



Australian Register of Naturopaths and Herbalists

Submission to TGA Consultation: Regulating the
advertising of therapeutic goods to the general
public

About ARONAH

The Australian Register of Naturopaths and Herbalists (ARONAH) was formally established as a registered non-profit entity in 2010 to provide an independent registration body for the profession of naturopathy and Western herbal medicine, precipitated by delays of the development of statutory registration of these professions caused by the move from individual state-based registration to the national registration and accreditation scheme, and the gap in public protection these delays caused.

The Constitution of ARONAH requires it to mirror the standards of the national registration and accreditation scheme administered by the Australian Health Practitioner Regulation Agency (AHPRA) and the National Law which guides this process. Despite numerous formal government assessments indicating the requirement for statutory regulation of naturopathy and Western herbal medicine, these professions do not currently fall under this scheme.

Following exhaustive national consultation with stakeholders in the development of standards specific to the professions of naturopathy and Western herbal medicine ARONAH began receiving applications for membership in June 2013. ARONAH is the first independent accreditation and registration body in these professions that ensures minimum standards of training and education and promotes the public's interests when visiting these practitioners. ARONAH works with all practitioner members from all professional associations and graduates of all accredited programs to set minimum benchmarks for training and practice, and to provide the public with an independent complaints handling mechanism, as well as liaising regularly with health commissioners, peak consumer groups, health insurers and other health professional bodies to ensure minimum standards across these professions. ARONAH standards can be found online at:

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

Due to the disadvantages and weaknesses of self-regulation ARONAH supports statutory regulation of the professions of naturopathy and Western herbal medicine to ensure public protection, and the ARONAH Constitution formally requires it to co-operate with any attempts to statutorily regulate these professions, should this occur in the near future.

ARONAH is committed to increasing standards of training, practice and accountability in the professions of naturopathy and Western herbal medicine. More information on ARONAH can be found on the website: <http://www.aronah.org>.

Thank you for the opportunity to make a submission on the recent TGA proposals re advertising of therapeutic goods to the general public. Please find our comments on specific proposals below.

PROPOSAL 1: Alternatives to the pre-approval scheme

As a practitioner register and accreditation authority ARONAH is not directly affected by this proposal. ARONAH is committed to independent regulation in preference to self-regulation, and would therefore favour an independent authority assume any approval function, particularly in relation to high risk medicines, provided that relevant expertise from persons with qualifications, technical knowledge and clinical skills specific to complementary medicines (in addition to sound understanding of scientific evidence underpinning claims) is present in matters relating to these medicines. ARONAH believes that **Option 4(b)** best expresses this and is in the best interests of public health and safety.

PROPOSAL 2: The complaints handling process

As a practitioner register and accreditation authority ARONAH is not directly affected by this proposal. ARONAH is committed to independent regulation over self-regulation, and would therefore favour an independent authority assume any complaints handling process, providing stakeholders are appropriately consulted, and provided that relevant expertise from persons with qualifications, technical knowledge and clinical skills specific to complementary medicines (in addition to sound understanding of scientific evidence underpinning claims) is present in matters relating to these medicines. ARONAH would therefore be in favour of **Option 2(b)**, which best expresses this and is in the best interests of public health and safety. However, safeguards are needed to ensure any independent authority would conduct these activities in a timely, efficient and cost-effective manner.

PROPOSAL 3: Provision of advice in relation to advertising matters

As a practitioner register and accreditation authority ARONAH is not directly affected by this proposal. ARONAH is committed to independent regulation over self-regulation, and would therefore favour an independent authority assume any complaints handling process, providing stakeholders are appropriately consulted, and provided that relevant expertise from persons with qualifications, technical knowledge and clinical skills specific to complementary medicines (in addition to sound understanding of scientific evidence underpinning claims) is present in matters relating to these medicines. ARONAH would therefore be in favour of **Option 2**, which best expresses this and is in the best interests of public health and safety. However, safeguards are needed to ensure any independent authority would conduct these activities in a timely, efficient and cost-effective manner.

PROPOSAL 4: Investigation and enforcement powers

ARONAH agrees with increased enforcement powers providing stakeholder consultation and education remains an intrinsic part of the TGA's preventive approach to minimise breaches occurring. This is best represented by **Option 2**.

PROPOSAL 5: Advertising of higher risk medical devices

ARONAH agrees with **Option 2**. ARONAH is aware of significant concern amongst practitioner groups on this proposal and how this may affect access and use of some therapeutic tools of trade. Although ARONAH is not of the opinion that appropriate and safe naturopathic and Western herbal

medicine practice will be significantly affected by this proposal, ARONAH would appreciate clarification on how this may affect practitioners, specifically in developing a more comprehensive and detailed practitioner-accessible list of examples of “higher risk medical devices”, as ARONAH believes this would help to reduce practitioner confusion over this proposal.

PROPOSAL 6: Advertising directed to health professionals

ARONAH supports naturopaths and Western herbalists remaining in the list of exempted professions under Section 42AA. ARONAH does not believe that Option 1 and Option 2 need to be mutually exclusive, and supports the inclusion of the three newly registered professions not currently included (occupational therapists, ATSI health workers and medical radiation therapists). ARONAH also believes that the defining qualified health professions solely as AHPRA-registered professions may limit other well-qualified health professions (such as dietitians), who are not currently part of the scheme.

Minimum standards are needed

ARONAH acknowledges that there is significant variability in standards and training in the naturopathic and Western herbal medicine professions. This is conflated by conflicts of interest that exist in many of the practitioner organisations, such as boards controlled by college owners who are able to set education standards for entry based on their own (often substandard) curricula. ARONAH would therefore agree with the TGA that the current mechanism (Schedule 1) does not ensure that practitioners are suitably qualified.

However, although there are practitioners purporting to be naturopathic or Western herbal medicine practitioners without appropriate qualifications, many practitioners may also have qualifications above and beyond practitioners in some AHPRA professions. ARONAH would note that while the majority of modern naturopathic graduates now graduate from a four-year degree program at least one AHPRA-registered profession mooted for inclusion (ATSI health workers), requires only a Certificate IV for registration. Naturopathic courses in the higher education sector (as opposed to the vocational sector) may compare favourably with qualifications amongst other AHPRA-registered professions in terms of health science and clinical training. Therefore, whilst ARONAH supports the retention of naturopaths and Western herbalists in the exemption list, it also fully supports increased minimum requirements for eligibility for this exemption, with full acknowledgement that this may result in many unqualified practitioners being removed from eligibility.

Although in early development, as an independent register modelled solely on the requirements of the national registration and accreditation scheme, committed to moving the professions to a four-year degree minimum level of training, independent complaints handling and rigorous continuing education standards, ARONAH membership may provide an interim solution with regards to identifying appropriately trained naturopaths and Western herbalists for exemption under this proposal.

AHPRA/AHMAC needs to complete its work in unregistered professions before this definition can be employed

ARONAH is also concerned that unnecessary removal of naturopaths and herbalists may incur an additional impost related to the changing regulatory status of naturopaths and herbalists. Every government report since 2000, both Commonwealth¹ and state²⁻⁴, that has explored the issue of

regulatory requirements of naturopaths and herbalists has highlighted the need for further statutory regulatory requirements for the professions of naturopathy and Western herbal medicine.

However, despite this agreement, and the Victorian government initiating moves to regulate these professions in 2006/7, there has been little movement on the moves to implement statutory regulation to ensure minimum standards of practice and training in these professions. ARONAH itself was developed to fill the hole in the absence of current momentum on this issue and provide some form of independent regulation in the absence of statutory registration, though as a voluntary register is unable to be fully as effective as statutory registration.

ARONAH has confirmed that the Victorian government was moving towards a regulatory regime for naturopaths and Western herbalists, in a similar model seen in the professions of acupuncture and Chinese medicine, and transferred the body of work to the national regulatory authority (or precursor authority) after the announcement of the National Registration and Accreditation Scheme. In the first few years following the announcement stakeholders were told that the development of AHPRA would consist of three stages: 1) the inclusion of professions currently registered in all jurisdictions (which occurred in 2010); 2) the consideration of partially regulated professions (which began in 2012 after a consultation phase), and; 3) the consideration of all currently unregistered professions for inclusion in the national registration and accreditation scheme. In 2011 this was changed somewhat to the exploration of the national rollout of a statutory code of conduct for all unregistered health practitioners, as based on the New South Wales model, and ARONAH was informed that individual professions would be considered after release of the initial report. However, although the report of this consultation was supposed to be released in late 2011, it has still not been released and remains 'under consideration', with any further professions being delayed indefinitely until issues surrounding this report have been finalised. This affects not only naturopaths and herbalists, but all currently unregistered professions, some of which have a risk profile warranting further regulation. ARONAH has highlighted that such delays are not conducive to the public protection function of the national registration process.

ARONAH has consistently asked for the current processes exploring the regulatory requirements of naturopaths and Western herbalists to be completed. ARONAH understands that – until the recent work AHMAC has undertaken on paramedics – naturopaths and Western herbalists were the only professions who had a formal government assessment against AHMAC criteria for the statutory registration of professionsⁱ. Not only have these delays caused problems with future planning of standards development in the profession, but the continuing delay in implementing government and public health recommendations for statutory regulation of these professions has also increased the variability in training and practice standards of the professions of naturopathy and Western herbal medicine. The increasing fragmentation and variability amongst the profession has been a pattern that has historically presented in the professions of naturopathy and Western herbal medicine when moves to statutorily regulate the profession are delayed or shelved⁵, as substandard colleges and associations proliferate once a realisation that few accountability measures will persist as the professions move back to a self-regulatory model that has been repeatedly been shown to be inappropriate².

ⁱ The formal criteria by which professions are considered for statutory regulation in Australia and inclusion in the national registration and accreditation scheme, now called the 'Intergovernmental Agreement Criteria'.

Given the fact that the number of practitioners, public utilisation, scope of practice and distribution of naturopathic and Western herbal medicine practitioners has increased since previous assessments, ARONAH believes it is unlikely that any assessment will view statutory registration as being less warranted than previous reports. ARONAH therefore believes that once AHMAC begins to consider new professions for inclusion in the national registration and accreditation scheme, naturopaths and Western herbalists will most likely be amongst the first tranche of new professions to be included. Rather than add additional imposts to the profession and the industry which supplies many of its therapeutic tools by removing and then reinstating naturopaths and Western herbalists, ARONAH would recommend that the TGA allow naturopaths and Western herbalists to remain in Section 42AA until the regulatory requirements for naturopaths and Western herbalists have been finalised by AHMAC.

As the investigations of new professions for consideration for inclusion in AHPRA have been unduly delayed, AHPRA-registration may be a poor proxy for defining 'qualified health professional'. AHPRA/AHMAC should be encouraged to complete this process before consideration of AHPRA-registration as defining 'qualified health professional'.

Lack of clarity on CPE and other TGA legislation

Although ARONAH understands that the current proposal will not affect access to therapeutic tools, the change in definition of qualified health practitioner to be based on AHPRA registration could pose practice problems for naturopaths and Western herbal medicine practitioners if extended to other TGA guidelines such as those on labelling and extemporaneous medicines. To help ensure safe and appropriate practice is promoted amongst these professions, ARONAH would seek clarification on what changes to the definition in this proposal may mean for the definition of health professionals in other areas of TGA legislation and guidelines.

ARONAH is also concerned on how these changes may affect continuing education exercises with company involvement. Although ARONAH is attempting to promote a sustainable independent CPE sector in the naturopathic and herbal medicine professions (which includes requirements that company CPE can make only a small portion of allowable CPE points per year to retain membership), ARONAH is aware of the reality that much CPE in these industries has traditionally been supported by product companies. ARONAH is concerned that dissemination of recent research to clinical communities (for risk as much as efficacy) may be limited by this proposal. ARONAH would also seek clarification on what would constitute 'advertising' in relation to CPE (for example, would associations still be able to seek sponsorship for their international conferences, as this could also limit the capacity of associations to provide CPE opportunities). Many practitioners currently receive detailed technical information on products, essential to safeguarding from potential adverse reactions or interactions, from manufacturers which is provided at a level higher than expected for public consumption. Whilst minimum guidelines and standards are welcomed, ARONAH requires clarifications on how the proposals may affect the education and practice sector more broadly.

Conclusion:

ARONAH supports neither Option 1 nor Option 2 in their totality but rather a modified option 1, which recognises the new AHPRA-registered professions whilst retaining exemption for naturopaths and Western herbalists, for at least as long as it takes for AHMAC to conclude its exploration of what

currently unregistered professions should be included in the national registration and accreditation scheme.

PROPOSAL 7: Advertising of Pharmacist-only medicines

As a practitioner register and accreditation authority ARONAH is not directly affected by this proposal, though sees merit in retaining all advertising requirements in one place, as proposed by **Option 2**.

PROPOSAL 8: The Price Information Code of Practice

As a practitioner register and accreditation authority ARONAH is not directly affected by this proposal, though sees merit in increased clarity, as proposed by **Option 2**.

References

1. Expert Committee on Complementary Medicines in the Health System. Complementary Medicines in the Australian Health System - Report to the Parliamentary Secretary to the Minister for Health and Ageing. Canberra: Commonwealth of Australia,; 2004.
2. Lin V, Bensoussan A, Myers S, McCabe P, Cohen M, Hill S, et al. The practice and regulatory requirements of naturopathy and western herbal medicine. Melbourne: Department of Human Services; 2005.
3. Social Development Committee. Inquiry into Bogus, Unregistered and Deregistered Health Practitioners. Adelaide: Parliament of South Australia; 2009.
4. Joint Committee on the Health Care Complaints Commission. Review of the 1998 report into 'unregistered health practitioners: the adequacy and appropriateness of current mechanisms for resolving complaints'. Sydney: Parliament of New South Wales; 2006.
5. Jacka J. Natural therapies : the politics and passion : a personal story of a new profession. . Melbourne: Ringwood Natural Therapies; 1998.