THERAPEUTIC GOODS ADIMINISTRATION

Submitted electronically to:
Complementary Medicines Reform Section
Complementary and OTC Medicines Branch

Reforms to the regulatory framework for complementary medicines assessment pathways - February 2017

Submission from

The Australian Naturopathic Practitioners Association

Excellence, Leadership and Integrity in Naturopathic Health Care

March 28th 2017

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The Australian Naturopathic Practitioners Association (ANPA) is pleased to submit comments on the review of **Reforms to the Regulatory Framework for Complementary Medicines – February 2017.**

About 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 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.

Introduction

The ANPA is in support of the changes to the Regulatory Framework for Complementary Medicines. These changes will offer the public more confidence in the process of bringing to market complementary medicines.

The ANPA recognises a much more serious issue is not being addressed by the TGA reforms and may not be in the scope of the TGA. Wherever the public has access to the self-selection of CAM there is a problem when these medicines are accessed without a formal health consultation. The public is at risk in pharmacies or health food stores where there are no well-trained naturopaths on staff who can offer these proper consultations. Australian naturopaths have undergone extensive training in the therapeutic and safe use of complementary medicines.

The scope of practice of well-trained naturopaths includes specialised knowledge in core areas of herbal medicine and nutritional medicine. Naturopaths are ideally suited to provide the public with expertise for the correct and safe use of these medicines. Their full health

history and current health status would be taken into account to establish their unique need. The pubic may in fact need higher therapeutic doses depending on their condition. Without a consultation they may not be achieving the therapeutic levels required. Self-selection without consultation is fraught and the public may be missing out and delaying the resolution of their health problem because dosages are not adequate.

- *ANPA strongly advocates for the public to seek out a proper consultation with a well-trained naturopath in a dedicated area in the pharmacy or the health food store where a proper consultation can be offered.*

Members of the public seeking the use of CAM often have complex health complaints. These complex conditions need proper assessment before any supplement is self-selected. The CAM needs to be checked against any already prescribed pharmaceutical medications for safety. Correct dosage of the necessary and indicated CAM can then be monitored for that person's unique requirements.

The majority of adverse reactions from CAM occur in the context of self-selection of product and where a proper consultation from a well-trained naturopath has not been conducted.

The pubic continues to be at risk when the *majority of doctors and pharmacists are not properly trained in herbal medicines or nutritional medicines.* These health professionals are clearly out of their scope unless they have equivalent training to that of naturopaths in herbal medicine and nutritional medicines if they offer the public advice on these medicines.

- *ANPA recommends that doctors, pharmacists and other health practitioners who do not have a scope of practice that includes CAM to refer to well-trained naturopaths.*

CONSULTATION QUESTIONS

A risk based Hierarchy for therapeutic indications:

3.1 Do you agree with the proposed indication hierarchy and the criteria proposed to distinguish the three medicine pathways?

Yes, the ANPA is in support of these changes.

3.2 Do you envisage any difficulties with criteria used to include or exclude products from the new pathway?

No, we do not see any difficulties with these criteria.

3.3 What other considerations may need to be taken into account in implementing the new pathway?

The NHMRC levels of evidence hierarchy continues to relegate *Traditional Evidence* into an area that does not give full recognition to these valuable medicines that have been used for many centuries in Traditional Cultures. We are concerned that if these medicines do not have the relevant research they will not be protected, or included, or in fact excluded because of lack of higher levels of evidence according to the NHMRC. Funding for research of these medicines is minimal. Naturopaths prescribe herbal medicines often based on traditional herbal knowledge and historical Materia Medica.

It is not unreasonable to suggest that given the vast number of naturally occurring therapeutic substances available, that potentially safe, quality and effective medicines which may solely have traditional evidence to support their use for prevention, alleviation of a disease or even a restricted representation could potentially be excluded from this pathway due to lack of scientific evidence.

We acknowledge the TGA must be vigilant in ensuring assessment pathways that effectively evaluate complementary medicine claims and health risks, however, this needs to be balanced against enabling access to product and information that should not be unnecessarily limited by a lack of scientific evidence. This acknowledges that traditional evidence is based on an extensive history of use, often measured over thousands of years. This history provides an accumulated repository of systematic observation that underpins the use of these traditional medicine and generally supports the safe and effective use of a medicine over a long period of time.

3.4 Do you agree with the proposed methods to establish efficacy for products included via the new pathway?

Yes, we support the proposed methods.

3.5 Is the proposed approach to establish efficacy for current listed products that have a restricted representation exemption appropriate?

Yes, we agree to the proposed approach to establish efficacy.

3.6 Are the evidence requirements appropriate for the new pathway?

The evidence requirement is appropriate, however our concern is for Traditional medicines that may be excluded based on the evidence hierarchy. This is a serious problem for those practitioners who have the knowledge base to prescribe these medicines. The ANPA does not want to see traditional medicines marginalised.

3.7 Do the proposed levels of assessment align with the proposed risk based hierarchy?

Yes, we agree the levels of assessment align with the risk based hierarchy.

3.8 What other considerations may need to be taken into account in implementing the new pathway?

Issues for Traditional medicines as mentioned previously.

4.1 Are the proposed criteria for inclusion of an indication on the permitted indications list appropriate?

Yes, except the issues related back to use and incorporation of Traditional medicines.

4.2 What other considerations should be taken into account in implementing the permitted indications list?

There are no other considerations needing to be taken into account in implementing the permitted indications list.

4.3 Is Option 2 for selecting indication for inclusion on the ARTG and on product labels and promotional material suitable to address the objectives for permitted indications?

Yes, we agree it is suitable.

4.4 What other considerations should be taken into account in implementing the permitted indications list?

No other considerations need to be taken into account.

5.1 Do the proposed criteria for the use of a claimer address the objectives for the recommendation?

Yes, we agree they do address the objectives for the recommendation.

5.2 What other considerations should be taken into account in implementing this recommendation?

No other considerations need to be taken into account.

5.3 Will the use of a claimer on complementary medicines have any unintended consequences?

We strongly advocate for the public to be directed to properly trained naturopaths. We believe the public with little health knowledge self-select products often without proper consultation and in the absence of the context of their health condition. We believe that public are at risk in spite of more specialised labelling on product. Claimers can in fact give the public a false sense of security when making a self-selection of a product off the shelf without a proper consultation with a well-trained naturopath.

5.4 Should the claimer be presented as a visual identifier as well as a statement?

A visual identifier is good as well as a statement. The statement always needs to include wording that makes a recommendation to see a well-trained naturopath.

5.5 Do you have any views on the possible wording or design of the label claimer?

No views on the design, but we do recommend a statement that recommends a full consultation with a well-trained naturopath.

5.6 What other considerations should be taken into account in implementing the claimer?

Wherever there are claimers there needs to be the additional vigilance for the public who often have complex health conditions. Every establishment that sells CAM should have on staff properly trained naturopaths. Or a label claimer that says ask your '**qualified CAM health professional'.**

6.1 Is the proposed process and mechanism to provide market protection for new ingredient appropriate?

Yes, we understand it to be appropriate.

6.2 Is the proposed 2 year period of exclusivity an appropriate period to reward the innovation and allow for return on the investment made?

Yes, we agree this seems reasonable.

6.3 Should multiple applicants be able to apply for exclusive use of the same new ingredients using their own data during the exclusivity period?

No multiple applicants. A company needs protection with an exclusivity period.

6.4 What other considerations should be taken into account in implementing the proposed incentive for innovation?

None that we can offer.

6.5 Is the proposed process and mechanism to provide data protection for efficacy data appropriate?

Yes, we agree it is appropriate.

6.6 Is the proposed 3 year data protection period for efficacy data appropriate to reward innovation and allow for return on the investment made? Is it excessive?

This is a difficult question to answer not knowing a manufacturers business plan. We do not think it is excessive.

6.7 Should protection be available for new uses of existing substances and / or be available for information that is not in the public domain?

Yes, if a company has done more research that provides new evidence it is reasonable to offer protection.

6.8 What other considerations should be taken into account in implementing the proposed incentives for innovation?

The considerations seem to be adequate.

7.1 Do you agree with the proposed principles to support transition arrangements?

Three years seems a reasonable time frame for the transition period. A waiver of the application fee during the first 18 months seems a generous offer for manufacturers.

7.2 What other factors should we consider?

While this reform is focused on the CAM in the over-the-counter domain, the risks to the public not easily accessing information from properly trained naturopaths when they are seeking to use over the counter formulations continues to be problem. Our strong recommendation is for the government to incorporate an education campaign as these changes are rolled out. This education campaign addresses what the changes are, as well as the continued risks to the public if they do not include a proper consultation from a well-trained naturopath.

Some CAM manufacturers have created a specific range of *Practitioner Only Products* (POP)'s. These products are not over-the-counter products for self-selection by the public. They do require a formal consultation before they are prescribed. The ingredients in these products are often at higher dosage ranges. The ANPA would recommend that these POP's become formally recognised in the new TGA reforms.