



**CHC Submission to the National Health and Medical Research Council on
Complementary and Alternative Medicine Resources for Clinicians**

To:

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From:

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Introduction

The Complementary Healthcare Council of Australia (CHC) welcomes the opportunity to provide comment on the two draft documents prepared by National Health and Medical Research Council on Complementary and Alternative Medicine Resources for Clinicians, dated July 2013.

The CHC is the peak industry body representing companies involved in all facets of the complementary medicine products industry from research organisations, sponsors, manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. The CHC is committed to a high growth and sustainable complementary medicines industry. We promote industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality, contributing to improved population health outcomes.

Complementary medicines and natural healthcare products include vitamins, mineral and nutritional supplements, special purpose foods, herbal and homoeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. Complementary medicines comprise traditional medicines, including traditional Chinese medicines, ayurvedic, and Australian Indigenous medicines. Complementary medicines are generally available for self-selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health.¹

There are over 300 complementary medicine companies in Australia generating around \$2 billion in annual revenues. Australian companies export around \$200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and The America's, and this continues to grow at a higher rate than domestic consumption.² In Australia the industry generates around 5,000 highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at \$US 83 billion annually.³

The CHC is the principal reference point for our members, government, media and consumers to communicate balanced information relating to complementary medicines and as such we would be interested in assisting with the dissemination of information to clinicians about evidence, effectiveness and potential risks of complementary medicines, subject to modification to sections of the document, as noted throughout this submission.

¹ Source: TGA, <http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm>

² CHC Complementary Medicines Industry Audit May 2011

³ The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, pp13

Specific Comments

The CHC commends the NHMRC on releasing a document that aims to encourage health professionals to communicate openly and respectfully to consumers about the current available evidence for complementary medicines.

1. Is the information and questions included in 'Talking about Complementary and Alternative Medicine - a Resource for Clinicians' (eight page document) useful and relevant?
 - a. Information on CAM: the term complementary medicine is referenced in the document from a US based resource that classifies both complementary medicines and therapies under the umbrella term 'Complementary Medicine'. Complementary medicines are defined in Australia as per the *Therapeutic Goods Regulations 1990* as: 'a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use'. It is important to note that the strong body of evidence associated with complementary medicines, as defined by this term, is distinct to the body of evidence that may be available for a variety of complementary and alternative practice modalities.
 - b. Questions on CAM (boxes page 3) Details of CAM practitioners: the CHC submits that the line of questioning under this section is inappropriate and unrealistic given the average time provided to a consumer for a conventional medical consultation. The questions asked of CAM treatment are not generally asked of for conventional treatments; for example costs per session or qualifications. Perhaps more relevant would be prompting open discussion around any adverse reactions experienced by either CAM and conventional drug interactions or CAM and CAM interactions that may not have been picked up through prompting on the client details form.
 - c. Information on discussions about evidence (page 4)
 - d. Questions on discussing evidence and reliability of information (box on page 4)

The Government regulator for complementary medicines is the Therapeutic Goods Administration (TGA), a division of the Department of Health and Ageing. The TGA recognise both scientific evidence and evidence of traditional use for complementary medicines (substances/products).

Traditional use refers to documentary evidence that a substance has been used over three or more generations of recorded use for a specific health related or medicinal purpose.⁴

⁴ Guidelines for levels and kinds of evidence to support indications and claims for Non-Registerable Medicines, including Complementary Medicines, and other Listable Medicines V1.1 April 2011

Traditional medicines are based on an extensive history of use, often measured over thousands of years. The use of traditional medicines is becoming more widespread in developed countries and this history provides an accumulated repository of systematic observation that underpins the use of these medicines. This evidence is utilised to both support the safety of complementary medicines, support indications for therapeutic use, and when TGA undertake a listing compliance review on these medicines.

The CHC considers that it is misplaced to consider that consumers may be using complementary medicine in place of proven effective conventional medicine. In fact the document does not acknowledge the potential well informed choice of the consumer to use these medicines.

- The CHC advocates for further research to be undertaken in establishing an ever-growing body of evidence for complementary medicines. We agree that consumers should seek to be informed about the best possible treatment options available to them. However, the line of questioning prompted by this section of the document places an unrealistic burden upon the consumer in terms of seeking and reviewing scientific evidence about complementary medicines. It does not consider that this choice may be because conventional treatment may be cost prohibitive, inadequate or be associated with significant side effects. Clinicians should be encouraged to acknowledge the reasons consumers seek CAM treatments, which may go some way to encourage consumers to provide further information to clinicians around CAM use.
- The discussion about evidence should also highlight the role of the TGA in evaluating the effectiveness of registered complementary medicines and how the consumer may identify these medicines with an AUST R on the label. The majority of listed complementary medicines are also assured in terms of quality and safety of the ingredients used, discussed further on page 6. To select only the type of information presented under this section of the document does not serve as a neutral piece of information for consumer use.

The CHC suggest that the above line of questioning be replaced with consumer-friendly information, such as a handout, outlining where to source appropriate evidenced based information on complementary medicines. The CHC suggests online reference tools such as the Natural Standards database for its consumer portal that visually rates the strength of different types of available evidence and includes a drug/ CAM interaction checklist. Additional resources are recommended on page 6.

e. Information on discussing effectiveness (page 5)

The CHC supports that consumers make informed and evidence based decisions about their health. The CHC suggests that consumers are well versed and informed in navigating marketing claims for a range of products they choose and rather than prompt discussion about marketing claims that may

breach the Advertising Code - regulated by the TGA, communication would be better spent on identifying any potential interactions with therapeutic goods.

It should be acknowledged that a consumer will be informed from a variety of sources, including those based in evidence, but may also involve individual choice, shared decision making with complementary and allied healthcare professionals and should involve a degree of respect for patient autonomy.

It is well established that few complementary medicines have undergone the same level of multi-centre, randomised controlled trial (RTC) as pharmaceuticals and indeed whether RTC is the gold standard or only relevant standard to which complementary medicines should be measured. This does not mean though that they won't be effective for the individual. Clinicians should be encouraged, through a patient-centred care approach, to document any positive responses even if mainstream evidence may be lacking.

f. Information on discussing potential risks (page 5)

The CHC supports that complementary medicines, like pharmaceutical drugs, have potential risks associated with their use. We support the NPS Medicine Wise finding that many consumers are not aware of the potential side effects of some complementary medicines or the risk of interactions with conventional medicines.

The CHC reiterates that rather than focusing on one or two complementary medicines adverse interaction profiles, one of which could be considered rare and idiosyncratic in its reaction, clinicians would be better served to point consumers in the right direction for a full list of known and common interactions with complementary medicines and conventional treatments.

Considering over 75% of Australians use complementary medicines and the majority of consumers can name the exact CM product they purchase and why², clinicians should consider becoming familiar with potential benefits and risks associated with complementary medicines or refer to a resource when they are uncertain about safety issues. One such resource, the Natural Standards Database contains an interactions tool for consumers or clinicians to check a substance against another (nutrient/complementary medicine/pharmaceutical).

- “The National Asthma Council Australia warns that Echinaceamay trigger an allergic response or exacerbate symptoms when used by asthma patients” It should be noted that a 2013 overview of systematic reviews investigating adverse effects of herbal medicines concluded that only minor adverse effect were noted for Echinacea species.⁵ Theoretically, individuals sensitive to members of the *Asteraceae* (Compositae) plant

⁵ Posadzki P, Watson LK, Ernst E. Adverse effects of herbal medicines: an overview of systematic reviews. Clin Med 2013 Feb; 13(1):7-12.

family may be more likely to experience allergic responses⁶ and therefore the herb is contraindicated in people with allergies to the *Asteraceae* (Compositae) family.⁷

- The statement that “St John’s Wort can reduce the therapeutic effects of many pharmaceutical medicines including anti-depressants”, should refer to the available evidence that based on *Hypericum perforatum* pharmacology suggest “it may interact with drugs....and concomitant use of drugs that elevate serotonin levels, such as tricyclic antidepressants or SSRIs, may result in additive or synergistic effects and increase the risk of serotonergic syndrome”.⁷

g. Information on regulation of CAM in Australia (page 6)

- Most but not all complementary medicines are classed as listed medicines, where they only contain ingredients that have been determined as being of low risk and only make limited therapeutic claims⁹, the footnote to the National Asthma Council Australia Asthma and Complementary Medicines Guide appears to be incorrectly referenced.
- This NHMRC resource may like to refer consumers to the TGA listed medicines information booklet that provides detailed information about listed medicines, including complementary medicines, supply, regulation and ‘what to tell health professionals’.⁸

h. Further information for clinicians and patients (page 7)

The CHC supports the NHMRC using a variety of evidence based resources for inclusion in the publication. As a minimum, we recommend the Council include the following references in the NHMRC publication and support the list of references outlined in the NICM submission.

- Braun L, Cohen M. Herbs and natural supplements – an evidenced based guide, 3rd edition. Sydney: Churchill Livingstone Publishers, 2010

Designed to meet the needs of healthcare professionals practicing in Australia and New Zealand and one of the few “quality resources” mentioned in the NPS Medicine Wise CAM information publications.

- Kotsirilos V, Vitetta L, Sali A. A guide to evidenced based integrative and complementary medicine , Sydney: Churchill Livingstone Publishers, 2011

Includes at the end of each chapter NHMRC guidelines to summaries the level of evidence for each of the proposed therapies. There is also a section entitled “Clinical tips handout”,

⁶ Echinacea allergy information - Natural Standard (www.naturalstandard.com)

⁷ Braun L, Cohen M. Herbs and natural supplements – an evidenced based guide, 3rd edition. Sydney: Churchill Livingstone Publishers, 2010.

⁸ Source: <http://www.tga.gov.au/consumers/information-listed-medicines-tga-role.htm>

which permits the practitioner to print this consumer-friendly information to give to patients.

- Natural Standard Database - Resource on Integrative medicine
Natural Standard provides evidence-based, peer-reviewed, consensus-driven, decision-support tools for sponsors, manufacturers, suppliers, retailers, practitioners and consumers. <http://naturalstandard.com/>
 - IM Gateway – Resource on Integrative medicine
Evidence-based, peer-reviewed information collected from over 700 medical and complementary medicine journals, summarised into clear concise monographs. www.imgateway.net
 - National Institute of Complementary Medicine (NICM)
NICM is the premier national academic research centre dedicated to complementary and alternative medicine. It was established to provide leadership and support for strategically directed research into complementary medicine translation of evidence into clinical practice and relevant policy to benefit the health of all Australians. www.nicm.edu.au
2. Is the information included in Talking to your patients about Complementary and Alternative Medicine (one page document) useful and relevant?

The one page summary document covers key messages that clinicians could focus on when discussing CAM with their patients. However, a distinction should be made between complementary medicines and complementary and alternative therapies as mentioned earlier at point 1a.

The CHC again submits that reference could be made that scientific evidence is not the only parameter that the Australian Medicines regulator takes into consideration and that the safety and quality of the medicines the consumer may choose is well established, also mentioned in point 1 of this document. The NHMRC resource should encourage clinicians to take into account benefits versus risk as well as the consumers expectations (preventative/ supportive/treatment) when considering complementary medicine use. If required, further advice can be sought from a qualified complementary/integrative healthcare professional.

3. Once these two documents are published, what is the best way for you to receive them? For example, print, email, editorial in a relevant journal, health professional organisational newsletter, e journal etc.

Subject to considerable amendment to these documents, the CHC would be able to assist in their dissemination through our membership base (including complementary/integrative healthcare professionals and consumer database), other complementary healthcare professional organisations, and NGO's (non-government organisations). The CHC may consider including reference to such resources (once finalised) in future CHC position statements and on the CHC website.

4. Would your organisation be interested in incorporating the two documents into training or professional development programs?

Subject to addressing the concerns raised in this submission, the CHC may support further dissemination of these documents within its professional development and educational programs.