Re. Submission: Australasian College of Natural Therapies Response to the TGA Consultation Regulation Impact Statement regarding the regulation of therapeutic goods to the general public.

To Whom It May Concern

The Australasian College of Natural Therapies has provided high standard, academic training in natural therapies disciplines for over 20 years. Our Advanced Diplomas of Naturopathy, Nutritional Medicine and Western Herbal Medicine are approved by the Australian Government and independently audited by TEQSA and ASQA to ensure they meet the relevant national standards for Natural Therapies education.

In response to the TGA Consultation Regulation Impact Statement regarding changes to the regulation of therapeutic goods to the general public, The Australasian College of Natural Therapies would like to voice strong opposition to the proposed changes outlined in proposals 5 and 6 as follows:

Currently Naturopaths are not covered by the National Registration and Accreditation Scheme (NRAS). Within the TGA Consultation Regulation Impact Statement (CRIS) it states "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". It then states that due to limited resources the TGA cannot assume that non-NRAS health professionals meet these standards. This assumption is misleading and incorrect as the majority of Naturopaths and Western Herbalists belong to professional associations which require members to be adequately insured, have minimal standards of education, adhere to ongoing professional development and adhere to ethical standards (Lin et al., 2009).

Under the current self-regulatory model (outlined above), practitioners are well qualified to critically evaluate advertising material relating to therapeutic goods (including relevant class III medical devices) and the TGA has provided no evidence that the current arrangement has posed a risk to the public. Furthermore within the TGA CRIS it states that about 300 to 400 complaints occur about advertising of therapeutic goods and that most of these are lodged by the therapeutic goods industry, not the general public. If the aim of reform is to "manage public health risks posed by exposure to false, misleading and socially irresponsible advertising of therapeutic goods", then it is clear the public are not voicing this concern. The argument that lack of public complaint is due to the complexities involved in doing so is inadequate, as there is no solid evidence provided to substantiate this assumption.

The Australasian College of Natural Therapies agrees in principle with the TGA goal of ensuring public safety via the dissemination of accurate and balanced information regarding therapeutic goods, our concern is the proposed amendments outlined in proposals 5 and 6 will increase the risk of
including anthropometric devices (skin fold callipers) and urinalysis dipsticks. These tools play a role in evidence-based practice for our graduates, as they do for other health professionals including physiotherapists, dietitians, medical doctors and exercise physiologists. Having access to training and references from manufacturers is important (as outlined in point 1), however, our graduates will be unjustifiably financially disadvantaged by option 2, which will limit advertisement of these tools as a part of the practitioner's professional service.

Proposal 6

1. Option 2 would limit important information for therapeutic medicinal products. Advanced Diplomas of Naturopathy, Western Herbal Medicine and Nutritional Medicine graduates are highly trained in the disciplines of nutritional and botanical medicine. This training provides critical evaluation skills and unbiased scientific data relating to the clinical efficacy and safety of complementary medicines. Removing access to advertising material from manufacturers of complementary medicines, including practitioner only brands (outlined above), will unfairly limit data relating to the evidence behind such products. A key component of appraising complementary medicines is accessing information about manufacturing processes e.g. molecular distillation of fish oil to remove mercury and other toxins. Our graduates offer the general public greater insight into the meaning of such claims, as they are trained in understanding the complexities of nutritional science. Access to this type of information allows practitioners to select products that are safe and environmentally responsible, thereby reducing risk to the public.

2. The general public seek access to specialists in the field of complementary medicines for advice. Our graduates provide these specialist skills and membership to professional associations ensures ongoing adherence to professional ethics and professional development. If our graduates do not have access to product information, the general public may be more inclined to self-prescribe and self-diagnose. At the Australasian College of Natural Therapies – it is our considered opinion (with over 20 years' experience in complementary medicine education), that self-diagnosis and self-prescription pose the greatest risk to the public. The proposed 'option 2', will therefore place the public at greater risk of delayed medical attention, adverse reactions, drug-nutrient-herb interactions and so on.

3. Our graduates will be financially disadvantaged by the proposed 'option 2', because it will dilute the difference between our highly trained health professionals, to an untrained member of the public. This may provide a lesser incentive for the general public to seek the services of our graduates.

4. The point raised in (3 – above), may financially affect The Australasian College of Natural Therapies, due to reduced enrolments into our Advanced Diploma programs.

5. Practitioners who are categorised under the NRAS, may be targeted (via advertising) by companies that produce complementary medicines and devices. However, a large number of these practitioners will not have had
References