the minister under the act.*[6]

Through the *Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013*, the ability to cancel products based on advertising is being broadened, without any prior notification of the actual or anticipated impact.

CHC Recommendation

The CHC is of the view that this broadening is effectively a new power, and there must be genuine and appropriate consultation with industry to ensure an efficient and cost effective advertising regulatory framework and an innovative and competitive industry BEFORE amendments to the underpinning Legislation are made.

Industry's concern is exacerbated by **the power to cancel a product *without notice* for non-compliance with advertising requirements**[7], please refer to '**section 1.1 CHC Comments' in the *CHC Response to the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013***

6. Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Explanatory Memorandum, pp. 8-9
7. The Hon Catherine King, MP, Op Cit, para 17.

PROPOSAL 1—ADVERTISING

Option 1: Status quo - maintain the current system.

Option 2: Extend the current system to:
(a) include pre-approval for medical devices
(b) cover subscription broadcasting ('narrowcasting') (pay-TV).

Option 3: Limit the current pre-approvals scheme to cover only "higher risk" categories of advertisements.

Option 4: Retain pre-approvals (modified or not as per option 2 or 3) and:
(a) maintain the current pre-approval delegations to industry associations, such as ASMI and CHC (with an appropriate medical devices industry group if option 2(a) is endorsed); or
(b) appoint an independent statutory office holder to undertake pre-approval function; or
(c) TGA to undertake the pre-approval function.

Option 5: Remove the pre-publication approval scheme.

CHC RECOMMENDATION – PROPOSAL 1

The CHC supports the extension to include pre-approval for 'narrowcasting' (Option 2 (b))

The CHC supports the retention of pre-approvals (Option 4(a)) *with modification* so that all complementary medicine advertisements are pre-approved by a single body

CHC COMMENTS – PROPOSAL 1

The CHC position is to maintain mandatory pre-approval for 'above-the-line' advertising. For complementary medicines, pre-approvals of advertisements should be delegated to a single body regardless of the type of media across an advertising campaign. This single body should have the capacity to service the peak times for approvals required by industry and for costs to remain competitive.

The CHC believes that with on-going training, Advertising Service Managers, as a Delegate to the Secretary for Health, should continue to provide the pre-approval function. This approval should provide a measure of protection against complaints; particularly they should work in the favour of the sponsor and limit any penalty in the instance of a complaint.

Pre-approval, as with all regulatory functions, should incorporate an industry support component, for example, presentation at industry seminars and provision of generic guidance in relation to advertising matters.

We recommend the CHC be the single body for pre-approvals of complementary medicine advertisements. Should this function be delegated to an independent statutory office holder, the CHC is concerned that there be sufficient complementary medicine specific expertise represented. This has not been achieved by the current CRP.

The CHC supports the idea of a system where claims and representations for a product – in all mediums – are pre-assessed and an approval number generated for a package of promotions for a product, rather than a specific advertisement. Once a package has been approved the advertisements (claims and representations) could be used in all mediums of advertising. Pre-approved claims under this system could still be subject to a complaint but the delegated approval should carry weight in the decision-making process.

The CHC recommends additional authority to companies (as recognition of compliance) in addition to Advertising Service Managers (ASMs). This additional authority could be to carry out minor variations to the already pre-approved packages only. Advantages of this option would be a reduced number of advertisements requiring pre-approval outside the company and a flow-on effect of reduced costs to businesses. These delegated approval agents should require industry accredited training and delegation may be revoked under yet to be defined criteria. It would not be expected that such approval would provide defence to complaints.

Having an industry-led, co-regulatory component in ensuring compliance with the Advertising Code would engage industry to a higher degree than is currently experienced. In the development of industry accredited training, the single body (the CHC), would liaise with the TGA to ensure an appropriate training program.

We would not support the TGA being the single body undertaking pre-approval for three main reasons:

(1) the temptation to conduct a full evidence review in place of an advertising review;
(2) the TGA would require dedicated resources; and
(3) being located within the TGA could lead to unanticipated extended time frames.

This would lead to more uncertainty for industry and increased costs to businesses and consumers.

PROPOSAL 2—THE COMPLAINTS HANDLING PROCESS

Option 1: Status quo - maintain the current system.

Option 2: All complaints about advertising of therapeutic goods to the general public to be handled by a single body, either:

(a) the TGA; or

(b) an independent statutory office holder

CHC RECOMMENDATION – PROPOSAL 2

The CHC supports the maintenance of the current system (Option 1), *with modification* so that all complementary medicine complaints are heard by a single body with Complementary Medicine expertise

CHC COMMENTS – PROPOSAL 2

The CHC believes that all complaints about advertising of therapeutic goods to the general public be handled by a single body. The basis of this single body could be *a* Complaints Resolution Panel (CRP), but only if this body is constituted correctly so that the vast majority of people assessing the complaints hold specific expertise in the complementary medicine field. This is not the case with the current CRP. When a person leaves the committee a replacement should be based on individual skill set and not an agency or organisation being represented on the committee. Complementary Medicine expertise would strengthen consistency in decision making.

Whilst the CHC is supportive of enhanced enforcement strategies, it is imperative to note that the Advertising Code is very subjective. Although penalties for breaches of law are justified, the current Advertising Code does not provide for consistency in judgement decisions, and therefore, nor can it provide a basis for the application of penalties.

The CHC strongly recommends that the Government require sponsors to subscribe to a Code of Marketing as a requirement of listing on the Australian Register of Therapeutic Goods (ARTG). This would enable the CHC and other associations to better enforce sanctions against non-compliant companies. While this recommendation was not supported by Government in 2011, the *Blueprint Reforms* state that if further encouragement is required for non-members to nominate a code, the Government will consider further legislative measures including the TGA seeking this information.

PROPOSAL 3— PROVISION OF ADVICE IN RELATION TO ADVERTISING MATTERS

Option 1: Status quo - maintain the current system.
Retention of CRP and Therapeutic Goods Advertising Code Council (TGACC) in their current form

Option 2: Establish an expert advertising advisory committee.
Establish one statutory advisory committee to replace the Panel and Council to provide advice to the Secretary (delegate)

CHC RECOMMENDATION – PROPOSAL 3

The CHC supports an expert advertising advisory committee (Option 2) *with modification* to ensure broad high level oversight (equivalent to the Advertising Code Council) and a high level of industry knowledge (Complementary Medicine Advertising Advisory Committee)

CHC COMMENTS – PROPOSAL 3

Whilst the CHC supports the TGA seeking advice from a statutory committee in relation to advertising matters, it should be *in addition* to maintaining a single body to handle Complementary Medicine product complaints.

The TGA Advisory Committee on Complementary Medicines (ACCM) could be used as a basis for this proposal and be referred to, if required by the CRP, for recommendations on Complementary Medicines. The recent call for expressions of interest to the expert committee should ensure a greater number of complementary medicines specific expertise are represented on the committee, including from the consumer point of view, than is currently the case.

PROPOSAL 4— INVESTIGATION AND ENFORCEMENT POWERS

Option 1: Status quo - maintain the current system

Option 2: Enhance investigation and enforcement powers

CHC RECOMMENDATION – PROPOSAL 4

The CHC supports the enhancement of investigation and enforcement powers (Option 2) *with modification* as described below

CHC COMMENTS – PROPOSAL 4

Whilst the CHC is supportive of enhanced enforcement strategies, it is imperative to note that the Advertising Code is very subjective and although penalties for breaches of law are justified, the current Advertising Code does not provide for consistency in judgement decisions, and therefore, nor could it provide a rational basis for the application of penalties.

The CHC supports the review of the TGAC 2007 by a TGA-formed committee with similar constituency to the Complementary Medicines Informal Working Group. The desired outcomes of this committee are to eliminate areas of subjectivity and to articulate the level of penalty to be enforced against the level of breach. At this point only, enforcement powers could be enhanced – this review should also articulate penalties for repeat offenders.

If a complaint is lodged that is outside the above review plus subjective in nature the investigation and enforcement process should be a legal procedure as per the consumer protection laws. This would provide industry and public visibility, ensure consistency in application, eliminate bias, ensure that repeat offenders are dealt with accordingly and allows for a robust appeals process. This would eliminate penalties being based on probability and ensure that the outcomes are beyond reasonable doubt.

The CHC calls for transparency on the detail of the TGA's risk profiling system, in particular the criteria for the higher risk categorisation and the process for review or removal from the high risk category. With the immense increase in penalty units, additional detail on compliance risk must be communicated widely, to enable industry compliance.

Where fines are enforced by the TGA any surplus to operational costs should be diverted back into improved industry education.

PROPOSAL 5— ADVERTISING OF HIGHER RISK MEDICAL DEVICES

Option 1: Status quo - maintain the current system.

Option 2: Prohibit the advertising of higher risk medical devices (applicable to Class III, Active Implantable medical devices and Class 4 in vitro diagnostic devices)

CHC RECOMMENDATION – PROPOSAL 5

The CHC in principle supports option 2, prohibit the advertising of higher risk medical devices (applicable to Class III, Active Implantable medical devices and Class 4 in vitro diagnostic devices.

CHC COMMENTS – PROPOSAL 5

The TGA advised the CHC (July 4, 2013) that this advertising recommendation does not affect in vitro diagnostic devices (IVD) devices that complementary medicine health professionals may use in clinical practice. As such, the CHC will not make any specific comment in relation to it.

As a separate reform process, the TGA In-Vitro Diagnostic devices regulations will require all commercial IVDs and Class 4 in-house IVDs for therapeutic use to be included in the ARTG from 1 July 2014. The future availability of these and other innovative devices to complementary medicine health professionals may be impacted due to greater scrutiny of the devices and indications on the ARTG.

PROPOSAL 6 – ADVERTISING DIRECTED TO HEALTH PROFESSIONALS

Option 1: Status quo - maintain the current system.

Option 2: Update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the Health Practitioner Regulation National Law.

This option specifically affects those professions not currently regulated under the Health Practitioner Regulation National Law such as Naturopaths, Homeopathic practitioners and Herbalists (other than Chinese herbal medicine practitioners registered by the Chinese Medicine Board of Australia). Under Option 2, advertising to groups of practitioners who are not registered with NRAS would be regulated in the same way as advertising to the general public.

CHC RECOMMENDATION – PROPOSAL 6

The CHC strongly supports maintenance of the current system (Option 1) *with modifications* to provide the TGA with certainty as to Complementary Medicine Health Professionals

The CHC, as the Peak Body for the Complementary Medicine Industry, is willing to discuss taking on the responsibility for the maintenance of the Schedule 1 Certificates for Advertising Exemption.

CHC COMMENTS – PROPOSAL 6

The proposed changes to advertising under Option 2 mean that complementary medicine practitioners will no longer have access to appropriate advertising or educational material from Complementary Medicine sponsors.

Many Australians prefer Complementary Health Professionals as their first choice in health care, making it vital that these professionals hold current and comprehensive scientific and technical knowledge for the products they prescribe and dispense.

The CHC's firmly held position is to maintain the current exemption for health professionals in section 42AA of the Act. The Consultation RIS does not demonstrate a need for change, and there is no evidence that a change is required based on a public safety platform.

The professions of Herbalists, Homoeopathic Practitioners, Naturopaths, and Nutritionists are being marginalised by these proposed reforms. These health professionals have undergone extensive Government-accredited education, which makes it difficult to comprehend the proposal to treat these professionals as 'lay people', only trusted to be equivalent to consumers in terms of the information they should receive from complementary medicine sponsors.

The Australian Register of Naturopaths and Herbalists (ARONAH) is one of a currently available number of systems for registration for complementary medicine health professionals. ARONAH's system of registration mirrors the Federal Governments National Registration and Accreditation Scheme for other health professionals. Such processes do provide confidence that there is strict qualification, ethical and

other professional obligations applicable to these professions. ARONAH, or a similar registration body, can co-exist with the current established Associations.

Whilst the CHC is fully supportive of Naturopaths and Herbalists being included under the Australian Health Practitioner Regulatory Agency (AHPRA), currently this is untenable for the reasons outlined below:

(1) The Australian Health Ministers' Advisory Council (AHMAC) has referred the task of developing a process for the management of requests for registration to its Health Workforce Principle Committee. Following advice from the Committee, AHMAC will determine a suitable process for managing requests for inclusion of additional professions into the National Scheme. No applications are currently being considered until this process is complete, with no defined timeframes detailed.
(2) AHPRA is, in addition, undergoing a 3 year review of the operation of the National Scheme. This will largely impact any efforts the industry is making towards National Registration.

The 2005 paper prepared by La Trobe University entitled *The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine* supports the registration process. However previous efforts to register the profession under AHPRA have met with feedback that Naturopaths and Western Herbal Medicine Practitioners did not pose a significant health and safety risk and therefore not considered suitable for registration under AHPRA.

The CHC is actively working on the issue of Statutory Registration of Naturopaths and Western Herbal Medicine Practitioners, however, any submissions seeking a decision to register professions would be considered by the AHWMC and hence actual timing of our campaign efforts are not known at this stage.

Complementary medicine Health Professionals must be able to access technical and scientific information, including contraindications, around the medicines they prescribe. The CHC strongly believes that if health professionals were not able to access this information, as would be the case under option 2, that this would increase the potential for harm to consumers. Further, this would encourage a greater use of the Internet for product knowledge, which would likely increase the illegal purchase of non-TGA registered products to be used for patient care, thus placing the population at an even higher risk.

PROPOSAL 7 – ADVERTISING OF PHARMACIST-ONLY MEDICINES

The CHC makes no comment in relation to Proposal 7 of this consultation document.

PROPOSAL 8 – THE PRICE INFORMATION CODE OF PRACTICE

The CHC makes no comment in relation to Proposal 8 of this consultation document.

Complementary Healthcare Council of Australia

Position Statement

CHC Advertising Reform Position Statement

Contents

Executive Summary

The Complementary Healthcare Council (CHC) is the only expert industry association representing businesses involved in all facets of the complementary healthcare industry. We are exclusively focused on complementary healthcare products resulting in information and services that are committed to a preventative healthcare model based on promoting long term wellbeing.

Complementary medicines cover a diverse range of products including vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products and natural cosmetics.

Roy Morgan Research[i] indicates that almost 75 per cent of Australians use complementary medicines. Recent research[ii,iii] showed that up to 2 billion dollars is being spent by consumers on complementary medicines and healthcare annually. With figures like these, it is clear that complementary medicines play a significant role in the health care choices of contemporary Australians.

This Position statement puts forward the aims of the Complementary Healthcare Council for the Advertising regulatory system for Complementary Medicines:

The CHC generally supports the regulatory approach to advertising and this position statement describes the three policy aims:

One: evaluation and modification of the Regulatory Framework for Advertising of Complementary Medicines to achieve key outcomes

Two: evaluation and modification of pre-approval of advertisements for complementary medicines to achieve key outcomes

Three: evaluation and modification of the handling of complaints for complementary medicines to achieve key outcomes

It also acknowledges that consumers and industry want advertising that provides accurate, adequate information about complementary medicines while preventing misleading claims and indications.

Industry also wants an effective co-regulatory system — and importantly, one that is on the front foot to ensure advertising issues are swiftly dealt with where possible, rather than slowly shuffling into motion only in response to complaints.

The regulator should also be involved where needed, and must be able to able to enforce decisions where necessary.

There is also a need for an oversight group with appropriate complementary medicine representation, retention of the TGACC, review of the complementary medicine specific Code of Practice and new, more efficient system processes.

The Australian complementary medicines industry is already one of the most highly regulated in the world.

It is our firm belief that advertising should retain existing self-regulatory processes, and have a more significant degree of stakeholder/ industry ownership and responsibility

Statements of Principle Underpinning the CHC Position Statement

This paper presents the CHC's position on proposed amendments to the current model for the advertising process. For any advertising system to provide certainty in advertising to consumers, the regulator and industry, it must embody the following seven key criteria. These criteria have been a recurring theme throughout the preparation of this position and all recommendations are reflective of these:

- Protect consumer health and safety;
- Provide accurate and adequate information about complementary medicines whilst preventing misleading claims and indications;
- Encourage and support innovation in the complementary medicine industry for the benefit of a healthy Australian community;
- Be cost effective to both industry and the regulator;
- Be consistent and yet flexible and enforceable;
- Be responsive to COAG principles; and
- Be co-regulatory.

The CHC supports the general principles of the current regulatory approach for advertising, however acknowledges that both consumers and industry want advertising that provides accurate and adequate information about complementary medicines whilst preventing misleading claims and indications.

Additionally, industry wants a system that is reflective of an effective co-regulatory model; embodies the COAG principle that regulatory measures should be the minimum required to achieve pre-determined and desirable outcomes; a management/oversight group with appropriate complementary medicine representation, retention of the TGACC, and review of the complementary medicine specific Code of Practice and new, more efficient system processes.

The CHC considers the model below to be the most appropriate for a co-regulatory environment:

Listing	Advertising		Post-Market Surveillance
Currently under Review	Pre-Approval	Complaints	Post-Market Surveillance
	Industry	Industry	Government

The CHC considers that the complementary medicines industry is one of the most highly regulated systems in the world and that advertising should therefore retain existing self-regulatory processes and comprise a more significant degree of stakeholder / industry ownership and responsibility. The system should be proactively ensuring advertising issues are dealt with efficiently wherever possible (and in conjunction with the broader regulatory environment) and not simply be reactive by responding to complaints. The regulator should also be involved where needed and must be able to able to enforce decisions where necessary.

It is important to note here that this proposal for the regulation of advertising of therapeutic products in Australia needs to be seen in the broader context of the overall regulatory framework. Industry has concerns around the requirements for quality and suitability of evidence for Listed products and will prepare a separate submission on the evaluation of evidence for complementary medicines.

The CHC also acknowledges that currently foods advertising illegal therapeutic claims are not covered by the Therapeutic Goods Advertising Code (TGAC) and intends to make representations in this regard to the State Food Authorities.

Policy Aims and Recommendations

The CHC believes that the main features of the new system should be defined by the policy statements in this document.

Policy Aim 1: That the Regulatory Framework for Advertising of Complementary Medicines be evaluated and modified to achieve key outcomes

Recommendations:

- The system should retain a co-regulatory model;
- The TGAC, a broad, principles-based Code, is appropriate at a high level, however revision is needed:
  - The TGAC needs to be more explicit in its enforcement;
  - Several key definitions including, but not limited to, advertisement, evidence, mainstream media, claim, indication, serious disease, bone fide news etc needs to be reviewed and/or developed by the TGACC in consultation with industry;
- The prohibition of advertising scheduled poisons and serious diseases should be reviewed to permit notification of drug interactions and contraindications in order to improve protection of consumer health and safety;
- A new industry-specific Code of Practice for the Marketing of Complementary Medicines (the CM Code of Practice) should be derived from and anchored in an updated TGAC[1];
- The management/oversight group of the CM Code of Practice should be broadly-based, and representative of its constituent industry; and
- The CM Code of Practice should be applied to the whole of the complementary medicine industry, by industry and be the only instrument standard for complementary medicines (pre- and post- marketing).

[1] It is anticipated that as a component of this model, the others sectors, being OTC and Devices, would have similarly constituted Codes of Practice.

Policy Aim 2: That Pre-Approval of Advertisements for Complementary Medicines be evaluated and modified to achieve key outcomes

Recommendations:

- Retain mandatory pre-approval for 'above-the-line' advertisements and implement additional delegated authority (within companies) for approvals (in addition to Advertising Service Managers (ASMs));
- Pre-approval evaluation be based on the CM Code of Practice;
- Delegation should be for all 'above-the-line' advertisements;
- Delegated approval agents to require industry-accredited training, assessment and professional development through an industry-approved training program;
- Delegation may be revoked and the circumstances leading to this should be defined; and
- Incorporate pre-approval assistance as an industry support component into the current pre-approval system

Policy Aim 3: That the Handling of Complaints for Complementary Medicines be evaluated and modified to achieve key outcomes

Recommendations:

- Only one committee to consider complementary medicine complaints modelled on the CHC's Complaints Resolution Committee (CRC) in that it is industry-run and the composition is focussed on complementary medicine expertise[2];
- Evaluation of complaints be based on the CM Code of Practice;
- The timeliness and effectiveness of corrective action and/or application of sanctions in cases where there is determined to be non-compliance with the CM Code of Practice must be defined; and
- Reporting non-compliance with the CM Code of Practice will incorporate reasons and the extent to which advertisements did not comply with the Code;
- The Complementary Medicines Committee will refer to the TGA illegal products; consumer health and safety issues; and non-compliance with sanctions; and
- Penalties and sanctions (with appropriate industry consultation) should be applied by the TGA in the cases mentioned in the dot point above; and that these penalties should be stronger than those imposed by industry.

[2] It is anticipated that as a component of this model, the others sectors, being OTC and Devices, would have similarly constituted Committees.

Appropriateness of the Model for Complementary Medicines

The CHC believes that collectively, the changes summarised above address the seven key criteria required for an advertising system to provide certainty in advertising to consumers, the regulator and industry. Protection of consumer health and safety is paramount to any regulatory system and is achieved here by engendering a high degree of stakeholder / industry ownership and responsibility through providing an improved pre-marketing experience, plus reinforcing the penalties of the system.

The requirement for the model to be consistent and yet flexible and enforceable have been demonstrated through the enhancement of the successful features of the current advertising system.

The proposed system also provides more certainty to consumers and industry alike that accurate and adequate information about complementary medicines whilst preventing misleading claims and indications is provided. This is achieved by improving consistency in decision making, both pre- and post- marketing. This will be through having a clear CM Code of Practice defining the advertising requirements, industry accredited delegated authorities that have undergone formal training and assessment and ongoing training of delegated authorities to review decisions. This model also retains the co-regulatory approach and is responsive to COAG principles which state that regulation should avoid imposing barriers to entry, exit or innovation and have minimal impact on competition. With industry able to take a larger role in the decision-making process, the complementary medicine industry will be able to develop responsibly.

Finally, resourcing and funding are discussed in this document, but using a similar cost-recovery model to that currently employed, this model would be cost effective to both industry and the regulator.

Advertising Regulation in 2009

A Brief Summary

The Therapeutic Goods Administration (TGA) is the regulator of therapeutic goods for supply in Australia. The advertising of devices and medicines (including prescription, over-the-counter and complementary) is co-regulated by the TGA and industry (including the CHC) to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of such goods, is socially responsible and does not mislead or deceive the consumer.

For the purpose of regulating complementary medicines, the *Therapeutic Goods Act 1989*[iv] (the Act) and the *Therapeutic Goods Regulations 1990*[v] (the Regulations) provide a definition of a complementary medicine and designate the types of ingredients that may be used in such medicines.

The advertising of therapeutic goods in Australia is subject to the advertising requirements of the Act (which adopts the *Therapeutic Goods Advertising Code* [TGAC] 2007[vi], including Section 4(1)(a) requiring advertisements for therapeutic goods to comply with the statute and common law of the Commonwealth, State and Territories)[vii], the supporting Regulations and the *Trade Practices Act 1974*[viii]. Complementary Medicines are further regulated by the *Complementary Healthcare Council of Australia Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products* (CM Code of Practice)[ix]. It should be noted that currently only members are required to adhere to the CM Code of Practice and that it is voluntary for non-CHC organisations.

Following the failure of the Trans-Tasman Harmonisation (TTH) process and the non-realisation of an Australia New Zealand Therapeutic Products Authority, the CHC has been lobbying to bring to reality those parts of the TTH scheme that were positive initiatives for both industry and consumers. One area that the CHC considers is in need of reform is advertising which was also signalled for future reforms by the Parliamentary Secretary for Health & Ageing in July 2008.

Criticisms of the Current Advertising System

It is appropriate that the Act and the TGAC should cover the whole range of therapeutic goods on the Australian market. However, the inadequacies of the current administrative system (highlighted below) are reflective of the requirement for separate administrative policies for complementary medicines.

Industry concerns with current regulatory framework for advertising

- Difficulty in communicating bone fide news (due to lack of clarity regarding its definition) and providing vital health information to consumers (ie: valid interactions with medical drugs and contraindications in specific diseases).

Industry concerns with the pre-approval system for advertising

- The pre-approval system is complex and involves two different delegated authorities depending on the type of media in which the product is to be advertised;
- The use of different delegated authorities for different media for advertisements of the same product creates an environment conducive to inconsistency in decision making;
- There is no currently provision of pre-evaluation assistance to advertisers or industry;
- Changes to approved advertisements can be costly;
- There is great difficulty in advertising certain product categories.

Industry concerns with the current process for handling of advertising complaints

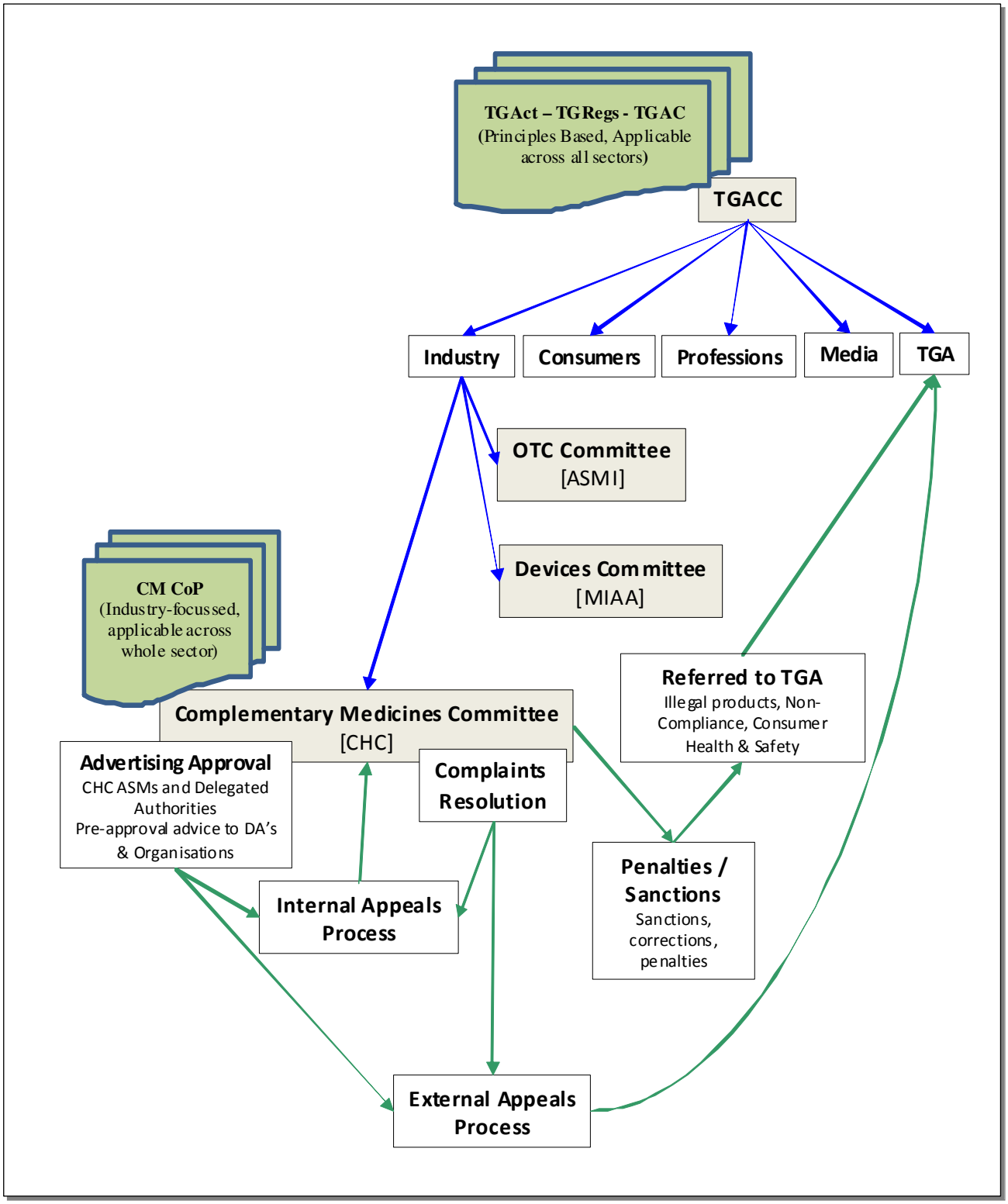
- Complaint handling for complementary medicines involves a number of different delegated authorities (CRC, CRP, ASMICP) and therefore has the clear potential for inconsistency in decision making;
- Time taken for handling complaints by some authorities can be two to six months (as per complaints decisions published on the CRP website), industry considers this to be too long;
- Statistical reporting in regards to complaints analysis are inadequate and present a skewed picture of complaints upheld and dismissed;
- Complaints about the efficacy of a complementary medicine ingredient are being upheld, however these are considered to be more issues with the listing system than complaints about the advertising of a product per se;
- The current process for handling of complaints is not appropriately sector based (for example, the current Complaints Resolution Panel currently has only 3 from 11 members (27.2%) with expertise in the complementary medicine sector); and
- There is a lack of an appropriate appeal mechanism in order to have decisions of the Complaints Resolution Panel reviewed. Note that the CHC's Code of Practice does include this provision under section 8.4.6.

Many of the criticisms with the current system arise because complementary medicines do not fit within a model designed primarily to accommodate OTC and prescription medicines. The CM Code of Practice is dedicated solely to complementary medicines and its sanction compliance rate provides evidence that a system focussed solely on complementary medicines would be sustainable and successful with the control designs recommended in this paper.

Overall, the advertising system has served its time relatively well, however, regulator, consumer and industry concerns are focussed on inadequacies in the system and the proposed solutions described in this document address those issues focussed on advertising. Some industry critic-driven issues, particularly those targeting pre-evaluation of evidence) are not best addressed by modifying the advertising system in isolation and further work is needed in these areas.

The Proposed Model

Diagrammatical Representation of Proposed Model as a Flow Chart



Advertising Committees and Composition

TGACC

Composition

- Health Industry Peak Bodies (CHC, ASMI, DSAA, PSA, PGA, MIAA, Food & Grocery Council)
- Consumers
- Professions
- Media Peak Bodies
- TGA

Responsibility

- Oversight of the TGAC
- External Appeals Process

Complementary Medicines Committee

Composition

- CHC (at least one and not more than two representatives)
- Health Industry Peak Bodies from Other Sectors (at least one and not more than two representatives)
- Industry (at least three and not more than five representatives)
- Consumers (at least one and not more than two representatives)
- Professions (one representative)
- TGA (at least one and not more than two observers)

Responsibility

- Oversight and management of the CM Code of Practice
- Advertising Pre-Approval Management
- Complaints Resolution Management (above- and below- the line)
- Internal Appeal Management

It is anticipated that similar models could be developed for over-the-counter products and devices.

Advertising Process & Procedures Management

CHC to provide secretariat services and management of the process.

Advertising Pre-Approval

- ASMs employed by CHC (fee for service)
- Delegated Authorities Management (fee for service)
    - Industry-based ie: located within companies
    - Same delegation as ASMs
- ASMs provide pre-Approval advice to Delegated Authorities and organisations (fee for service)
- Only required for above-the-line advertising
- Underpinned by TGACC and the CM Code of Practice

Complaints Resolution

- Above- and below- the line advertising
- Complaints re complementary healthcare products only
- Reference to the TGAC and the CM Code of Practice
- Timeliness and transparency of the process

Internal Appeals Process

- Referred to Complementary Medicines Committee for action
- Non-resolution referred to the TGA for action
- Triggered by the defendant company
- Can be by-passed (companies can apply directly to the TGACC)

Penalties and Sanctions

- Not same decision-makers as per the approval committee
- Potentially lower financial penalties and lesser sanctions than imposed by the TGA (clear procedures for referral to TGA required)

External Appeals Process

- Referred to TGA for illegal products, non-compliance, consumer health & safety issues
- Internal TGA decision as to penalties and sanctions applied, but industry expects to be consulted prior to policy changes as per usual consultation processes.

Further Considerations

Resourcing

Funding of the Complementary Medicines Committee would potentially require a similar model to the current CRC funding scheme to allow for independence from industry. Use of such a model has provided successful co-regulation with the complaints mechanisms for both industry and government. Funded organisations provide a mechanism for information flow between the Australian Government and relevant stakeholders; draws together views on issues of relevance to their industry sector and the Australian Government; and provides a consultative mechanism for the TGA and industry.

Currently resourcing is provided for four committees – the TGACC, CRP, ASMICP and the CRC. In 2008/9, these committees received funding as stated: TGACC & CRP: $ 444,806.30; ASMICP: $ 53,421.50; and CRC: $ 66,764.28 - a total of $564,992.08. This funding total could be rationalised across the three industry-run bodies and the TGACC which should result in a reduction in overall cost to the Therapeutic Goods Administration. The TGACC could also be taken in-house by the TGA which would result in additional cost saving.

Alternatively, an initial seeding grant over three years could be sought to effectively establish these committees based on the assumption that the financing and operation of the Complementary Medicines Committee would be held at arms length from the CHC. A seeding grant would enable the CHC to ensure separateness from the CHC's industry representative roles and to employ a professional secretariat, with a demonstrable commitment to natural health care principles and use. Initial funding would assist setting of timeliness and transparency best practice and ensure a focus on protection of consumer health and safety; and provision of accurate and adequate information about complementary medicines whilst preventing misleading claims and indications. Continuous funding could then be provided in a number of negotiable ways including: charges to advertisers, education & training, costing of justified complaints and fines to breaching sponsors (with appropriate consultation to industry).

Enforceability

Having an industry-led, self-regulatory component in enforcing the Advertising Codes would engage industry to a higher degree than is currently experienced. Evidence of this can be seen with the Medicines Australia Code. Compliance with an Industry-developed Code would be strengthened by not having a second separate body looking at components of advertising. Additionally, TGA could require sponsors to subscribe to a Code of Marketing as a requirement for listing. This would enable associations to better enforce sanctions against non-complaint companies. This has been a successful measure used in other Australian industries, a *similar* model has been employed by the Department of Education, Employment and Workplace Relations.[3] This would mean that companies not willing to join an industry association would still be required to abide by the relevant industry Code and may potentially be exposed to the more imposing TGA penalties and sanctions.

[3] In brief, this model, Section 22 of the ESOS Act requires registered providers to belong to a tuition assurance scheme, unless exempted by regulation these schemes are provided by industry associations. Section 24 of the ESOS Act requires non-exempt providers to contribute to the ESOS National Assurance Fund, which was established under Part 5 of that legislation. Those providers who are unable/unwilling to join an industry association to access a scheme are required to pay much higher premiums to the Government Scheme.

Conflicts of Interest

Many Australian complementary medicine experts are involved with industry. The Complementary Medicines Committee would need strict procedures surrounding conflict of interest in decision-making. This would be overcome by the Advertising Sub-committee involving the regulator and consumer representatives.

There is also the potential of a perception issue and appropriate measures within the Terms of Reference would be implemented.

Consistency

Having, for complementary medicines, only one advertising pre-approval committee and one complaints committee would eliminate the issue of inconsistency that is currently problematic for an industry trying to achieve consistent marketing messages across multi mediums. Inclusion of published results and/or an appeals mechanism are also supported by this consideration.

A CM Code of Practice will provide clearer guidelines for industry to enable better understanding of the requirements; additionally there is also the potential for a guidance document to contain examples. The delegated authority training and assessment system will mean the same training program across the industry is used. Consistency will be guaranteed if this training is clear, documented for later reference and has regular follow up or refresher courses (continuing professional education).

Sanctions by the Complementary Medicines Committee

Industry self-regulation, ie: the voluntary association of organisations to control their collective action, has long been proposed as a complement to government regulation. Without explicit sanctions such structures will potentially be subject to increasing opportunistic behaviour. It is therefore anticipated that the CM Code of Practice would have associated sanctions and penalties enforced. Sanctions and penalties would include monetary, corrective and future process requirements. Non-compliance would bring about referral to the TGA and subsequent exposure to more severe sanctions and penalties.

Communication, Education & Training

An industry-accredited training program for delegated authorities (and companies) would be a feature of the proposed model, particularly in relation to training of delegated authorities. Commonly seen deficiencies through the complaints process and public display of determinations addresses the consumer concerns and would assist consistency of decisions.

Conclusion

The CHC has established a self-regulatory process for the complementary healthcare industry. Its focal point is its Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products which seeks to self regulate the marketplace by managing compliance with relevant Commonwealth and State legislation. The major objective of the CHC's complaint handling mechanism is to resolve advertising problems identified in the marketplace.

Having only one committee of experts assessing information dedicated to complementary medicines complaints will alleviate concerns about inconsistencies in decisions. By having experts within the field of complementary medicines (in relation to complaint resolution) and industry-based delegated authorities and ASMs (in relation to pre-approval of advertisements) will also ensure decisions relating to evidence provided will be viewed in the context of the complementary medicine paradigm (rather than pharmaceutical).

The *Productivity Commission's Report on Australia's Consumer Policy Framework* (released in August 2008) recommended "After further consideration of the most appropriate model, the Australian government should streamline and clarify advertising rules and work with state and territory governments to ensure reforms also address the need for a simplified system for complaints about national advertising".

The government has a stated commitment to "deregulation". This co-regulatory model allows for deregulation with appropriate oversight by the government.

This position statement has presented the CHC's position on proposed amendments to the current model for the advertising process. For any advertising system to provide certainty in advertising to consumers, the regulator and industry, it must embody seven key criteria. The policy statement made in this document have a focus on protection of consumer health and safety; provision of accurate and adequate information about complementary medicines whilst preventing misleading claims and indications; encourage and support innovation in the complementary medicine industry for the benefit of a healthy Australian community; being cost effective to both industry and the regulator; being consistent and yet flexible and enforceable; being responsive to COAG principles; and being co-regulatory.

References

[i] Roy Morgan Research 2008 Consumer Research, provided by Catalent Australia

[ii] Stephen P Myers, Alastair H MacLennan, and Anne W Taylor - *The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004* (MJA 2006; 184: 27–31)

[iii] *Vitamins And Dietary Supplements in Australia*, Published by: Euromonitor International, May 2009.

[iv] *Therapeutic Goods Act 1989,* Section 52F 'Definitions'. Available at: www.austlii.edu.au/au/legis/cth/consol_**act**/tga**1989**191/s**52f**.htm

[v] *Therapeutic Goods Regulations 1990,* Schedule 14 'Designated Active Ingredients'. Available at: www.austlii.edu.au/au/legis/cth/consol_reg/tgr**1990**300

[vi] *Therapeutic Goods Advertising Code 2005*. Available at: http://www.tga.gov.au/advert/tgac.htm

[vii] Reference State and Commonwealth Law – see list below

[viii] *Trade Practices Act 1974*. Available at: www.austlii.edu.au/au/legis/cth/consol_**act**/tpa**1974**149/index.html

[ix] *The Complementary Healthcare Council of Australia Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products.* Available at: http://www.chc.org.au/AboutUs/CodeofPractice/

Australian Legislation having a potential impact on Health Product Advertising

Additional Commonwealth Legislation:

Broadcasting Services Act 1992
http://www.comlaw.gov.au/ComLaw/Management.nsf/lookupindexpagesbyid/IP200401834?OpenDocument

Food Standards Australia New Zealand Act 1991
http://www.austlii.edu.au/au/legis/cth/consol_act/fsanza1991336/

Therapeutic Goods Act 1989
http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/26624F6E54AAD779CA256F71004DE7D9

Trade Practices Act 1974:
http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/7A3BC5E238FB4006CA2575EB00010975?OpenDocument

ACCC Fair treatment? Summary of the guide to the Trade Practices Act 1974 for the advertising or promotion of medical and health services 2000.
http://www.accc.gov.au/content/item.phtml?itemId=309076&nodeId=464a3722ecc6330b0ca0c45b8d58a569&fn=Fair%20treatment%E2%80%94summary.pdf

State Legislation Therapeutic Goods:

VIC Therapeutic Goods (Victoria) Act 1994
http://www.austlii.edu.au/au/legis/vic/consol_act/tga1994280/

TAS Therapeutic Goods Act 2001
http://www.austlii.edu.au/au/legis/tas/consol_act/tga2001191/

No other states have a Therapeutic Goods Act

State Legislation Fair Trading:

NSW Fair Trading Act 1987
http://www.austlii.edu.au/au/legis/nsw/consol_act/fta1987117/

QLD Fair Trading Act 1989
http://www.austlii.edu.au/au/legis/qld/consol_act/fta1989117/

VIC Fair Trading Act 1999
http://www.austlii.edu.au/au/legis/vic/consol_act/fta1999117/

ACT Fair Trading ACT 1992
http://www.austlii.edu.au/au/legis/act/consol_act/fta1992117/

ACT Fair Trading (Consumer Affairs) ACT 1973
http://www.austlii.edu.au/au/legis/act/consol_act/ftaa1973270/

WA Fair Trading Act 1987

http://www.austlii.edu.au/au/legis/wa/consol_act/fta1987117/

SA Fair Trading Act 1987

http://www.austlii.edu.au/au/legis/sa/consol_act/fta1987117/

TAS Fair Trading Act 1990

http://www.austlii.edu.au/au/legis/tas/consol_act/fta1990117/

NT has no fair trading Act.

State Legislation Food:

NSW Food Act 2003

http://www.austlii.edu.au/au/legis/nsw/consol_act/fa200357/

QLD Food Act 2006

http://www.austlii.edu.au/au/legis/qld/consol_act/fa200657/

VIC Food Act 1984

http://www.austlii.edu.au/au/legis/vic/consol_act/fa198457/

WA Food Act 2008

http://www.austlii.edu.au/au/legis/wa/consol_act/fa200857/

SA Food Act 2001

http://www.austlii.edu.au/au/legis/sa/consol_act/fa200157/

ACT Food Act 2001

http://www.austlii.edu.au/au/legis/act/consol_act/fa200157/

TAS Food Act 2003

http://www.austlii.edu.au/au/legis/tas/consol_act/fa200357/

NT Food Act

http://www.austlii.edu.au/au/legis/nt/consol_act/fa57/

State Legislation Health:

QLD Health Act 1937

http://www.austlii.edu.au/au/legis/qld/consol_act/ha193769/

WA Health Act 1911

PART VIIA -- Animal produce, drugs, medicines, disinfectants, therapeutic substances and pesticides

http://www.austlii.edu.au/au/legis/wa/consol_act/ha191169/

State Legislation Health Practitioners:

NSW Medical Practice Act 1992 No 94

http://www.legislation.nsw.gov.au/xref/inforce/?xref=Type%3Dact%20AND%20Year%3D1992%20AND%20no%3D94&nohits=y

QLD Medical Practitioners Registration Act 2001

http://www.austlii.edu.au/au/legis/qld/consol_act/mpra2001358/

VIC Medical Practice Act 1994

http://www.austlii.edu.au/au/legis/vic/num_reg/mpr2004n104o2004318.txt/cgi-bin/download.cgi/download/au/legis/vic/num_reg/mpr2004n104o2004318.txt

SA Medical Practice Act 2004

http://www.austlii.com/au/legis/sa/consol_act/mpa2004128/

WA Medical Practitioners Act 2008

http://www.austlii.edu.au/au/legis/wa/consol_act/mpa2008215/

ACT Health Professionals Act 2004

http://www.austlii.edu.au/au/legis/act/consol_act/hpa2004224/

TAS Medical Practitioners Registration Act 1996

http://www.austlii.edu.au/au/legis/tas/consol_act/mpra1996358/

NT Health Practitioners Act

http://www.austlii.edu.au/au/legis/nt/consol_act/hpa223/

Australian Self Regulation Advertising:

Free TV Australia Flow Chart of Food Advertising Regulations

http://www.freetv.com.au/SiteMedia/w3svc087/Uploads/Documents/4b51fd36-269d-4f47-8aec-5ff89eabf3ef.pdf

Advertising Federation of Australia List of Links to Advertising Codes and Regulations

http://www.afa.org.au/public/content/ViewCategory.aspx?id=306

Advertising Standards Bureau of Australia

http://www.adstandards.com.au/pages/index.asp