12.7.13

Advertising Consultation
Recalls and Advertising Section
Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Advertising Consultation

As a practicing naturopath I am concerned about the proposed regulation of advertising of therapeutic goods to consumers and the consequences of these proposed changes on the professions of naturopathy.

I am submitting to you my own paper on the issue as an attachment and included in the hard copy. I also uphold the views of the Australian Naturopathic Practitioners Association (ANPA).

Naturopaths currently hold TGA exemption from Part 5-1 of the Therapeutic Goods Act; this allows them to receive technical information from companies regarding herbs and supplements regarded as tools of trade for naturopaths.

My concerns relate to the following proposal:

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.
This proposal does not directly affect the in clinic use of in-vitro devices for naturopaths. Proposal 5.2 is supported in principle. However, it is important to note that if Proposal 6.2 is implemented it will deny naturopaths access to tools of the trade such as In-Vitro Diagnostic...
devices—for example, bio-impedance analysis, live blood analysis, urine analysis and other in-clinic testing and monitoring devices or tools.

**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*.

Either the current list of health professionals should remain (option 1) or naturopaths be added to the new list. As previously mentioned, option 2 deprives herbalists and naturopaths tools of trade to practise effectively and safely. Option 2 would also restrict trade of a government approved profession. The potential consequences of not considering these suggestions will have an impact on the following:

**Public safety:** Currently practitioners receive important technical information on efficacy and safety of listed therapeutic goods from companies both in written material and via face-to-face seminar activities that comprise a portion of continuing education for the professions. Such activities encourage not only the updating of knowledge vital for safe professional practice but also employ critical analysis of research, sharing of professional knowledge, and promote other professional behaviours such as adverse reaction reporting. All these elements contribute to public safety.

**Maintaining expertise:** Naturopaths currently hold expertise in herbal and nutritional medicine, in particular holding the highest qualification resulting in the prescription of herbal and nutritional medicines. A recent study confirmed herbalists and naturopaths had similar knowledge to pharmacists in clinically proven benefits of herbal medicines, and significantly better knowledge than pharmacists of clinically significant interactions\(^1\). These findings provide

evidence that contradicts the TGAs argument for excluding naturopaths as recognised health professionals.

Scope of Practice: The current minimum standard to practice for naturopathy is an advanced diploma. However, the professions are moving toward Bachelor degree as minimum standard, and many holding post-graduate qualifications. The professions are also moving from a mainly tradition based body of knowledge to evidence based practice (EBP)\(^1\).

ARONAH: In 2011 an independent register The Australian Register of Naturopaths and Herbalists (ARONAH), was formed to mirror the government statutory regulated boards of AHPRA. ARONAH began taking applications for registration on 1 July 2013. The main stated purpose of ARONAH is the provision of minimum education standards for herbalists and naturopaths in Australia, and it will also provide an easily transferable model of statutory registration should herbalists and naturopaths achieve registration with AHPRA. ARONAH may provide a good interim solution with regards to identifying appropriately trained naturopaths once it is better established.

I would recommend the TGA maintain the status quo (6.1) or add naturopaths to the new exemption list as they are legitimate qualified health practitioners. To do otherwise is to add risk to public safety and adversely affect the practice of naturopathy, potentially resulting in professional and financial hardship and reduced choices for the public.

Yours sincerely

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Response to the Therapeutic Goods Administration, (TGA) consultation document 2013. Australian Governments, Department of Health and Aging, Consultation Regulation Impact Statement
Regulating the advertising of therapeutic goods to the general public

Version 4.6, May 2013

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Member: Australian Naturopathic Practitioners Association, Association of Solution Focused Counsellors and Hypnotherapists, Psychotherapy And Counselling Federation of Australia (National Register), Australian Association of Massage Therapists, Australian Society of Sex Educators, Researchers and Therapists, World Professional Association for Transgender Health.

Educated at Derby University (UK), Open University (UK), American Institute of Hypnotherapy, Australian Institute of Applied Sciences, Charles Sturt University (AU).

Background

The issuing of the TGA consultation paper has caused considerable public concern with regard to how it proposes to restrict advertising to naturopaths and Western herbalists. The proposed move in government policy has so far been without proper consultation with the natural and traditional medicine professions.

The use of traditional medicine and naturopathic and herbal medicines has a long history in Australia. The traditional owners of the land, the Aboriginal people, used their traditional medicines before Westerners arrived (Clark, 2008). Those settlers themselves brought with them traditional knowledge around the use of natural medical treatments and medicine philosophies. So the Australian public have always had access to natural medicine remedies and treatments (Baer, 2009).

The TGA’s paper seems to be concerned with keeping the public safe by attempting to control the quality of advertising to the public.
“The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines, medical devices and biologicals.” (TGA, 2013)

The TGA reports (TGA, 2013 p.23) that it receives around three hundred to four hundred complaints each year concerning advertising of therapeutic products. It also states that the majority of the complaints are from the therapeutic goods industry and not from the general public. It does not break down specifically who these complaints are from, what bodies are complaining about what products or what are the results of the complaints. There is no critical data or analyses.

It also proposes that manufacturers and suppliers of medicines and therapeutic goods should not be allowed to provide information to naturopaths and Western herbalists because they are not currently government-registered professions under the National Registration and Accreditation Scheme (NRAS) (TGA, 2013, p. 44).

The World Health Organization (WHO) and its member states cooperate to promote the use of traditional medicine for healthcare. It can be seen from the below statement that the WHO has supported traditional medicine as part of a primary healthcare medical system.

“The collaboration aims to:

- support and integrate traditional medicine into national health systems in combination with national policy and regulation for products, practices and providers to ensure safety and quality;
- ensure the use of safe, effective and quality products and practices, based on available evidence;
- acknowledge traditional medicine as part of primary healthcare, to increase access to care and preserve knowledge and resources; and
- ensure patient safety by upgrading the skills and knowledge of traditional medicine providers.” (WHO fact sheet, 2008)

WHO also states:

“Strategic direction
With regard to policy, WHO's strategic direction is to facilitate the integration of TM/CAM into the national health systems, with a focus on better regulation of traditional medicines and practitioners. The collection and use of better evidence on quality, safety and efficacy will be promoted. The contribution of TM/CAM to primary healthcare will be explored and, where relevant and possible, promoted. Special emphasis will be put on promoting and upgrading the knowledge and skill of the providers of TM/CAM to ensure patient safety; and to build national capacity in the field of TM/CAM according to the identified country needs. Where needed, countries will be assisted in protecting the intellectual property rights on their traditional knowledge.” (Continuity and Change, Implementing the Third WHO Medicines Strategy 2008-2013, p.14.

http://apps.who.int/medicinedocs/documents/s16880e/s16880e.pdf)
It can be seen from the WHO guidelines that member countries and signatories need to be guided by the Continuity and Change document. This directs that national governments need to integrate CAM/TM into national health systems, not exclude them. The TGA document proposes the option to exclude naturopaths and Western herbalists from the national scientific medical arena (TGA, 2013).

The National Institute of Complementary Medicine (NICM) reports that the complementary medicine industry in Australia turned over $3.1 billion in 2010 and is growing at 6% per annum (NICM, 2013). A large percentage of that business was through naturopathic consultations, naturopaths working in private practice in health centres, health food stores and pharmacies. Western herbalists tend to work in private practice, dispensaries in specialist pharmacies or health food stores. (http://www.nicm.edu.au/understanding-cm/importance-of-cm)

The Australian Naturopathic Practitioners Association (ANPA) suggests there could be as many as 10,000 practising naturopaths in Australia (ANPA, 2013). Training standards vary but a large number of practitioners have a graduate and post-graduate level of education in natural medicine, certified by government-accredited institutions. Many of those are also trained as Western herbalists and homeopaths.

The Royal Australasian College of Physicians (RACP) reported that more than 1.5 million people suffer from the side effects of allopathic medication in Australia every year. There is no legal obligation to report such occurrences to the TGA by health workers. These adverse effects of medications result in at least 400,000 visits to GPs and 190,000 hospital visits with a cost of $660 million in 2008 to the public purse (RACP media release, 22 February, 2013).

In 2010 the TGA reported that the most popular 10 drugs used in Australia in the past five years have resulted in 67 reported deaths. It warned that 2% of drugs supplied to children under 17 years old may result in side effects. There were no reported deaths from the side effects of naturopathic treatment or Western herbal usage (Cornish and Dunlevy, 2012 http://www.news.com.au/national-news/bad-medicine-takes-toll-on-australians/story-fndo4eg9-1226474568593).

Discourse

Naturopathy and Western herbal medicine

Naturopaths and Western herbalists operate on a set of philosophies and principles that determine that they and their patients encourage the power of nature to promote, maintain and restore health. They operate through a vast resource of knowledge. Naturopaths and Western herbalists in Australia are scientifically trained.

There are many systems of knowledge within naturopathy. Naturopaths use dietetics, vitamin and mineral supplementation, body manipulation, herbal medicine, homeopathy and counselling within their practices. An initial naturopathic consultation is in-depth, lasting from between one to two hours. Naturopaths ask hundreds of questions of patients in order to find the source of a disease so a remedy may be found. They are also trained in physical examination, medical
sciences, pathophysiology and toxicology. Many millions of naturopathic consultations take place in Australia every year.

Western herbal medicine practitioners also train in basic medical sciences, pathology and physical examination.

It is a myth that these professions have only existed for 150 years as they incorporate knowledge that has been used in medicine successfully for thousands of years.

One of the major fundamental principles of both disciplines is “do no harm” with a strong adherence to the Hippocratic oath principles. They are also very focused on disease prevention and unquestionably Australia is a healthier country for their participation in the healthcare system.

Naturopaths and Western herbalists often work side by side with allopathic practitioners in an integrated medicine approach in caring for patients. Naturopaths and Western herbalists often refer patients to allopathic doctors and vice versa.

The training of naturopaths and Western herbalists in Australia

The TGA paper suggests by their proposed exclusion from receiving manufacturing advertised material that naturopaths and Western herbalists in Australia are not sufficiently trained. This is, to a large part, incorrect. In Australia naturopaths and herbalists are trained to advanced diploma, degree and masters level of education at establishments and universities accredited by the Australian government. Indeed the Australian government makes funds available for people to train in natural medicine and therapy through educational grants such as the HECS scheme.

The practitioners then go on to become registered with professional associations who vet their qualifications and number of post-qualification training hours, equivalent to those required for a nursing degree. Practitioners are required annually to be involved in continual education to remain on professional registers. Much of that post-qualification education is supplied by manufacturers and suppliers of natural therapeutics. If those parties can no longer advertise to practitioners, the standard of education will plummet in Australia and put the public in danger.

What will also likely happen is that foreign companies will provide advertising and education via the internet and customers will be more likely to buy products online from other countries. The Australian government could not stop this happening, no matter what laws it brought in. People will pursue the kind of therapeutics with which they feel most comfortable and it is clear that the public is comfortable with natural medicine approaches.

Registration

Naturopaths and herbalists are in the process of trying to attain the status of being a government-registered profession in Australia. They have lobbied for that to happen since 2005 but the government has indicated it did not wish to register them as it did
not consider them a high enough risk to the public. For the government to damage those professions and their patients, with the sword of Damocles, by excluding them from the scientific arena, whilst this process is happening is counterproductive to the public good and endangers the public.

Registration under the NRAS is not a gold standard in Australia for clinical competence. There are health professions who are not registered under this scheme which provide valuable healthcare to the general public in Australia. Many of those practitioners are trained to a very high level of scientific proficiency including naturopaths and Western herbalists.

Scientific competency

It is a popular sport amongst many academic, allopathic practitioners and allopathic drug manufacturers to posit traditional and natural medicine as untried and untested. (Schwager, 2012). Nothing could be further from the truth. Many herbs in use have been used by traditional medicine practitioners very successfully for thousands of years to treat a range of medical conditions.

The scientific literature is teaming with both quantitative and qualitative research validating the use of naturopathic medical and therapeutic approaches. The TGA paper, however, seems to ignore this or has been advised that such evidence does not exist, when it does.

Vitamins and minerals are, by their very identification, essential dietary nutrients. Modern farming and manufacturing leads to depletion in nutritional sources in foods. This affects the health of the populous and since naturopaths are trained to identify these deficiencies, supplementation is deemed safe and necessary.

There is no epidemic or scientifically proven problem with hyper-vitaminemia in Australia. Naturopaths monitor blood serum levels and tissue morphology as part of their clinical practice.

The myth of incompetency

Naturopaths and Western herbalists with degree-level education are trained in Evidence Based Medicine. It is mandatory training for those professions. They are trained in chemistry, biochemistry, biology, physiology, pathophysiology, toxicology and medical sciences and sufficiently scientifically trained to make clinical and scientific judgments.

The TGA, by its exclusion of these facts in its paper, suggests a level of incompetency by naturopaths and Western herbalists. This is not true. In 2012 the Health Care Complaints Commission of NSW (HCCC) received the following number of complaints.

“Medical practitioners, dental practitioners, nurses and midwives, pharmacists and psychologists. Complaints about these professions accounted for 92.0% of all complaints about individual practitioners in 2011-12. The largest number of
complaints were about medical practitioners, with 1,488 complaints received in 2011-12. This is an increase on the 1,337 complaints received in the previous year. It also represents an increase in the proportion of all complaints about health practitioners. In 2011–12, 57.0% of all complaints about health practitioners were about medical practitioners, compared to 52.0% in 2010-11.” (New South Wales Health Care Complaints Commission, Annual Report, 2011-2012, p.14)

Complaints against naturopaths and herbalists in NSW were minimal and not identified as to be disproportionately significant. It can be seen from the numbers of complaints that in fact allopathic medicine was complained about more than naturopathy or herbalism. The public were not, on the whole, in danger from naturopaths and herbalists in NSW.

Whilst it is true there are people operating in NSW calling themselves naturopaths and herbalists who have no academic credentials, they are doing so without complying to the NSW HCCC guidelines and ethical standards. The organised and accredited professions of naturopaths and Western herbalists should not be held responsible for these persons as they should be policed by the government which has already made laws to deal with that situation in all states. The failure to enforce such laws must be laid squarely at the government’s door.

So it is abundantly clear that the public are not at any elevated risk from naturopaths, Western herbalists or their therapeutics or biologicals. No such evidence has been scientifically proffered by the TGA or any Australian government body. Such suggestion is solely based on fallacy, not sound scientific evidence, facts or figures.

**Evidence-based practice**

Qualified naturopaths and Western herbalists who are registered with government-recognised professional associations in Australia are required to take scientific approaches to their treatments. Training in evidence-based medicine is a standard part of their practice.

Evidence-based medicine has a tri-access of application:

1. Consultation of the scientific literature. Much of the time this is quantitative research but it is also valid scientifically to use qualitative research that reports therapeutic affect. This is true in all medical and therapeutic approaches.

2. The use of clinical knowledge. Practitioners of all kinds build up clinical knowledge about how medication and therapeutics are likely to affect patients and their knowledge is a source of clinical judgment. This includes checking for possible contraindications of any therapeutics.

3. Respecting the patient’s choice. Regardless of the kind of therapeutic discipline, all clinicians need to respect patients’ choices.
The creation of a black market

Traditional medicine has existed since the beginning of civilisation. People will not stop wanting the supply of its services and goods. Such medicines are available internationally at the click of a button on the internet. Many of those are supplied in countries where there is no quality control of such goods. In restricting the practices of naturopaths and herbalists in Australia it will increase the international market for naturopathic and Western herbal supplies.

In Australia the production of such therapeutics is controlled under the rules and regulation of therapeutic goods by the TGA. An increase in black market herbs from abroad, however, would create a whole new set of problems that already exist in the Chinese medicine market. If one walks through any Chinatown in any city in Australia there are many illegal, imported therapeutic goods available that are not approved for sale in Australia. Their description is in Chinese characters with no listing of contents (Australian Acupuncture and Chinese Medicine Association, 20 April, 2012)

In Australia manufacturers are obliged to check the authenticity of herbs and often standardise constituents to guarantee the therapeutics. Prohibition of knowledge would cause an increase in adulterated herbs from abroad. Presently no such problem for naturopaths and Western herbalists exists, but that problem would come about in a prohibition type market.

The wild craft market for herbs in Australia is very small. The vast majority of naturopaths and herbalists rely on manufacturers to supply the herbs they use in their practices. Those manufacturers are governed by the TGA guidelines so practitioners are guaranteed quality of herbal tinctures and preparations. Should the intellectual link between manufacturers and practitioners be interrupted by prohibition of advertising, it will likely lead to growth in the wildcrafting market. The wild craft market cannot be regulated so there will be a drop in the standards of therapeutic herbs, herb substitution, adulteration, inability to standardise ingredients and the presence of mould. Naturopaths and Western herbalists rely on Australian manufacturers to check for these problems during production of therapeutic herbs and mineral preparations.

There would also be a problem with lack of efficacy for the production of vitamins and mineral solutions. When people order from aboard there is no guarantee they are actually getting what they ordered.

Prohibition in any market rarely works, as can be seen from the Chinese Cultural Revolution which severely damaged the health of the Chinese people. Prohibition of scientific knowledge is antidemocratic and unscientific.

Who will benefit from naturopaths and herbalists not having access to product and services information?

If naturopaths and herbalists are not able to receive advertised information and services by product manufacturers and suppliers, it will lead to a lower level of service they are able to provide to patients. Patients will be more likely to avail
themselves of allopathic medical services because their choices are reduced, so *allopathic medical doctors* will gain from an increase in business. This will, however, put a greater strain on the Medicare budget as naturopaths and Western herbalists are part of the private healthcare system in Australia.

*Chinese herbalists and Torres Strait Islander traditional practitioners* will also benefit as Western-style trained naturopaths and herbalists lose their quality of information to treat their patients.

*Large international drug conglomerates* will also gain as they provide isolated chemical-style medicines and naturopathic medicine markets are closed down. This will lead to a vast increase in profits for these companies as the natural medicine market would be partly closed down by the restrictions of manufacturers advertising to naturopaths and Western herbalists.

**Who will suffer from naturopaths and herbalists not having access to products and services information?**

*The general public* will suffer from this change in the law as they experience a reduced choice of medicinal and therapeutic solutions in the Australian market. It will mean naturopathic and Western herbal practitioners will have poorer sources of information by which to make clinical decisions.

*Naturopathic and herbal practitioners* will suffer because the change in the law will cause a loss of income. It could mean the closure of practices, loss of income, loss of superannuation and old age pension facilitation. Many of those practitioners are the major household bread winners and this change in law will mean loss of income for the whole family.

*Educational establishments* that teach naturopathy and Western herbal medicine. Students will not want to enrol in a course for a profession that cannot get professional scientific information about products legally in their country of residence. Many people come to Australia to study those subjects. These foreign students can be in Australia for four years, completing their studies and spending over $250,000 each including living expenses. All of that income will be lost from the economy. Colleges will have to cancel courses and many colleges will have to close.

*Manufacturers and distributors of natural medicine supplies* will suffer dramatic losses of income and they will be threatened with the closure of their business and loss of income for their families. Their staff will also lose their jobs.

*Economic damage* to the natural medicine and therapeutic market will run into billions of dollars per year.

*Scientific intellectual damage* will occur by excluding naturopaths and Western herbalists from the scientific arena. Australian research into natural medicine and therapeutics will be irreparably damaged. Funding for such research is led by the private manufacturing sector, just as it is in allopathic medicine.
Whilst pharmacists, allopathic doctors and nurses may use natural medicine approaches as part of an integrated medicine model, they are not experts and the majority of natural medicine’s proponents are naturopaths and Western herbalists. The loss of income to manufacturers will lead to a decline in research and put the Australian public in danger, not keep them safer.

Unclear aims

There is little doubt that the TGA in its paper is attempting to protect the public. However, the strategies employed are misconceived. Not only will excluding naturopaths and herbalists from product advertising and information not protect the public, it will also harm the public by reducing their therapeutic choices and standards. The aims and objectives of excluding naturopaths and herbalists from the scientific arena in the TGA paper are unclear and unscientific.

A better alternative

A better alternative to the proposals in the TGA paper is to continue to allow naturopaths and herbalists to operate within the scientific area, receive advertising material from manufacturers and suppliers of therapeutics. Instead the TGA should strive to support the call for naturopaths and herbalists to be a government-registered profession. This would better serve the public, those professionals and raise therapeutics integrity in Australia.

Naturopathy and Western herbalism in Australia attempts to work hand in hand with allopathic practitioners. Integrated medicine is the better way forward for the Australian public and naturopaths and Western herbalists have an important, vital role to play in primary and supportive healthcare.

- The TGA in its consultation paper has not identified any tangible public danger from naturopaths and Western herbalists.
- The are no statistics or identifiable significant data to support the concept that naturopaths or Western herbalists are a danger to the Australian public.
- All the data and evidence supports the reality that the public are more in danger from the side effects from allopathic medication rather than naturopathic therapeutic treatments.
- Naturopathy and Western herbal medicine operates by quantitative, qualitative and traditional knowledge.
- The World Health Organization’s health policies direct member countries to respect and accommodate natural medicine systems.
Educational standards and professional associations for naturopaths and Western herbalists in Australia produce a framework for monitoring professional competency.

The law in every state in Australia already requires naturopaths and Western herbalists to operate with professional competency and requires them to carry professional insurance.

In order for naturopaths and Western herbalists in Australia to get professional insurance from insurance companies they must prove their qualifications.

The Australian public is not in danger from naturopaths or Western herbalists any more than other medicinal disciplines or practitioners but their removal from the scientific arena by excluding them from product advertising would place the public in danger.

The best way to protect the Australian public is for the TGA to support the registration of naturopaths and Western herbalists on the Australian Health Practitioner Regulation Agency scheme.

We support Proposal 6: Advertising direct to health professionals – Option 1: Status Quo – Maintain the current system.

Bibliography


World Health Organization: Integrating TM within national health systems and PHC programmes, promoting research and development, training and good manufacturing practices. (Continuity and Change, Implementing the third, WHO Medicines Strategy 2008-2013) [http://apps.who.int/medicinedocs/documents/s16880e/s16880e.pdf](http://apps.who.int/medicinedocs/documents/s16880e/s16880e.pdf)