



NHAA Response to TGA Consultation: Regulating the advertising of therapeutic goods to the general public.

Submitted by the National Herbalists Association of Australia

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ABOUT THE NHAA

The NHAA is a peak professional association representing appropriately qualified Western herbalists and naturopaths using herbal medicines as their primary treatment modality. It is the oldest professional association of complementary therapists, founded in 1920 with a current full membership of approximately 850 (our total membership is around 1200 including student and companion members). This represents approximately one third of practising Herbalists and Naturopaths in Australia. The NHAA is the only national professional association specifically concerned with the practice and education of Western herbal medicine (WHM) in Australia. Members are required to adhere to the Association's Constitution and the Code of Ethics (including standards of practice). Details of the constitution and Code of Ethics and Standards of Practice of the Association are detailed in Appendix 1 and 2.

The primary aims of the NHAA are to:

- Promote, protect and encourage the study, practice and knowledge of medical herbalism.
- Disseminate such knowledge by talks, seminars and publications.
- Encourage the highest ideals of professional and ethical standards.
- Promote herbal medicine within the community as a safe and effective treatment option.

The vision held by the NHAA for the professional practice of herbal medicine is summarised in the following statements.

- Practitioners and the practice of herbal and naturopathic medicine are fully integrated into the primary healthcare system in Australia.
- The NHAA is recognised as the peak body for herbal and naturopathic medicine.
- Herbal and naturopathic medicine is accessible to all.
- The integrity of the profession of Western herbal medicine and naturopathy is maintained.
- The standards and quality of education of the profession continue to be promoted.
- Career opportunities and research pathways for herbalists and naturopaths are created.
- The integration of traditional medicine and evolving science is continued.

The NHAA is governed by a voluntary Board of Directors. Full members of the Association elect the Board of Directors, with each board member serving a two-year term after which they may stand for re-election.

Full members of the NHAA have completed training in Western Herbal and Nutritional medicine sufficient to meet the educational standards as determined by the Examiners of the Board. These standards are set in consultation with tertiary educational institutions (standards in line with but exceeding the requirements of the NSW Health Training Package), and all members must adhere to a comprehensive Code of Ethics and Continuing Professional Education (CPE) program (see Appendices 2, 3 & 4). Membership consists of practitioners of Western herbal medicine who choose to use herbal medicine as their major modality of practice including Naturopaths, GPs, Pharmacists and Registered Nurses.

The NHAA publishes the quarterly *Australian Journal of Herbal Medicine*, a peer reviewed subscription journal covering all aspects of Western herbal medicine, and holds annual seminars on herbal medicine throughout Australia. An *International Conference on Herbal Medicine* has been held every 2-3 years since 1992.

Since its inception, the NHAA and its members have been at the forefront of herbal medicine and have been influential in areas ranging from education and practice standards, to government regulation and industry standards. The NHAA has a strong commitment to achieving high educational standards in herbal medicine practice and supports the regulation of the profession.

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BACKGROUND

The purpose of this submission is to respond to the TGA consultation on the regulation of advertising of therapeutic goods to consumers, highlighting the impact this may have on the practice of Western herbal medicine (WHM) and naturopathy practitioners.

The NHAA recognises the purpose of the proposed regulatory changes is to improve and simplify the regulation of advertising of therapeutic goods to consumers, in particular to protect the general public from false product claims and potential adverse effects that may ensue from inappropriate use of therapeutic goods resulting from such claims. The NHAA wholeheartedly endorses the purpose of these changes, but has identified some consequences that will impact both public safety and our member's ability to practice as health professionals effectively.

Western herbalists and 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 these professions. It has been noted that *proposal 6.2* will have a detrimental impact on the practise of WHM and naturopathy, and *proposal 5* will also have a deleterious impact should *proposal 6.2* be implemented.

DISCUSSION

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.

The NHAA are in favour of this *proposal 5.2* in principle, *except* that *proposal 6.2* will then deny Western Herbalists and 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*.

The NHAA believes the current list should remain (option 1) or Western herbalists and naturopaths be added to the new list. As previously mentioned, option 2 deprives herbalists and naturopaths tools of trade to practise effectively and safely.

PUBLIC SAFETY

The NHAA has determined that removing herbalists and naturopaths from the list of practitioners exempt from Part 5-1 of the TGA act may have unintended consequences of risking 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.

Denying exemption is unlikely to completely discourage practitioners from prescribing therapeutic goods, but they will not be as informed.

Another consideration is the effect on company behaviour when deprived of their natural commercial target group. Seeking to recover promotional opportunities they are likely to target registered health practitioners with little or no knowledge of listed therapeutic goods (specifically herbal medicines). Chiropractors and osteopaths are already making forays into ingestive therapies despite a lack of education in herbs and nutritional supplements. The result would likely be an increased risk to the public, negating any perceived benefits of the reforms. They could of course be denied exemption under new regulations, but as the secondary purpose for the proposals are simplicity this starts to look much more complex than the current system.

MAINTAINING EXPERTISE

Herbalists and naturopaths currently hold expertise in herbal and nutritional medicine, in particular holding the highest qualification resulting in the prescription of herbal medicines. It is estimated that 56% of the population uses some form of herbal medicine, either prescribed by herbalists or self-prescribed (1), and it is therefore vital that the expertise of herbalists and naturopaths is maintained as a public resource, particularly in pharmacies where naturopaths and herbalists are often employed to give advice on supplements. 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 (2). These findings provide evidence that contradicts the TGAs argument for excluding naturopaths and herbalists as recognised health professionals.

SCOPE OF PRACTICE

The current minimum standard to practice WHM and naturopathy is an advanced diploma. However, the professions are moving toward Bachelor degree as minimum standard, with 70% of NHAA members holding at least a degree, and with many holding post-graduate qualifications. The professions are also moving from a mainly tradition based body of knowledge to evidence based practice (EBP) (2). This is supported by current education standards in all tertiary education sectors and NHAA course accreditation requirements for research, clinical sciences, herbal therapeutics and toxicology (see appendix 5).

The infrastructure supporting the continued application and growth of EBP in naturopathy and WHM is evident and includes minimum education standards, the availability of baccalaureate and postgraduate coursework qualifications and continuing professional education opportunities such as seminars (including those run by supplement advertisers), conferences and publications. There is also support for research capacity building through the proliferation of peer-reviewed journals targeting research relevant to the practice of naturopathy and WHM alongside the existence of research organisations focused on the examination of a range of CAM including naturopathy and WHM. These activities not only support EBP but prepares the practitioner with critical analysis skills that enable them to be a discerning consumer of advertising information, distinct from the general public.

Stringent workplace, health and safety studies also contribute to relevant scope of practice related to use of in-vitro diagnostic devices and in-clinic testing. Practitioners may also undertake post-graduate training to improve skills in use of diagnostic equipment; this is again in contrast to the general public.

An identifiable framework for scope of practice is reflected in the proliferation of insurance companies willing to provide professional indemnity insurance to herbalists and naturopaths. Insurance is a requirement for full practicing membership of naturopathic and herbal medicine professional associations, including the NHAA. This constitutes tacit agreement of the expertise of herbalist and naturopaths within their field.

In point 7 of the TGA's consultation regulation impact statement, the following statement was given:

"Practitioners registered with national boards participating in the NRAS can be taken to be appropriately qualified, insured and subject to professional and ethical conduct requirements".

Western herbalists and naturopaths are currently educated in state and nationally accredited courses. The curriculums must also meet the requirements of a multitude of professional associations in what universities and colleges have often complained is the most regulated field in Australia. Full membership to associations has professional indemnity insurance, yearly CPE and a current first aid certificate as requirements. Members are also required to adhere to a strict association professional code of conduct on top of the HCCC code of conduct for unregistered practitioners. The NHAA believes this more than meets the stated observation.

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 herbalists and naturopaths once it is better established. See Appendix 6.

RECOMMENDATIONS

Proposals 1-4, 7 and 8

The NHAA are happy to accept proposals 1-4, 7 and 8 without further comment.

Proposal 5

Unless proposal 6.2 is abandoned we cannot support proposal 5.2 as it would affect access to tools of trade of herbalists and naturopaths. Therefore we recommend keeping the status quo (5.1).

Proposal 6

The NHAA recommends either maintaining the status quo (6.1) or adding herbalists and naturopaths to the new exemption list. To do otherwise is to add risk to public safety and adversely affect the practice of herbal medicine and naturopathy, potentially resulting in professional and financial hardship.

CONCLUSION

The current proposals issued by the TGA in this consultation is the latest in several potential risks to the professions of Western herbal medicine and naturopathy and the right of the public to choose their mode of health care and disease prevention. This era of marginalisation was underlined by the attempt of Friends of Science in Medicine to remove complementary medicine modalities from universities and continue with the recent government inquiry into private health rebates for complementary medicine modalities (yet to be determined). This is ironic as it highlights the conundrum of the unregistered health professions whom despite undertaking an unprecedented period of modernisation and integration into the health care system, are denied long sought statutory registration (since 1930's), and are then continually discriminated against for its lack. The TGA and complementary medicine professions have by and large had good working relationships resulting in compromise that maintains public safety without overtly undermining CAM practice. The NHAA hopes the TGA will consider this when making a final decision on the above proposals.

REFERENCES

1. Shorofi SA. Complementary and alternative medicine (CAM) among hospitalised patients: Reported use of CAM and reasons for use, CAM preferred during hospitalisation, and the socio-demographic determinants of CAM users. *Complementary Therapies in Clinical Practice*. 2011;17:199-205.
2. Braun, LA, Spitzer, O, Tiralongo, E, Wilkinson, JM, Bailey, M, Poole, SG, & Dooley, M. (2012). Naturopaths and Western herbalists' attitudes to evidence, regulation, information sources and knowledge about popular complementary medicines. *Complementary therapies in medicine*. 2012;21:58-64.

APPENDICES

APPENDIX 1 - NHAA CONSTITUTION

<http://www.nhaa.org.au/about/constitution> and attached as a separate file.

APPENDIX 2 - NHAA CODE OF ETHICS AND STANDARDS OF PRACTICE

<http://www.nhaa.org.au/about/codeofethics> and attached as a separate file.

APPENDIX 3 - NHAA CONTINUING PROFESSIONAL EDUCATION GUIDE

http://www.nhaa.org.au/docs/CPE/CPE_Guide_2013.pdf and attached as a separate file.

APPENDIX 4 - NHAA CONTINUING PROFESSIONAL EDUCATION DIARY

http://www.nhaa.org.au/docs/CPE/CPE_Diary_Print_2013.pdf and attached as a separate file.

APPENDIX 5 – NHAA COURSE ACCREDITATION MAIN

<http://www.nhaa.org.au/docs/Examiners%20News%20and%20CAS/NHAA%20CAS%20WHM%202.1.pdf> and attached as a separate file

APPENDIX 6– THE AUSTRALIAN REGISTER OF NATUROPATHS AND HERBALISTS (ARONAH)

<http://www.aronah.org/aronah-documents/>