

AUSTRALIAN NATURAL THERAPISTS ASSOCIATION LTD (ANTA)

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ACN 000 161 142

Submission on

Reforms to the regulatory framework for complementary
medicines: Assessment pathways

Submitted to

Complementary Medicines Reform Section
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

28th March 2017



This submission is lodged by the Australian Natural Therapists Association (ANTA) in response to the TGA invitation to interested parties on a range of reforms to the regulatory framework for complementary medicines to address Government-agreed recommendations from the Review of Medicines and Medical Devices Regulation.

A profile of ANTA is enclosed with this submission – see Appendix

The TGA has advised the purpose of the consultation is to provide an opportunity for consumers, health professionals and sponsors to contribute to the development and implementation of a range of reforms aimed to improve the regulation of complementary medicines in Australia. These reforms aim to increase transparency for consumers, provide additional flexibility for industry and support innovation, while maintaining the safety and quality of therapeutic goods available in Australia.

The scope of the consultation is focused on the following four elements:

- The development of a three-tiered risk based framework for the regulation of complementary medicines. This will introduce a new assessment pathway sitting between the existing listed medicine (low risk) and registered medicine (high risk) pathways.
- The development of a list of permitted indications which must be used by the lowest risk complementary medicines.
- Allowing sponsors to claim that their medicine has been assessed by the TGA for efficacy where that medicine has undergone pre-market assessment by the TGA.
- Mechanisms to incentivise innovation for the complementary medicines sector.

The Expert Panel conducting the Review of Medicines and Medical Devices Regulation made recommendations that aimed to:

- ease regulatory requirements where they do little to improve consumer protections and are a barrier to business and innovation
- ensure a level of regulation that is commensurate with the potential risks to public health and safety posed by complementary medicines
- balance these risks and the potential benefits to be obtained by users from the availability of these products in Australia
- ensure consumers and health professionals have sufficient, accurate information to enable them to select and use complementary medicines safely and effectively



The Australian Natural Therapists Association Ltd (ANTA) in principle supports the aims identified by the expert panel above.

The easing of regulations where they do little to improve consumer protection and are a barrier to business and innovation is supported by ANTA providing there are adequate control measures to ensure product quality is maintained.

Ensuring there is a level of regulation that is commensurate with the potential risks to public health and safety in the opinion of ANTA is already in place and effectively monitored by the TGA.

Balancing the risks and the potential benefits to be obtained by users from the availability of these products is in the opinion of ANTA currently carried out effectively by the TGA under the current system.

Ensuring consumers and health professionals have sufficient, accurate information to enable them to select and use complementary medicines safely and effectively is in the opinion of ANTA being effectively carried out by sponsors under the current system.

To ensure the public are consistently using the appropriate complementary medicine for their health and lifestyle issues, ANTA recommends all medicine and supplement information should encourage the public to consult with their trained complementary medicine practitioner.

The Australian Government responded to the Expert panel review by recommending a strategic and systems-based approach to achieve long-term sustainable reform to the regulation of therapeutic goods in Australia and identify ways to improve access the therapeutic goods for consumers and remove unnecessary red tape for industry whilst maintaining the safety of therapeutic goods in Australia.

ANTA agrees in principle with the approach outlined in the Australian Government response. The TGA has over many years effectively regulated the safety and quality of complementary medicines in Australia and the safe use of complementary medicines by the public can be further strengthened by recommending to users of complementary medicines that they consult with and seek advice from their qualified and trained complementary medicine health professional.

The consultation paper proposes a three-tiered risk based hierarchy of indications categorised into the following levels of risk:



Low level indications:

Low level indications refers to general health maintenance, enhancement and dietary deficiency.

The TGA has advised Low risk indications would be consistent with listed complementary medicines under the current framework based on traditional use and scientific evidence and that it is proposed medicines carrying low risk indications are not evaluated by the prior to inclusion on the ARTG

Intermediate level indications:

Intermediate level indications refers to prevention or alleviation of non-serious forms of disease, conditions or ailments and present a higher risk than low level indications.

The TGA advised intermediate level indications would require demonstrated evidence for efficacy and would continue to be pre-market assessed by the TGA.

High level indications:

High level indications refers to the treatment, cure or prevention of a serious disease, disorder or condition that may not resolve in a timely manner or may worsen if not treated effectively.

The TGA advised high level indications would require individual assessment for safety, quality and efficacy before being made available.

ANTA supports the above three tier approach by the TGA provided it does not remove/restrict complementary medicines that are currently being effectively and successfully used by trained complementary medicine practitioners.

List of permitted indications:

The Government has advised the TGA should establish a list of permitted indications from which sponsors must exclusively draw to include listed medicines in the ARTG.

Currently, sponsors when applying to list a medicine on the ARTG can enter the indications of their choice noting they have evidence to support those indications.

The TGA claims this system has resulted in significant rates of non-compliant indications being included in medicine entries in the ARTG. ANTA notes that no evidence was provided to support these claims by the Government or the TGA.



If the claims by the Government and TGA are valid that would seem to suggest the TGA has been ineffective in monitoring indications and acting upon them in a timely manner.

The consultation paper stated the TGA will prepare a legislative instrument comprising a consolidated list of all permitted indications that sponsors must select from.

ANTA advises that it is essential that sponsors have input on the development of the list of permitted indications prior to implementing this system. Development of the list of permitted indications should not be at the sole discretion of the TGA and should as a minimum include input and review mechanisms to allow all sponsors to participate in the system.

Incentives for Innovation:

The Government supports recommendations to improve the competitiveness of the Australian complementary medicine industry and provide incentives for innovation.

ANTA notes the consultation paper outlines that full cost recovery for the proposed new system is proposed and it is intended to create:

- an application fee for assessing whether a medicine meets the eligibility requirements for assessment
- an evaluation fee for medicines that undergo pre-market efficacy assessment
- an application fee for assessing whether a proposed new indication meets the criteria for inclusion

ANTA supports the government approach to improve the competitiveness and provide incentives for innovation however, a system based on high fees will have the opposite effect and will stifle innovation and make the industry uncompetitive.

ANTA recommends the TGA implement a fair equitable and transparent approach to cost recovery that fully supports and deliver the goal of innovation and competitiveness.

Summary:

ANTA believes the TGA in the main has been effective in regulating complementary medicines and assessment.

The proposal outlines new legislation is proposed to regulate complementary medicines in Australia to deliver increased transparency, additional flexibility, support innovation, improve competitiveness while maintaining the safety and quality of products.



ANTA in general supports the objectives outlined in the consultation paper. As significant changes are proposed, ANTA has concerns the ability to deliver a system that is fair, equitable, transparent, innovative and competitive may not be achieved unless supported by changes to make the system more efficient and cost effective.

A concern for ANTA is that access to the tools of trade, complementary medicines utilised by trained complementary medicine practitioners must not be compromised, restricted or removed under any new system or legislation.

Appendix

Profile of the Australian Natural Therapists Association Ltd

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The Australian Natural Therapists Association Limited (ANTA) is the largest national democratic association of *'recognised professional'* traditional medicine and natural therapy [Complementary Medicine] practitioners who work in the areas of health care and preventive medicine.

ANTA was founded in 1955 and represents the multi-disciplinary interests of approximately 10,500 accredited practitioners Australia-wide. ANTA is one of the original *Schedule 1* bodies as defined in the regulations of the Therapeutic Goods Act 1989.

ANTA was recognised by the Australian Taxation Office, in November 2002, under a private ruling as *'...a professional association that has uniform national registration requirements for practitioners of traditional medicine and natural therapies...'* thereby allowing ANTA practitioners of Acupuncture, Chinese Herbal Medicine, Naturopathy and Western Herbal Medicine to practise GST- free.

ANTA:

- provides an egalitarian representation of all disciplines accredited by the association
- possesses infrastructure, systems, policies and procedures which enables the association to encompass all aspects of the profession
- represents the interests of individual disciplines
- acts as advocate for practitioners of all disciplines accredited by the association
- promotes the health and safety of consumers of traditional medicine and natural therapy health services

The disciplines recognised by ANTA and accredited by the Australian Natural Therapists Accreditation Board (ANTAB) are:



Acupuncture	Aromatherapy
Ayurvedic Medicine	Chinese Herbal Medicine
Chiropractic/Osteopathy	Homoeopathy
Naturopathy	Nutritional Medicine
Oriental Remedial Therapy	Remedial Massage Therapy
Traditional Chinese Medicine	Myotherapy
Counselling	Musculoskeletal Therapy
Western Herbal Medicine	Shiatsu

ANTA supports Statutory Registration of Natural Therapists

ANTA is committed to continuous quality improvement and providing the Australian public with the highest possible standards for the conduct and safety of traditional medicine and natural therapy practitioners, and addresses standards for conduct and safety through:

- The high standard of entry requirements for potential members
- Yearly review of entry standards to maintain currency and ensure relevance
- Active participation in setting standards at national and state levels via industry reference group and working committee participation
- Free student membership to the Association
- Yearly review of the courses on offer within the profession, and courses currently accredited by ANTAB
- Compulsory yearly proof of minimum continuing professional education requirements of members
- Provision of “free” continuing professional education seminars in all states of Australia
- Provision of online continuing professional education services for members
- Provision of free continuing professional education webinars for members
- Compulsory up-to-date senior first aid certificates
- Compulsory specialised professional indemnity and public liability insurance
- The Association enforces a strict Code of Professional Ethics
- The Association maintains effective public complaints handling and resolutions mechanisms outlined in the Constitution
- The Association maintains a National Administration Office, which is open five days a week and staffed by an Executive Officer and fully trained support staff
- The Association maintains fully computerised membership, accreditation and course recognition databases and systems



- Provision of communication via the Members' page on the ANTA website of the most up to date information related to the profession
- Provision of regular Newsletters and ANTA e–News detailing information of current interest to the profession
- Provision of a Professional Publication 'The Natural Therapist', four times a year offering the latest information available on topics of interest to the profession
- Provision of an ANTA website to allow interested persons and consumers to obtain information about the Association, natural therapies and traditional medicine and the location of accredited practitioners of the Association
- Provision of a free Natural Therapies APP to allow interested persons and consumers to obtain information about natural therapies and details of ANTA practitioners in their area
- Provision of free access by members to the latest scientific publications and health resources published by eMIMS
- Provision of free access by members to the latest scientific publications and health resources published by EBSCO Host including:
 - 2800+ full text medical journals
 - Access to the worlds' most reputable bibliographic indexes for medicine, allied health and complementary/alternative medicine (CINAHL, MEDLINE & AMED)
 - 700+ evidence based articles for consumer health researchers
 - 300+ full text books & monographs
 - Hundreds of special reports and booklets and much more.
- Provision of free access by members to the latest up to date scientific information and health resources published by IM Gateway including:
 - 300 Herbs
 - 350 Diseases & Conditions
 - 250 Supplements
 - Herb – Drug Interaction Guide
 - Supplement – Drug Interaction Guide
 - Treatment Options
 - Organ & Body Systems
 - Drug Induced Depletions
 - Evidenced Based & Peer Reviewed Information
- Provision of funding grants for research into traditional medicine and natural therapies
- Provision of online resources and latest research for members
- Provision of annual ANTA Student Bursary Awards totalling \$12,000 p.a. to encourage excellence in the study of traditional medicine and natural therapies
- Setting of standards for clinics, hygiene and infection control
- Setting of standards for skin penetration



- Setting of standards for keeping and maintaining patient records
- Making public the requirements for recognition of traditional medicine and natural therapy courses by ANTA for membership purposes
- Making public details of traditional medicine and natural therapy courses recognised by ANTA for membership purposes
- Only recognising government accredited courses that meet ANTA's stringent requirements (note – ANTA does not recognise courses delivered totally by distance education)
- Making public details of ANTA membership criteria and qualifications
- Consultation with Members on matters of importance. The Association uses the Members' web page, consultation meetings, newsletters, ANTA e-News, social media and the magazine to consult with Members
- A '1800' free-call number promoted to consumers and practitioners, facilitating a direct path of communication with the Association's national administration office staff
- A '1800' free-call number and web page promoted to consumers and practitioners, to identify appropriately qualified practitioners in the consumer's geographical area
- Undertaking ongoing internal audits of its policies and processes of operation and all matters to do with professional practice
- External audits of procedures, policies & processes to ensure compliance with the principles of best practice
- Publishing an Annual Report on the activities and performance of the Association
- Undertaking a yearly audit of its Constitution which includes the Association's Complaints, Ethics & Disciplinary Panels
- Undertaking a yearly audit of its Code of Professional Ethics
- Ongoing consultation and collaboration with other professional associations
- Ongoing dialogue and correspondence with ministers, government departments and regulatory bodies
- Ongoing research of policies in overseas professional associations and policies of overseas governments
- Maintaining a Natural Therapy Adverse Events Register
- On line polling of Members and the Public on relevant professional and health issues
- Democratic voting system for the election of directors by members

ANTA is a public company limited by guarantee, and is governed by a National Council [Board of Directors] which is elected by the Members of the Association for a term of 3 years. The Council in turn elects all office bearing positions within the Association, which are for a term of 1 year.



National Council is supported by the services of a full time Executive Officer, full time Company Secretary and full time National Administration Office Staff.

ANTA practises a policy of consultation with representatives of all stakeholders of traditional medicine and natural therapies, as well as being available to all government and regulatory bodies associated with the professions.

Persons wishing to discuss with ANTA any matters relevant to the professions of traditional medicine and natural therapies should contact:

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