Department of Health and Ageing
Therapeutic Goods Administration

Consultation Regulation Impact Statement
Regulating the advertising of therapeutic goods to the general public
(Version 4.6 May 2013)

Submission from

Australian Naturopathic Practitioners Association Inc.

Excellence, Leadership and Integrity in Naturopathic Health Care

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Introduction

The Australian Naturopathic Practitioners Association (ANPA) thanks the TGA for the invitation to comment on the possible consequences to naturopaths and their patients as a result of the Consultation Regulation Impact Statement (CRIS) on ‘Regulating the advertising of therapeutic goods for the general public.’ The ANPA acknowledges and supports the TGA’s efforts to improve current arrangements for the regulation of therapeutic goods advertising. We support the TGA’s moves to improve transparency, increase detailed monitoring and reporting and develop more effective approaches to sanctions and penalties for breaches of advertising requirements.

It is apparent to the ANPA gauging the many responses from naturopath members, the profession in general, and manufacturers that there is a high level of interest and concern about the CRIS. The TGA has certainly struck a nerve in the profession. Perhaps, this was not the intention of the TGA. The ANPA suggests that this could have been avoided if our association and other professional stakeholders were consulted directly while the CRIS was in development and before it was put out for comment. Much of the concern is related to how the TGA arrives at the definition of a health professional. If Proposal 6, Option 2 is adopted, it negates naturopaths’ being health professionals by deeming them as no more than consumers. The Therapeutic Goods Regulations 1990 (the Regulations) are clearly deficient if the TGA defines a health professional as only an AHPRA ‘registered’ health professional. Exclusion of naturopaths by the TGA deserves serious attention and prompt action to rectify this omission.

Naturopaths are a primary care profession integral to the health landscape of this country. The education arm of the government accredits naturopaths at both a Bachelors and an Advanced Diploma level. Naturopaths meet all six criteria for inclusion under the NRAS to be a registered profession¹. Since 2005, this recommendation has not been enacted. The ANPA appreciates that this consultation is an excellent opportunity for naturopaths to have their voice heard. It also highlights the need for the ANPA to work far more closely with the TGA to avoid the unnecessary angst that has been created by the TGA with this CRIS.

Naturopaths offer the Australian public approximately 4.9 million consultations per year². Naturopaths are the largest group of complementary and alternative medicine practitioners in Australia³. Determining accurate numbers of naturopaths continues to be a problem because there is no formal register. There could be as many as 10, 000 naturopaths in Australia. This is substantially more than 4000 - the total number of Chinese medicine practitioners registered in 2012⁴. Nearly 10% of Australian women consult naturopaths⁵ and this number rises to 16% in conditions such as cancer⁶. The public are turning to naturopaths for many reasons: they prefer natural medicine approaches, they have experienced adverse side effects from pharmaceuticals and conventional medical approaches, want to try other options and want a more holistic approach⁷.
The ANPA is currently included on the government *advisory panel for the Review of Evidence to maintain Private Health Insurance Rebates for Natural Therapies*. The ANPA submission of evidence for the profession of naturopathy can be viewed on the separate attachment to this document or on the government website at:


**The ANPA**

The ANPA was founded in 1975 and is a national association representing naturopaths. All members must have a minimum of an Advanced Diploma of Naturopathy, although many have much higher qualifications. Our members abide by a strict code of ethics as well as other association policies that guide clinical practice.

The ANPA represents naturopaths in the following ways:

- Advocacy to government at State and Federal levels.
- Support statutory registration for naturopaths.
- Panel member to the government on the Review of Private Health Insurance Rebates for Natural Therapies.
- Advocacy to private health insurers.
- Participation in the review of the Health Training Package (VET Sector).
- Foundation member and continued support for the Australian Register of Naturopaths and Herbalists (ARONAH).
- Significant focus on support for students and new graduates as they enter the profession.
- Ongoing educational and professionalization support for naturopaths.
- Collaboration with other health professionals creating bridges of understanding to improve health outcomes for the public.
- Communication with education providers across Australia and overseas offering naturopathy training.
- Regular contributions to the media raising the profile of naturopathy and awareness for the profession amongst other health professionals, the public and the media.

**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.

The ANPA supports Option 2 in principle; however, there are consequences if Proposal 6 Option 2 is implemented.
Naturopaths will be denied 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.

The ANPA supports Option 1 – maintain the status quo and the current system.

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 and homoeopathics regarded as tools of trade for naturopaths.

**SAFETY Impacts on the general public if Option 2 were implemented.**

*If there were restricted access to professional education and literature linked to naturopath’s tools of trade, safety and efficacy may be compromised for the public.*

**Naturopaths prescribe ingestible substances**

According Lin et al\(^1\), herbal and nutritional medicines produce both predictable and unpredictable effects. These can include: toxicity related to overdose, interaction with pharmaceutical medications, allergic and anaphylactic reactions as well as idiosyncratic reactions. This report further stated that official reporting of adverse events is underestimated, and interactions between herbal medicines and pharmaceuticals are increasingly being reported in the literature.

Naturopaths are trained to access and research important technical information about products and medicines independently. We understand that this independent critical analysis and appraisal of technical information would not be restricted in Proposal 6. **However, important technical information on efficacy and safety of listed therapeutic goods from manufacturers both via written materials and via face-to-face seminar activities is part of the broader educational process for naturopaths.** These activities support the updating of knowledge important for safe professional practice. Written materials and other educational activities encourage naturopaths to critically analyse research, share professional knowledge, and promote other professional behaviours such as adverse reaction reporting. The public would be disadvantaged if naturopaths were kept “in the dark” on some scientific developments. This could impact important prescribing decisions. All these elements contribute to public safety.
Restriction of trade for a government approved profession.

“The TGA has no formal mechanism to determine that all practitioners in the groups listed under section 42AA of the Act are more competent than ordinary consumers to assess advertising about therapeutic goods. Therefore, the TGA has no formal assurance that those groups of practitioners not included in the NRAS are able to exercise specialist judgement when either treating consumers with advertised therapeutic goods, or advising consumers about the use of advertised therapeutic goods.” p28 CRIS

Naturopathy, a bona fide health profession is de-legitimised and marginalised if the TGA deems naturopaths are the same as consumers, and thereby government approved qualifications for naturopathy offered by Registered Training Organisations are not recognised. ANPA members must hold a minimum of an Advanced Diploma of Naturopathy. The profession is ultimately moving towards a minimum of a Bachelor's degree. Many of our members already have degree qualifications. The HLT60507 Advanced Diploma of Naturopathy is specified by the Department of Education, Employment and Workplace Relations. (See Appendix 1: Advanced Diploma of Naturopathy).

Two competencies within the health training package include:

- Analyse health information (HLTAP501B)
- Apply literature research findings to clinical practice (HLTNUT601C)

These study units prepare naturopaths with specialised training to assess information that is required to practice safely. To exclude naturopaths as health professionals and regard them as untrained and unable to discriminate between the information provided in advertising by companies supplying therapeutic goods relevant to our clinical training clearly contradicts the competencies achieved in approved education training modules.

Supporting Option 2 risks public safety and adversely affects the practice of naturopathy, potentially resulting in professional and financial hardship and reduced choices for the public.

Maintaining expertise: protecting public safety

Naturopaths currently hold expertise in the use of herbal, nutritional medicine and homeopathic medicines. Naturopaths are one of the professions holding the highest level qualifications underpinning the prescription of herbal, nutritional and homoeopathic 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. These findings provide evidence that contradicts the TGAs argument for excluding naturopaths as recognised health professionals. Many therapeutic goods are manufactured specifically for those prescribing herbal medicine. Those most highly trained are the most qualified to assess the appropriateness of herbal products for the public. This does not include GP’s, pharmacists or other registered health practitioners when they are insufficiently trained in herbal, nutritional or homoeopathic pharmacology and therapeutics.
Advertising purporting to be directed exclusively to herbalists, homeopathic practitioners and naturopaths would be regulated by the TGA under Part 5-1 of the Act unless or until national boards registering those groups became accredited under NRAS and those groups became regulated health services under the Health Practitioner Regulation National Law. This would provide a degree of protection for the public that is not provided by the law currently.

**Registered Health Practitioners beyond their scope of practice are a risk to the public**

Registered health practitioners who provide health services unrelated to their scope of practice are posing a safety issue for the public. These registered practitioners should not be entitled to the tools of trade used by naturopaths. Conventional medical training for registered professions does not include the same curriculum, principles of the profession, or specific scope of practice necessary to safely prescribe nutritional or herbal medicines or homoeopathics. Some restricted herbal medicines and nutritional supplements that naturopaths are specifically trained to prescribe can now only be prescribed by GP’s, Dentists and Vets, most of whom have had very limited or, indeed, no training in herbal or nutritional medicine.

Naturopaths are significantly trained in two of the main modalities the public are frequently seeking information about: herbal medicine as well as nutritional medicine (that includes vitamins, minerals and other related supplements). Herbal medicine as well as nutritional medicine require significant in depth training with no less than four units of study in each of these domains. Non naturopath registered health professionals working beyond their scope of practice who offer this advice with limited training in herbal or nutritional medicine are a risk to the public. The public is at risk when these health practitioners are ‘holding out’ to have knowledge in these areas. Less than half the medical community feel sufficiently knowledgeable about CAM when compared to CAM therapists⁹. The community are at risk when community pharmacists are reporting that less than 15% are confident to answer queries about safety, interactions or benefits of CAM¹⁰.

The registered professions should comply with the same education requirements as naturopaths if they are entering into the practice-domains of the naturopathy profession. Registered health practitioners should be required to upgrade their qualifications to meet the same professional standards as Naturopaths. Only when they have met these criteria should they be allowed to prescribe products related to herbal or nutritional medicine as well as homoeopathics.

Consumers are confused by the blurring of professional boundaries when, for example, a consumer goes, in good faith, to a health care provider who purports to work naturopathically but may have only undertaken a weekend course in nutrition or herbs. For the public at present, there is no obvious way of knowing if they are under the care of a practitioner with appropriate levels of training in the modalities of naturopathy.
The current system of limiting access to certain herbs via the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) denies competent naturopaths access to important tools of their trade.

**Australian Register of Naturopaths and Herbalists (ARONAH)**

Following the implementation of registration for Naturopaths under the NRAS, it would become possible to more easily identify qualified, registered practitioners. Access for these fully qualified practitioners to scheduled herbal preparations would then be possible under state government drugs and poisons legislation.

As a pre-registration measure, an independent register: The Australian Register of Naturopaths and Herbalists (ARONAH), was formed in 2011 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 when herbalists and naturopaths achieve registration with AHPRA.

**Support Statutory Registration for Naturopaths**

ANPA believes that any model of statutory registration should include protection of title and core Naturopathic practices. The legislative frameworks and operational arrangements used for other health professions can be easily adapted and applied to Naturopathy. This has already been done in the case of Chinese medicine. The Register of Naturopaths and Herbalists (ARONAH) board could easily be integrated into the existing national board to improve efficiencies of operation and reduce costs to practitioners.

**Statutory Registration will offer the public:**
- a regulatory structure with a register making it easier to identify properly skilled and qualified Naturopaths. With restriction to entry only those Naturopaths that meet the standards set may hold themselves out to be and use the title ‘Naturopath’.
- a structure for dealing in a timely manner with practitioners who may be predatory or exploitative
- the ability to identify de-registered practitioners
- an independent and unbiased complaints mechanism
- an improved mechanism for reporting adverse drug reactions from CAM practitioners
- reassurance of quality standards and safety protocols for the use of Naturopathic and Western herbal medicines (WHM)
- the same protection to consumers of Naturopathy and WHM as is currently available to consumers of conventional medical services.
- More access to competent naturopathic support through the register giving reassurance to GPs and other primary health care professionals, enabling them to
liase and refer more readily, so avoiding misunderstandings, lack of information and inconsistent management / treatment strategies for their patients.

Naturopathy as a Profession

The profession of Naturopathy was founded by Benedict Lust who defined the name in New York in 1896¹¹. **Naturopathy is a distinct health profession: both an art and a science and its model of care is underpinned by six foundational principles.** These principles are kept in mind when a naturopath takes the case, develops a treatment plan, and supports a client’s ongoing wellness. These six principles are:

- **Utilising and harnessing the power of nature** – that the body, mind and spirit has the inherent ability and potential to self correct and achieve homeostasis.
- **first do no harm** – that whatever we suggest or prescribe, whether it be ingestible substances, or a lifestyle or dietary change, we are not causing harm.
- **find and treat the cause whenever possible** – we do not ignore the symptoms, we treat and alleviate them, but are always seeking to identify and treat the underlying driver of the problem and find the underlying cause.
- **treat the whole patient** – identifying early on what the clients’ beliefs are about their health care, who their support systems are, what matters to them, what are their priorities, and how we can align care with who this person is beyond only referencing their labelled diagnosis.
- **education** – naturopath as teacher and facilitator fully informs, empowers and guides improved understanding so that the client is more likely to make improved health choices.
- **prevention** – naturopathy is a different paradigm from conventional medicine. This difference is apparent in how we take a case, identify and understand and treat a disease or functional physiological imbalance long before it becomes a diagnosable pathology. This ability is a true strength of what the paradigm of naturopathy has to offer. We are preventative medicine specialists.

Naturopathy is also defined as:

*Naturopathy applies traditional, empirical, biomedical and scientific knowledge to optimise health and to prevent and treat disease. The principles of naturopathy are: supporting the body’s innate healing power; identifying and treating the causes of illness; treating the whole person; promoting optimum health and preventing disease; and educating and actively engaging patients in the management of their health. Naturopathy is underpinned by holistic considerations of human health - physical, mental, spiritual and environmental. The practice of naturopathy utilises a range of modalities that are congruent with these principles. These commonly include dietary and lifestyle advice, nutritional medicine, herbal medicine, tactile therapies and homeopathy (Southern Cross University, SHHS, 2009).*
Naturopathy is recognised as a traditional medicine by the World Health Organisation

WHO member states cooperate to promote the use of traditional medicine for health care.

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 health care, to increase access to care and preserve knowledge and resources; and
- ensure patient safety by upgrading the skills and knowledge of traditional medicine providers. Australia is a WHO member state.

http://www.who.int/mediacentre/factsheets/fs134/en/

Conclusion

The ANPA has welcomed this opportunity to clarify some of the issues that may impact naturopaths and the general public. We support maintaining the status quo in proposal 6 until naturopathy is included as a registered health profession under AHPRA. We also include additional information that will support the current issues that are affecting the profession of naturopathy so that the TGA has a broader context for its decisions that impact the naturopathy profession and the public we serve.

Recommendations

Recommendation 1.
Create an additional list of qualified health professionals including naturopaths or add naturopaths to an exemption list as they are legitimate qualified health practitioners.

Recommendation 2
The TGA meets directly and includes the ANPA regularly when regulatory arrangements are being considered that may affect the profession of naturopathy.

Recommendation 3
Registered health professions with inadequate or no education in modalities used by naturopaths – for example herbal medicine, nutritional medicine or homoeopathy be required to refer patients requiring and seeking this expertise to well-trained naturopaths.

Recommendation 4
Registration for naturopaths is supported at the highest level of government to enact the laws for inclusion under AHPRA.

Recommendation 5
Herbs limited presently under the SUSPD be made available to naturopaths with expertise in herbal medicine.
References


5. Adams, J, Sibbritt, D, Young, AF. Consultations with a naturopath or a herbalist: the prevalence of use and profile of users amongst mid-aged women in Australia. Public Health 2007, 121, 954-957.


Appendix 1: Advanced Diploma of Naturopathy

**PACKAGING RULES**

26 units of competency are required for award of this qualification, including:

- 24 core units, comprising 12 common units and 12 specialisation units
- 2 elective units

A wide range of elective units is available, including:

- Group A electives which are required to provide and manage acute homœopathic treatment
- Group B electives for work in massage therapy
- Units of competency to address workplace requirements and packaged at the level of this qualification or higher in Health and/or Community Services Training Packages
- Where appropriate, to address workplace requirements, units of competency packaged at the level of this qualification or higher in other relevant Training Packages

**Core units**

*Common units*

- BSBFLM303C Contribute to effective workplace relationships
- CHCORG428A Reflect on and improve own professional practice
- HLTAP401B Confirm physical health status
- HLTAP501B Analyse health information (Note pre-requ: HLTAP401B)
- HLTCOM404C Communicate effectively with clients
- HLTCOM406C Make referrals to other health care professionals when appropriate
- HLTCOM502C Develop professional expertise
- HLTCOM503C Manage a practice
- HLTFA301C Apply first aid
- HLTHER501B Maintain an effective health work environment
- HLTIN504C Manage the control of infection (Note pre-req: HLTIN301C)
- HLTOHS300B Contribute to OHS processes

*Specialisation units*

- HLTHER603C Operate a western herbal medicine dispensary
- HLTHER608C Provide specialised western herbal medicine treatment
- HLTNAT601C Provide naturopathic treatment
- HLTNAT602C Provide western herbal medicine treatment
- HLTNAT603C Provide naturopathic nutritional treatment
- HLTNAT605C Plan naturopathic treatment strategy
- HLTNAT606C Perform naturopathic health assessment
- HLTNAT607C Manage work within a naturopathic framework
- HLTNAT608C Apply naturopathic diagnostic framework
- HLTNAT609C Work within a naturopathic framework
**Group A electives - required to provide and manage acute homoeopathic treatment**
The following units must be selected to provide and manage acute homoeopathic treatment.

- HLTHOM612C  **Work within a homoeopathic framework**
- HLTNAT604C  **Provide acute homoeopathic treatment**

**Group B electives - for work in massage therapy**
Two of the following units may be selected for work in massage therapy. Selection of all 5 massage electives below would result in an additional qualification: *HLT40307 Certificate IV in Massage Therapy Practice.*

- HLTREM401C  **Work within a massage framework**
- HLTREM406C  **Provide massage treatment**
- HLTREM407C  **Plan massage treatment**
- HLTREM408C  **Apply massage assessment framework**
- HLTREM409C  **Perform massage health assessment**