The Project Officer
Advertising Consultation
Regulatory Reform
Therapeutic Goods Administration
PO Box 100
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27 August 2010

Dear Secretariat

CHC Submission – Advertising Therapeutic Goods in Australia: Consultation Paper

Thank you for the opportunity for the complementary healthcare industry (through the Complementary Healthcare Council (CHC)) to provide comment on the reform to the regulatory arrangements for advertising therapeutic goods in Australia.

The CHC is the leading expert association exclusively committed to a vital and sustainable complementary healthcare products industry. We are unique in representing all stakeholder groups in the complementary healthcare industry; our members include importers, exporters, raw material suppliers, manufacturers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi-level marketers and consumers. The CHC is the principal reference point for members, government, the media, and consumers to communicate about issues relating to the complementary healthcare industry.

The CHC provides the following comments for consideration:

1. Overall awareness of the arrangements for advertising of therapeutic goods:
Are the current arrangements for advertising of therapeutic goods in Australia known to you? Should these be better known or understood?

The CHC believes that the current arrangements for advertising therapeutic goods in Australia are well known to the large majority of the complementary medicine industry, particularly CHC members.

The CHC proposes that for an advertising system to provide more certainty in advertising to consumers, the regulator and industry must embody the following criteria: protect consumer health and safety; provide accurate and adequate information about complementary medicines whilst minimising misleading claims; encourage and support innovation in the complementary medicine industry; be cost effective to both industry and the regulator; be consistent and yet flexible and enforceable; be responsive to COAG principals and be co-regulatory.

The CHC advocates the regulatory approach to advertising of therapeutic goods as outlined in the attached CHC Position Statement (August 2009).

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2. Do you have comments or complaints about the current advertising arrangements?

The CHC strongly recommends that the Complaints Resolution Panel (CRP) should not be evaluating product efficacy. The CRP as it currently stands does not hold the appropriate complementary medicine expertise to competently evaluate product efficacy.

Under the *Therapeutic Goods Regulations 1990* - 42ZCAGA(1) the CRP can refer a complaint to another authority (ie: the TGA) if they're satisfied that it involves a matter that could more effectively dealt with by another authority. We therefore ask that if the CRP is to be retained, the TGA direct them to refer all matters of efficacy back to the TGA (under TGReg 42ZCAGA) to be dealt with by the TGA.

The CHC stresses that, as a minimum, any complaints mechanism must handle complaints quickly, efficiently and prioritised according to potential impact on the consumer. For example, an advertisement appearing on television which is in breach of the *Therapeutic Goods Advertising Code 2007*, should be prioritised over a minor breach based on a technical issue, such as incorrect positioning of the approval number in a print advertisement. The present CRP complaints handling process is far too unresponsive and laborious and is therefore inefficient and costly. It is the view of the CHC that the current Complaints Resolution Panel invests too much time in issues of efficacy which not only slows the process down but can be more appropriately and more effectively dealt with by the Regulator or by an industry complaints panel.

The CHC, as suggested in its Position Statement, recommends that only one body/committee handle complaints for all types of complementary medicine media so that the right mix of appropriately skilled and experienced expertise can be utilised. By maintaining an industry run committee, modelled on the CHC's current Complaints Resolution Committee, we could directly address issues of consistency, efficacy and increase consumer confidence on an industry-wide basis, across an entire advertising campaign, and without the potential competing interests of the OTC industry.

We recommend that the evaluation process of complaints be based on the Complementary Medicine Code of Practice (CM Code) which also incorporates the therapeutic goods advertising provisions. Any corrective action and/or application of sanctions in cases where non-compliance with the CM Code has been determined must be clearly defined. Any non-compliance with the CM Code will incorporate detailed reasoning behind each decision and the extent to which breaching advertisements have not complied. To prioritise consumer health and safety, the Complementary Medicines Committee (as identified in our Position Statement) will refer immediately to the TGA any illegal products, and non compliance with sanctions of advertising found in breach. Further, once TGA referral has been necessary, (following appropriate industry evaluation) penalties and sanctions applied by the TGA should be stronger than those imposed by industry.

Having two separate bodies with the delegated responsibility for approving therapeutic goods advertising appearing in specified media is conducive to forum shopping. This leads to inconsistency and imposes a lesser degree of certainty for advertisers than would be

available to them in an environment where we have a single body, the CHC, charged with the responsibility to approve all complementary medicine advertising in specified media. This would facilitate a review across an entire campaign in specified media and ensure that time was not spent on the same issues being raised by different bodies only because the advertising was appearing via a different media.

3. Using the advertising arrangements: Do you currently use the arrangements to place approved advertisements? OR Do you find advertisements of therapeutic goods helpful?

The CHC's membership base does utilise the current advertising arrangements for approval and the comments and positions put forward by the CHC are based on what users of the current system let us know via our various committees and individually.

4. The Pre-approval process: Should the current pre-approval process for advertising be retained? If so should all form of advertising be considered in this process?

The CHC believes that mandatory pre-approval for all 'above-the-line' advertisements, excluding Internet, should be retained. The use of different delegated authorities, ie the Australian Self Medication Industry (ASMI) and CHC, for different media for advertisements of the same product creates an environment conducive to inconsistency in decision making and forum shopping. The CHC therefore recommends that all approvals for the complementary medicine industry are handled by the CHC exclusively.

The CHC would further propose that additional delegation for pre-approval of advertisements be investigated for companies to provide in-house approvals within agreed parameters. Further information can be found in the attached Position Statement.

The pre-approval evaluation of complementary medicines advertising would best be based on a Complementary Medicine Code of Practice that incorporates the advertising provisions. Given the difficulty in changing the *Therapeutic Goods Advertising Code* in a timely manner and affording all stakeholders appropriate consultation in advance, a Complementary Medicine Code of Practice as an overarching set of principles enables greater flexibility in responding quickly to changes that may become necessary in order to address consistent advertising breaches of a specific nature.

The CHC suggests that pre-evaluation assistance for CHC members should be incorporated as an industry support component and an appropriate appeals mechanism be established in order to have decisions of the complaints mechanism reviewed. The CHC highlights that its Code of Practice has always included an effective appeals provision (section 8.4.6).

The CHC believes that having only one advertising pre-approval and one complaints committee for complementary medicines would contribute to eliminating the issue of inconsistency that is currently problematic for an industry striving to achieve a consistent marketing message across multi mediums.

It is CHC's firm belief that advertising should retain existing self-regulatory processes, ie: the voluntary association of organisations to control collective action, and further incorporate a

greater, more significant, degree of stakeholder/industry ownership and responsibility. The CHC therefore does not support compulsory pre-approval of below-the-line or Internet material.

5. Questions for consideration: Should the Therapeutic Goods Administration (TGA) publish on its website information related to products removed from the Australian Register of Therapeutic Goods (ARTG)?

The CHC supports the concept of publishing information related to products that have been removed from the ARTG, so long as the context in which the breach was found is displayed as well as the reasoning for such drastic action. This will assist in preventing issues where limited information is provided. For example, it may be assumed that there is no evidence to support the claims whereas the reason for removal from the ARTG may be the inadequacy of the sponsor to provide other information which is unrelated to efficacy.

The CHC disagrees that the TGA should be given the power to refuse to list a product substantially similar to one that had been cancelled because this power may deny the sponsor natural justice in scenarios where they have addressed properly matters that have been raised in order to have their 'similar product' listed on the ARTG. Regardless, no action can be taken on progressing this point until such time as industry and the TGA can agree on a workable definition of "substantially similar".

6. Should the Complaints Resolution Panel (CRP) be reconstituted as an independent body?

The CHC considers that the Australian complementary medicine industry is already one of the most highly regulated in the world and so does not support reconstitution of the CRP in the first instance. The CHC's position is that complaints handling should increase existing self-regulatory processes so that there is one self-regulatory complaints mechanism across the entire complementary medicine industry. This will also foster a greater degree of stakeholder/industry ownership and responsibility. Where required, the CHC anticipates that the regulator would provide enforcement power to uphold decisions, as required.

The CHC recommends that it is beneficial to have significant industry representation on any complaints resolution body as these representatives understand the products, guidelines and the framework within which the complementary medicine industry operates and in general would understand the products to a greater capacity than an independent body with no access to this knowledge.

Conversely, a wholly independent body would have limited expertise in products, evidence and would most likely have over-representation by the non-complementary medicine sectors, that is, the pharmaceutical and medical sectors.

7. Should the CRP consider complaints about all forms of advertising?

The CHC does not support the CRP considering complaints about all forms of advertising. The CHC proposes that industry specific bodies, for example, the current Complaints

Resolution Committee (CRC), and the Medicines Australia Complaints Committee be strengthened. That is, the CRC be convened by the CHC to review complaints about all forms of advertising related to complementary medicines, on the basis that the same body can utilise industry specific experience and expertise to consistently review all forms of advertising related to a complaint as part of the total advertising campaign. There should be a vetting system whereby trivial or minor complaints may be dealt with differently to other more serious complaints which should be handled quickly and more effectively with the full weight of the Committee.

8. Should civil penalties apply for breaches of the regime?

The CHC believes that a sliding scale of penalties for minimal to serious breaches should apply following appropriate industry consultation with respect to the civil penalty fitting the breach. The CHC proposes also that other consequences be utilised as penalties such as suspension or removal of a product from the ARTG, perhaps a prohibition on any advertising for a period of time, or even compulsory pre-approval for all advertising regardless of whether or not it is appearing in specified media

9. In addition to the pre-identified consultation questions the CHC provide the following for further consideration:

In association with adopting the reforms proposed both in this document and CHC's Position Statement, the CHC remains supportive of the general principals of the current regulatory approach to advertising complementary medicines, however acknowledges that both consumers and industry want advertising that provides accurate and adequate information about complementary medicines whilst minimising misleading claims.

Lastly, the complementary healthcare industry requires a system that is reflective of an effective co-regulatory model; embodies the COAG principal that regulatory measures should be the minimum required to achieve pre-determined and desirable outcomes; a management/oversight group similar in structure to the Therapeutic Goods Advertising Code Council (TGACC) albeit with the secretariat independent of ASMI to remove any potential or perceived conflict of interest, and review of the complementary medicine specific Code of Practice.

The CHC would welcome the opportunity to discuss any matters relating to this submission and if you require further information please do not hesitate to contact me.

Yours sincerely

Dr Wendy Morrow
Executive Director

Complementary Healthcare Council of Australia

Position Statement

CHC Advertising Reform Position Statement

Position Statement Disclaimer

The Complementary Healthcare Council of Australia (CHC) publishes its position statements as a service to promote the awareness of industry issues to its members and other stakeholders. The CHC advises its stakeholders to carefully and independently consider each of the recommendations. The CHC reserves the right to rescind or modify its position statements at any time.

This material may be found in third parties' programs or materials. This does not imply an endorsement or recommendation by the CHC for such third parties' organisations, products or services, including these parties' materials or information.

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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

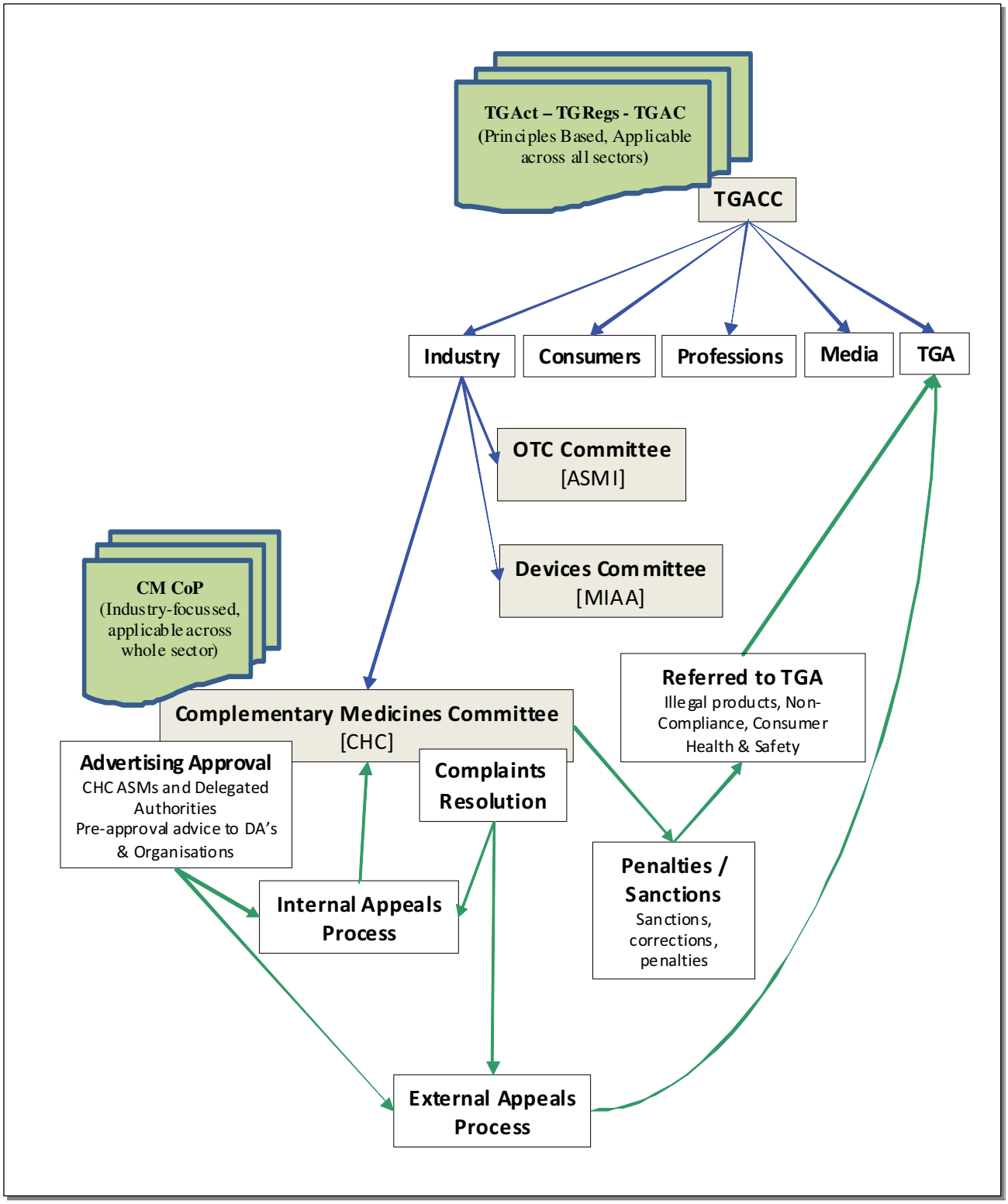
- Complaint handling for complementary medicines involves a number of different delegated authorities (CRC, CRP, ASMICP) and therefore has the clear potential for inconsistency in decision making;
- Time taken for handling complaints by some authorities can be two to six months (as per complaints decisions 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