

THERAPEUTIC GOODS ADMINISTRATION

Electronic submission.

Consultation: Options for the future regulation of “low risk” products

from

**The Australian Naturopathic
Practitioners Association**



Excellence, Leadership and Integrity in Naturopathic Health Care

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The Australian Naturopathic Practitioners Association (ANPA) is pleased to submit comments on the ***Consultation: Options for the future regulation of low risk products.***

About the Australian Naturopathic Practitioners Association (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 code of ethics as well as other 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.
- Advocacy to private health insurers.
- 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 and consultation with education providers across Australia and overseas offering naturopathic education.
- Regular contributions to the media raising the profile of naturopathy and awareness for the profession amongst other health professionals, the public and the media.

Introduction

The TGA Consultation for the future Regulation of Low Risk Products is an important regulatory review process. The public must have continued confidence in the regulation of complementary medicines. The well considered questions the TGA is asking about the current regulation of low risk complementary medicine products is of concern to all conscious health consumers and health professionals.

As the only professional association exclusively representing Australian naturopaths, it is important to note that homeopathy has been a core competency for a large percentage of Australian naturopaths.

A formal complaint about the NHMRC Report on Homeopathy is currently being investigated by the Ombudsman.

This investigation is focused on the process that underpinned the development of this

report and its consequent findings. This investigation is not complete. This report should not have been cited in this consultation paper. In addition, the UK government review cited in this consultation paper was rejected by the UK government. Including this UK review may imply validity to the findings of the review. This is misleading. The review was rejected by the UK government. Importantly, the NHMRC Homoeopathy Review applied much higher levels of evidence than required by the TGA. The TGA may accept a study of 10 participants for studies in natural medicine, however the NHMRC chose to create a new threshold minimum of 150 participants for a trial to be reliable. The TGA's use of the new threshold criteria for the inclusion of evidence is discriminatory and lacks fairness. Homeopathic medications should not be subject to higher standards of evidence and assessment than other complementary medicines.

While the NHMRC Review complaint is being investigated by the Ombudsman no actions related to homeopathic products listed on the TGA should be made. Health Minister Hunt should block any action by the TGA and protect the fair access to these medicines for all Australians.

Many ANPA members use homoeopathic medicines regularly when treating their clients. Homeopathy is within the scope of practice of naturopaths if the curriculum has been included in their training. Not that long ago all naturopaths were trained in homeopathy. Nowadays, homoeopathy is an elective program on many campuses in Australia. Homeopathy has been part of the education curriculum approved by the government for decades. In line with overseas education, homeopathy is included in the training of naturopathic physicians in both the United States and Canada.

Australia is a signatory to the World Health Organisation (WHO). The WHO includes homeopathy as a traditional health profession. Homeopathy is the healthcare of choice for millions around the world. Homeopathy is practiced widely in Europe, India, North America, South America, Africa and New Zealand. Australians deserve to continue to have the choice of using very low risk homeopathic medicines. Australians need to be assured that these medicines are available as the basic tools of trade prescribed by properly trained health professionals who can take a homeopathic case and prescribe the relevant and appropriate remedy. Homeopathic remedies are identified as 'very low risk' oral medicines as per the Low Risk Classification System. This is even lower risk than Oral Water Soluble Vitamin products that are classed as 'low risk'.

The TGA and the Health Ministry are at serious risk of losing credibility with international agencies if they continue to pursue the current approaches that consider de-legitimising homeopathic remedies in Australia. In addition, de-legitimising these medicines impacts the businesses and livelihoods of numerous manufacturers of these medicines.

The public deserve choice in their healthcare. This means the continuity of access to homeopathic medicines prescribed by those trained to practice homeopathy as well as products that can be self-selected over the counter.

Appendix 2 of the Low Risk Consultation fails to include the classifications of homeopathic medicines in Switzerland, India, France or countries of South America where Homeopathy is used widely. A Swiss report on homeopathy stated 'there is sufficient evidence for the pre-clinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared to with conventional treatment'. This report was excluded. It is the responsibility of the TGA to supply transparent and comprehensive information.

CONSULTATION OPTIONS

AROMATHERAPY PRODUCTS

Option 1: Maintain the status quo regulation of aromatherapy products.

The high level of confidence will be maintained for essential oils for the Australian public. Naturopaths use essential oils and expect the quality and good manufacturing standards to be maintained with no changes.

Health claims about aromatherapy oils must continue to be listed and regulated by the TGA to maintain GMP and protect the safety of the public.

Rapid entry to the market is not in the interest of the public. Continued scrutiny and vigilance for these products ensures higher standards in manufacture, reassures practitioners and continues to protect the public. The TGA is recommended to include this approval

REHYDRATION OR FORMULATED SPORTS PRODUCTS

Rehydration and formulated sports drinks include ingredients that are therapeutic and prescriptive. They should both be classed by the on the ARTG as medicines. The ANPA supports the clear demarcation between sports drinks and rehydration drinks so that the public who often self-select these products understand the different rationale for their use. Ideally, these products should only be sold in places where there is a health professional available to offer proper advice for the safe use of these products. Selling electrolyte drinks in the same category as non-alcoholic beverages and soft drinks is misleading to the public and health practitioners.

VITAMINS AND MINERALS

Option 1: Maintain the status quo regulation of vitamins and minerals.

HOMOEOPATHY

Option 1 - Maintain the status quo regulation of homeopathic products and

Option 2 - Serious therapeutic claims must be supported by scientific evidence.

Homeopathic medicines should be afforded the same opportunity to meet the criteria as other complementary medicines for traditional or scientific evidence. Regulatory monitoring is required to ensure public safety (e.g. adverse reaction monitoring). This includes ensuring that products sold in Australia are manufactured according to Good Manufacturing Practice. TGA's role is to protect public safety, not make value judgments about products Australians freely choose to use as therapeutic goods.

Option 3 - Exemption from listing in the ARTG and/or GMP - NOT SUPPORTED

Option 4 - Declare homeopathic products not to be therapeutic goods - NOT SUPPORTED

- These two options are contrary to many international jurisdictions.
- Australia's close regulatory partner ACSS Consortium in Switzerland is giving homeopathy the same status as conventional medicine by May 2017 when it comes to health insurance.
- The TGA consultation paper selectively excludes any mention of the Swiss situation, or the widespread inclusion of homeopathy in multiple other international jurisdictions.
- The TGA paper selectively excludes mention of multiple positive research published on homeopathy, including a positive Swiss Health Technology Assessment, which the TGA would have in its library
- Australians deserve the full and free access to homeopathic medicines. There should be no value judgements on a very low risk medicine that offers good outcomes.
- Homeopathy is a legitimate health care option, recognised internationally. Access to the medicines must remain available for all Australians.