Jon Wardle
Room 324 Edith Cavell Building
School of Public Health
University of Queensland
Herston Q 4006
j.wardle@sph.uq.edu.au

Friday 27 August 2010

Dear Sir/Madam,

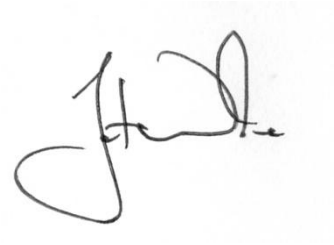
Thank you for the opportunity to make a submission on improving advertising for therapeutic goods. Please find attached my submission in response to your specific questions below.

Although I acknowledge that there are a number of areas of therapeutic goods that fall under the advertising regulations, my submission is focused upon the area of complementary medicines (CAM). However, many of the recommendations in this submission are appropriate to all therapeutic goods. The proposals outlined by the TGA surrounding this submission seem entirely appropriate to afford the public a higher degree of protection.

However, in relation to advertising for CAM there are a number of other issues that have not received the attention they deserve – namely the confusion surrounding 'practitioner only' products and issues of product specificity in claims. These are outlined in the submission below.

Thank you again for this opportunity and for considering this submission.

Yours sincerely



Jon Wardle

Question 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 current arrangements for advertising therapeutic goods in Australia are known to me.

However, the current arrangements are not broadly known outside the manufacturer or academic communities and there is much confusion, particularly amongst health professionals, in relation to these arrangements. Under the current arrangements, health professionals need to be made aware of what current TGA advertising legislation – particularly in relation to 'practitioner dispensing only' products – actually means. In terms of CAM this issue is part of a far broader problem surrounding knowledge of TGA and product safety arrangements. CAM practitioners are unaware of many of the arrangements surrounding therapeutics goods legislation, which are not limited to advertising but also include measures such as being unable to identify how to go about reporting adverse events[1]. It is imperative that the TGA makes arrangements known not just to industry, but in a way that is appropriate to health practitioners as well. It is perhaps also appropriate that the TGA increases it practitioner outreach more generally, but also that it extends its existing practitioner services to a broader group of practitioners, including CAM practitioners.

In specific relation to advertising regulation, which often focus on advertising to the public, this is appropriate as not only are health professionals (including CAM practitioners) often directly the target of deceitful advertising, they are also have a role in 'translating' claims of advertising directed at their patients as well.

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

There are a number of areas where the current advertising arrangements are inappropriate. However, the focus of this submission is on two areas that I feel are currently ignored in current regulations. The two major areas, as they relate to CAM, which are often overlooked relate to 'practitioner only' products and the issue of generic interchangeability.

Practitioner only products

Under current arrangements, the TGA notes that current advertising requirements do not 'apply to advice or information given directly to a patient by a healthcare professional in the course of treatment of that patient'. As per Section 42AA this exemption extends to a broad range of regulated health practitioners, as well as a CAM practitioner that is a member of one of the 43 professional associations listed in *Schedule 1* of the *Therapeutic Goods Register* (as per below).

Column 1 Item No.	**Column 2 Body**
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
2A	Association of Natural Health Practitioners Limited
3A	Aust China Acupuncture and Chinese Medicine Association Inc.
3B	Australasian Federation of Natural Therapists Inc.
4	Australian Acupuncture Association Ltd.
5	Australasian Association of Ayurveda Incorporated
5A	Australian Association of Exercise and Sports Scientists
6	Australian Association of Professional Homoeopaths

6A	Australian College of Acupuncturists Ltd
7	Australian Committee of Natural Therapies Inc. (SA)
9	Australian Federation of Homoeopaths
9A	Australian Federation of Homoeopaths (Qld.) Inc.
9B	Australian Federation of Homoeopaths (WA) Inc.
10	Australian Natural Therapists Association Ltd
11	Australian Naturopathic Practitioners and Chiropractors Association
11A	Australian Society of Homeopaths Inc
12	Australian Traditional Chinese Herbalists Association (Qld)
13	Australian Traditional Chinese Medicine Association Inc.
14	Australian Traditional Medicine Society
14A	Australian Unani Medicines Society Inc.
15	Chinese Medicine Association Pty Ltd
15A	Chinese Medicine Association of Australia Inc.
16	Complementary Medicine Association
16A	Federation of Chinese Medicine and Acupuncture Societies of Australia
17	Homoeopathic Education and Research Association
17A	International Association of Trichologists
17B	International Christian Association of Natural Therapists Ltd (ICANT)
18	National Herbalists Association of Australia
18A	Naturopathic Physicians Association of Australia Inc.
19	Queensland Naturopathic Association
20	Register of Acupuncture and Traditional Chinese Medicine
21	Society of Natural Therapists and Researchers [SNTR] Inc.
22	Society of Classical Homoeopathy Ltd
23	Traditional Medicine of China Society Australia
24	Society of Chinese Medicine and Acupuncture (Vic) Inc.
25	Naturopathic Practitioners Association Inc.
26	The Acupuncture Association of Australia, New Zealand and Asia
26A	The Alumni Association of Natural Medicine Practitioners Inc.
26AA	The Australian Association of Homotoxicology Incorporated
26B	The Australian Podiatry Association (NSW)
26BA	The Homeopathic Medicine Association Inc.
27	The New South Wales Research Association of Traditional Chinese Medicine

The TGA's information (http://www.tga.health.gov.au/advert/schedule1.htm#att1) states:

"Healthcare professionals that fulfil the above criteria may receive advertising material about therapeutic goods which contain statements and claims about those goods (including those made on product labels) which are not permitted in advertising to the public - who may not possess a sufficient knowledge of active ingredients and human health and disease conditions to enable an objective assessment to be made of promotional information.

There is no restriction on the supply of therapeutic goods (including unscheduled vitamins, herbs, massage oils, and flower remedies) to a retailer or a practitioner providing the relevant statutory requirements relating to entry in the ARTG, labelling and advertising have been satisfied. This is, of course, provided that the therapeutic good is not scheduled as a prescription-only, pharmacist-only or pharmacy medicine (and not otherwise permitted under State and Territory legislation).

Therapeutic goods whose labelling contain claims that are not permitted in advertisements to the public, or which are for 'practitioner dispensing only' and whose labels do not state what the product is for, cannot be supplied by retailers to the public. Sponsors of such products are required to restrict the supply of such goods to healthcare professionals (as per Attachments 1 and 2)."

However, the professional associations represented on this list (as per above) exhibit enormous variation in entry standards and minimum training requirements and may not be guaranteed to 'possess a sufficient knowledge' to make such critical judgement. For example, workforce surveys have indicated that up to 10% of naturopaths registered with these associations may have no formal training at all[1]. In addition, many of the current Australian CAM qualifications recognised by these associations would not meet minimum clinical training requirements for CAM courses set by the World Health Organization[2, 3].

The major problem is that such extraordinary variation in standards and levels of training can lead to practitioners taking manufacturer-provided information at face value, rather than being able to critically claims made by manufacturers. This is particularly true in the category known within the CAM professions as 'practitioner only' products. There are numerous anecdotal reports that suggest that in many cases product manufacturers maintain to the practitioner community that 'practitioner dispensing only' equates to issues that have little to do with advertising code exemption, and make unsubstantiated claims in practitioner literature and continuing professional education. Reports of the claims made include statements to the effect that the products are of higher quality, higher efficacy, higher dose or are otherwise 'superior' to publicly accessible products. Whilst in some individual situations this may be true, it is a mistaken perception that has in many cases been deliberately promoted by the industry. This is particularly true in CAM professions such as naturopathy, where the unregulated and fragmented nature of the industry has meant that over 90% of continuing professional education, as well as a substantial amount of undergraduate education, is provided directly by manufacturers[4].

This is further confused by the voluntary restriction of sales to practitioners, and the fact that these products too can be labelled 'practitioner only'. TGA information goes on to state:

"Some sponsors have labelled their products with claims which are acceptable in terms of public advertising and yet include the additional statement "Practitioner Use Only". This is a commercial decision made by the sponsors of the goods and the TGA has no objection to such voluntary restriction upon supply."

The same confusion surrounding 'practitioner dispensing only products' may also be exploited by some companies to infer without any substantiation that these products are of superior quality. There is nothing intrinsically wrong with restricting products to practitioners voluntarily, however, practitioners need to be able to identify why such products are restricted.

It is the opinion of the author that in many cases product manufacturers are making commercial decisions to market their obligations for compliance with advertising regulations in a deceitful way. There should be a clearer distinction between products that are voluntarily restricted that do otherwise comply with acceptable public advertising and those that are merely exempt from these regulations by virtue of their restriction to practitioners. It should also be made more apparent what these terms imply. Examples of could include:

"PRACTITIONER USE ONLY: VOLUNTARILY RESTRICTED"

"EXEMPT FROM TGA ADVERTISING REGULATIONS: FOR PRACTITIONER DISPENSING ONLY"

The current situation in CAM education cannot ensure that CAM practitioners will necessarily have the critical evaluation skills to make appropriate clinical judgements based on promotional material

not subject to advertising regulations. However, if practitioners are made aware of which products do have tested claims and which ones don't, this may reduce their ability to be swayed by potentially misleading statements.

Whilst it is the opinion of the author that the TGA should include appropriately trained CAM practitioners in this clause, the extraordinary variance in education and training of these practitioners has left them open to receiving – and taking at face value – false information on products. In addition to closing this loophole that seems to be increasingly exploited by product manufacturers, it is highly recommended that the TGA consider developing minimum entry standards for professional associations to be included in Schedule 1. In this respect the TGA should consider supporting, in principle, increasing standards of regulation for CAM practitioners.

Interchangeability of product

It is becoming increasingly acknowledged that the generic interchangeability that exists in pharmaceutical medications simply does not apply to CAM, and that there may be significant differences in efficacy and safety profiles of the same 'substance' not only between different manufacturers, but also between batches of the same product. Glucosamine is an example that has garnered considerable attention, particularly after a 2005 Cochrane Review found compelling evidence for just one formulation in osteoarthritis, thought to be due partly to the increased quality control procedures in place for that product[5]. However, the fact that products made from the same 'substance' (glucosamine) can be so significantly different mean that any conclusions drawn from research can really only be related to the specific formulation that had been studied[6]. It can therefore be difficult for both the general public and health professionals to identify which products are effective and which aren't.

The use of research results to validate indications or claims for individual CAM products should therefore be limited to products that can demonstrate that they possess similarity not only in quality control or manufacturing processes, but also in raw material used (for example many European products including the Ze440 extract of *Hypericum* which has shown promise in depression have controlled growing standards as well as post-harvest processing standards. However, many Australian manufacturers simply purchase raw herbal material as an interchangeable commodity. When standardisation does occur, it is usually focused on one marker that may or may not be the therapeutic agent, and this does not reflect the biochemical complexity of herbal medicines.

Also, in instances where traditional evidence is utilised, products should demonstrate their similarity to traditional preparations and extraction (for example, *Withania* is traditionally used as a decoction with milk, though few Australian products are used this way). There is a misconception amongst the public and many health professionals that CAM containing the same 'substances' will be equally effective. CAM manufacturers may use research based on high-quality or standardised products to substantiate poorer quality substitutes. This has not only led to many potentially ineffective products being marketed as effective, but is also a serious disincentive for CAM manufacturers to fund research to validate their own specific products. It may also be argued that it is a disincentive to manufacture CAM of a higher quality than competitors, particularly if this incurs extra cost or reduces profit margins.

The TGA needs to take a more proactive role in acknowledging the variation between CAM products not just in advertising but in other areas as well. For example, some commentators have suggested

that the variation observed in CAM products makes it difficult to develop post-market surveillance or regulatory and legislative solutions to the direct risks of CAM products [7]. Whilst the introduction of simple principles such as good manufacturing practice (GMP) will help to reduce direct risks associated with issues such as adulteration and contamination, it does not address the broader indirect and economic risks associated with the variable quality of CAM products. This is particularly relevant in Australia where nearly three quarters of the population overestimate the level of government testing of therapeutic quality, claims and efficacy of individual CAM products[8].

Any monitoring of advertising for CAM products needs to take into account product specificity when assessing claims and indications.

Question 2: Using the advertising arrangements:

Do you find advertisements of therapeutic goods helpful?

The advertising of therapeutic goods can be helpful in educating consumers and health professionals as to the availability of new products, or the range of products available to them. However, any advertising needs to be ethical and truthful in nature, and appropriately policed by an independent authority to protect the public against any potential nefarious activity or fraudulent action (i.e. false claims etc).

Question 3: The pre-approval process:

Should the current pre-approval process for advertising be retained? If so, should all forms of advertising be considered in this process?

It is strongly encouraged that all forms of advertising should be included in any pre-approval process. However, any extension of the current pre-approval process would be cumbersome, resource draining and logistically challenging – particularly in relation to finding qualified staff for this process. It is also understood that this process is often quite burdensome on industry – particular in relation to the costs incurred to new or smaller industry players.

It may be more effective, and considerably more cost-effective, to promote a self-regulated pre-approval process and invest in an independent monitoring program for advertising. However, any such monitoring program needs to be linked with an independent CRP with statutory punitive powers that act as an efficient deterrent.

It is acknowledged that there is a place for industry self-regulation in therapeutic goods advertising in Australia. However, it is felt that this role should not be a reactive one resolving complaints of advertising breaches, but rather a proactive one that reduces potential breaches and makes industry more accountable. The current self-regulatory bodies that currently handle advertising complaints not handled by the TGA could assume this role, with the role of complaints resolution handled by an independent authority.

Whilst the internet does create a number of other issues in relation to jurisdictional matters, a marker of quality or advertising approval (such as that observed in wine appellation or organic certification) could be developed and marketed by industry bodies so that the public can identify ‘pre-approved’ products that have substantiated claims. In this case, any self-regulatory authorities that are

demonstrated to have repeatedly pre-approved advertising that breaches TGA standards should also be subject to punitive action.

It is the opinion of the author that appropriate deterrents (such as increased monitoring and the introduction of civil penalties) could be as efficient as the current pre-approval process in preventing fraudulent claims being made. However, any penalties need to be actively enforced to be effective as a deterrent.

Question 4: Complaints mechanisms:

Should the Therapeutic Goods Administration (TGA) publish on its website information related to products removed from the Australian Register of Therapeutic Goods (ARTG)?

The publishing of information related to products removed from the ARTG is actively encouraged. However, transparency should not be limited to products removed. The TGA should also publish on its website other breaches, for example, when a review determines that a sponsor cannot substantiate indications for a product, or if a sponsor has voluntarily withdrawn a product before review. The TGA should also list all individual manufacturers/sponsors, and the list of any action or removals made against them, in a similar fashion to that used for individual practitioners on the website of the Board of the *National Registration and Accreditation Scheme.*

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

To protect public safety it is imperative that the complaints resolution process is independent and the CRP is reconstituted as an independent body. The fact that virtually all complaints considered by the CRP are related to members or potential members of organisations represented on the panel proffers clear and persistent potential for conflict of interest, though this conflict may not necessarily be acted upon.

Though reasons related to potential conflict of interest should be enough to highlight the importance of developing an independent arbiter, there are also other pragmatic considerations. The current legislation, whilst attempting to be broadly inclusive, in fact locks many stakeholders out from this process. This is particularly true in CAM Whilst the TGA recognises 43 professional associations representing CAM practitioners for Schedule 1 exemption under Section 42AA of the Act, only one (the *Australian Traditional Medicine Society* – ATMS) is allowed to be represented on the two statutory committees relating to CAM advertising (the *Therapeutic Goods Advertising Council* as well as the *Complaints Resolution Panel*) under current arrangements.

Notwithstanding that this denies other professional associations representation; it in fact denies CAM practitioner representation. The Constitution of ATMS explicitly makes it explicitly clear that its executive is made of college owners, rather than being democratically elected, and practitioner members are unable to vote or provide any input on such appointments[9]. Whilst undemocratic appointments may be appropriate for some organisations, this seems inappropriate in this case given that the spirit of inclusion of ATMS on these bodies seems to have been to provide CAM practitioner community input (for example the unfounded statement that ATMS represents 65% of the profession on the websites of both the *Therapeutic Goods Advertising Code Council* and the *Therapeutic Goods Advertising Complaints Resolution Panel*). If CAM practitioner representation is desired on these or any other TGA committees, it should be done in a way that the CAM practitioner community can have some input into the appointee.

It is the opinion of the author that rather than being made up of nominees from specific organisations, which may or may not have vested interests, it would be more appropriate that nominations were open to persons of appropriate experience chosen on their individual merit to provide objective and informed opinion. This would be a similar arrangement to other committees within the TGA such as the *Australian Committee on the Safety of Medicines*, the *Australian Committee on Complementary Medicines*, the *Australian Committee on Non-Prescription Medicines* and the *Australian Committee on Prescription Medicines*.

Should the CRP consider complaints about all forms of advertising?

The CRP should definitely consider complaints about all forms of advertising. The current arrangements are both confusing and inefficient. Many self-regulatory authorities have the potential to exhibit conflict of interest in complaints handling on these matters, though it is acknowledged that this may not be acted upon. Moreover, self-regulatory complaints bodies have no jurisdiction over breaches by non-members. Having one body handling all complaints would reduce inefficiencies, streamline the process and provide the public with a "one-stop shop" that reduces confusion as to where complaints should be directed. Extending the scope of the CRP is particularly relevant for CAM, where many of the more potentially deceptive forms of advertising fall outside of the current CRP remit[10].

Though not directly related to product sales or the remit of the TGA, it should be noted that a similar situation (numerous complaints bodies and organisation being required to handle similar complaints) had been observed in CAM practitioner regulation. When Chinese medicine practitioners were regulated by the Victorian government a clear complaints handling mechanism was developed by one authority (the *Chinese Medicine Registration Board*). This resulted in the complaints against Chinese medicine practitioners rising fivefold in the first year and maintaining that level since (see Table below). These complaints were not thought to be 'new', but rather were complaints that had previously gone unreported due to confusion over where to report, or had been 'lost in the system' and had not been acted upon by self-regulatory authorities. It can be reasonably expected that a streamlined complaints authority handling all complaints would similarly make it easier for breaches to be reported and acted upon, possibly resulting in a similar increase of complaints being received.

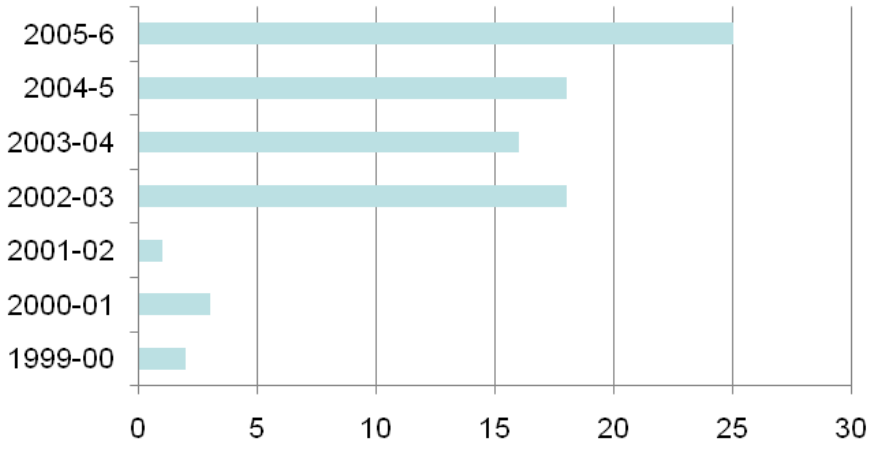


Figure 1: Number of complaints made about Chinese medicine practitioners in Victoria 1999-2006 (Source: CMRB)

It is acknowledged that many complaints handled by the CRP may be of a trivial nature; however, it is firmly believed that an independent authority with statutory punitive authority can act as a more effective deterrent in addition to more effectively resolving complaints around advertising.

Should civil penalties apply for breaches of the regime?

Civil penalties should apply for breaches. It is noted that the proposed Trans Tasman Agency had incorporated a level of civil penalties. Given that Section 42DM of the Act essentially requires a criminal case being put forward to the public prosecutor the current legislation is unwieldy. Civil penalties would act as a suitable deterrent and provide more flexibility for the CRP to police advertising in therapeutic goods. The sanctions regime under the legislation should be strengthened to include civil penalty contravention provisions and court-imposed remedial action for advertising breaches. The TGA could also be given the power to refuse to list a product that was substantially similar to one that had been cancelled unless and until the relevant remedial action had been taken.

If civil penalties should apply, then an independent CRP should have decision making powers to this effect.

References

1. Bensoussan A, Myers S, Wu S, O'Connor K. Naturopathic and Western herbal medicine practice in Australia-a workforce survey. Complementary Therpies in Medicine 2004;12:17-27.
2. World Health Organization. WHO Guidelines for Quality Assurance of Traditional Medicine Education in the Western Pacific Region. Manila: World Health Organization; 2004.
3. McCabe P. Education in naturopathy and western herbal medicine in Australia: results of a survey of education providers. Complement Ther Clin Pract 2008;14:168-75.
4. Lin V, Bensoussan A, Myers S, et al. The practice and regulatory requirements of naturopathy and western herbal medicine. Melbourne: Department of Human Services; 2005.
5. Towheed T, Maxwell L, Anastassiades T, et al. Glucosamine therapy for treating osteoarthritis. Cochrane Database of Systematic Reviews 2005;2:10.1002/14651858.CD002946.pub2.
6. Vlad S, LaValley M, McAlindon T, Felson D. Glucosamine for pain in osteoarthritis: why do trial results differ? Arthritis & Rheumatism 2007;56:2267-77.
7. Basch E, Servoss J, Tedrow U. Safety assurances for dietary supplements: Policy issues and new research paradigms. Journal of Herbal Pharmacotherapy 2005;1:3-15.
8. MacLennan A, Myers S, Taylor A. The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004. Medical Journal of Australia 2006;184:27-31.
9. Wardle J. Regulation of complementary medicines: A brief report on the regulation and role of complementary medicines in Australia. Brisbane: The Network of Researchers in the Public Health of Complementary and Alternative Medicine; 2008.
10. Harvey K, Korczak V, Marron L, Newgreen D. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. Medical Journal of Australia 2008;188:21-5.