The Project Officer
Advertising Consultation
Regulatory Reform
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

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).

AFA House, 39 Geils Court
Deakin ACT 2600
PO Box 104
Deakin West ACT 2600
P +61 2 6260 4022
F +61 2 6260 4122
W www.chc.org.au
E chc@chc.org.au
ABN 34 874 859 470

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