Submission on the draft guideline: Evidence required to support indications for Listed medicines (excluding sunscreens and disinfectants).

To:

Project Officer

Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

ocm@tga.gov.au

From:

Dr Wendy Morrow

Executive Director

Complementary Healthcare Council of Australia

PO Box 450

MAWSON ACT 2607

Date:

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Introduction

Thank you for the opportunity for the complementary medicines industry, through the Complementary Healthcare Council of Australia (the CHC), to provide comment on the government's consultation document *'Evidence Required to Support Indications for Listed Medicines (excluding sunscreens and disinfectants)*' ('the document').

The CHC acknowledges that this consultation is in response to Recommendation 3 of the Informal Working Group Examining Complementary Medicines, as outlined in the 'TGA Reforms: A Blueprint for TGA's Future', dated 8 December 2011. The recommendation was to 'Update Guidelines for levels and kinds of evidence' and include in the regulation' and received in principle agreement from Government with further consultation to be undertaken with stakeholders.

The Australian National Audit Office Performance Report No3. 2011-2012 (ANAO) recommendations, as accepted by the Department of Health and Ageing, also recommended the timely completion of key guidance material for complementary medicines by providing the target date for completion and publication of each key guidance document. The ANAO objective of this recommendation was to achieve a level of clarity and certainty for industry on how to engage with the regulatory system, provide a level of assurance for consumers and to strengthen the perceived regulatory integrity of the TGA.

The enclosed submissions have been prepared by the CHC within the timeframe stipulated by the TGA. **In the CHC's view, the timeframe for submission is inadequate and unreasonable**. In the circumstances, these submissions include reference to the provision of further details to be consulted with industry. The CHC wish to register our disappointment that the request to (reasonably) extend the deadline to 8 June was rejected by the TGA. The CHC recommends members of the Office of Complementary Medicines/Industry Consultative Group (OICG) engage with Industry meaningfully to assist with the redrafting of the guideline.

Overall, the CHC considers the document **excessively onerous, complex and unworkable for industry** and recommends **extensive consultation be undertaken on the rewrite of the document**. The document contains a number of proposed changes, including new concepts and requirements not previously raised or discussed with the CM industry, yet which will have a **significant impact, most notably financial, on industry members and therefore consumers.** The CHC provides an industry estimate on the Regulation Impact this will have on industry (see att. 5a) and provides a number of estimates from individual member company's in-confidence to you (see att 5. 1-9).

Please note: the CHC are in the process of finalising its submission in respect of the draft and that part of that submission will be submitted by the closing date. In general terms, the CHC's submission includes sections critical of the draft and sections setting out necessary improvements/alternatives to the draft. The sections of the CHC submission setting out the improvements/ alternatives will not be fully completed by the closing date. The CHC reserves its right to provide additional and supplementary improvements/ alternatives to its submission/s after the closing date.

An Alternative Model

The CM Industry proposes an alternative model that is designed to be a simple, clear and concise legislative entry to underpin the requirement to hold appropriate evidence to support indications and claims. This entry would deal with guidance by reference: e.g. that the evidence held meet the standards specified, and be provided in the format described, in the current version of the Australian Regulatory Guidelines for Complementary Medicines (ARGCM). This approach would give legislative underpinning to the evidence requirements while allowing the guidance document to be amended and updated, in consultation with industry, as necessary.

This submission provides draft models prepared by industry of the standards of evidence appropriate to different types of claims and indications; model templates; and a model guidance section for incorporation into the relevant section of the ARGCM. Due to the severe time constraints, it must be stressed that these are preliminary drafts and more time is required for consultation with industry to explore workable solutions.

Attached to this submission are:

- A detailed analysis of the draft guideline, prepared by the peak industry associations (att. 1);
- An alternative model prepared by industry, including templates (att. 2-4);
- Preliminary information on the effects on industry to be considered in the Regulation Impact Statement (RIS) (att. 5. 1-9).

<u>Key Concerns/ Recommendations:</u>

Insufficient time: It is disappointing that Industry was afforded only 5 weeks consultation on such an important proposal for reform. This is inadequate to prepare a fully informed response on the proposed changes, which have the potential to adversely impact on the complementary medicines industry and the local manufacturing industry and therefore current and future jobs. We understand that where a change in regulation is required a full Regulation Impact Statement (RIS) must be conducted and provided to the Office of Best Practice Regulation (OBPR). However, given that the legislative change may not occur until 2013, **such a short timeframe for assessment is totally without precedent and is viewed as unacceptable.** Industry therefore requests extensive meaningful consultation be undertaken on the rewrite of the document.

Principles-based: The legislated standard should be principles-based, concise and straightforward. Additional guidance and reference material should be adopted by reference. Please see att. 2 - 4 for an example prepared by industry for inclusion within the ARGCM.

Ineffective response: Without increased and effective enforcement activity, the proposal will have little or no effect on non-compliant sponsors. In contrast, it will have a major adverse impact on the vast majority of sponsors who do comply with the requirements. It is conceivable that the cost burden of the proposal could force smaller compliant Australian sponsors to close down. It could be anticipated that sponsors could move product manufacturing offshore, for online purchase, or could de-list and present them as foods (see att. 5a).

Context: Industry is aware that the TGA is working on a number of reforms regarding complementary medicines, including the Coded Indications Project, which the ANAO also recommended be finalised as soon as practicable. As this important and parallel reform are yet to be circulated for consultation, industry can only judge the impact of the evidence guideline in isolation and this makes it difficult to provide an informed response.

Disproportional: The Council of Australian Governments (COAG) principles state that government action should be proportional to the issue being addressed. The requirements laid out in this document appear to be **equivalent to or higher than those for registered over-the-counter medicine, yet are applied to listed medicines which may only carry list able indications/claims**. The CHC considers this to be inappropriate for listed medicines which are low risk by definition[1].

Expert requirement: The CHC believes that the summary of evidence should be judged on whether it meets the stated requirements, not on whether it has been prepared by a prescribed 'expert'. In this regard, the TGA has proposed an overly prescriptive qualifications profile that is not only out of step with available credentials across the industry but does not even mirror the profile employed by the TGA. The CHC strongly states that it is the sponsor's responsibility to appoint a suitably qualified and experienced person to perform this role. Please see att.3B for an alternate approach to the expert requirement.

Indications/Claims: The document **fails to clarify the distinction between an indication and a therapeutic claim.** By stating that 'the reference to "indication" in this document includes a "claim" as that expression is used in paragraph 26A(2)(j) and subsection 28(6) of the Therapeutic Goods Act' , does not address the ambiguity in interpretation. There needs to be clear distinction between an indication (possibly explain as a "health benefit" or "implied health benefit" claim) compared to a "marketing claim/statement", e.g. "Number one selling women's multivitamin".

Reporting requirements: The draft appears to **require a full systematic review of every ingredient and/or every indication for every product.** Sponsors of multi-ingredient products would be severely affected by such a cost burden, with NO apparent benefit to the regulator, the industry or importantly the Australian consumer. **The CHC therefore considers that this does not achieve the Blueprint/ANAO stated objective.**

Biomarkers: The CHC suggests that mixing specifications of requirements for study populations into examples is not acceptable. Specific requirements for biomarkers should be in one section. The recommended 10-15% range is still within the normal range of health factors, trials using a population group with elevated biomarker levels but are otherwise healthy should be acceptable to use as supporting evidence if justified within the evidence held by the sponsor**. Industry do not agree with this proposed table and seek further consultation and discussion on this important issue**.

Algorithms: the requirements to prepare complex algorithms, and to calculate clinical significance based on theoretical and unproven methodologies, **are inappropriate for low-risk medicines.**

[1] http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm

Repetition: If respected authorities such as governments, the Wold Health Organization (WHO) and the Cochrane system have already produced well-constructed and robust assessments and systematic reviews, it would seem completely unnecessary for Sponsors or the TGA repeat the process many times over simply adding cost burden to the end consumers with NO apparent advantage in safety and quality of the products.

Anti-competitive: This proposal is highly prejudicial to small to medium businesses and could be seen as anti-competitive on several grounds. It also adds a significant barrier to entry in the terms of additional regulatory burden to all businesses in contrast to best practice regulation benchmarks.

Harmonisation: The requirements of the document appear to be **at variance with those of comparable regulators such as Health Canada.** The Baume report[2] (1991) recommended that Australia reflect global practices rather than set up another set of Australian regulations.

General Concerns/Recommendations:

Clarity: The overall readability of the document is not user friendly and is not comprehensible to the average sponsor.

Straightforward: Requirements should be clearly spelt out and not added in as examples only.

Advisory Statements: There is no place for advisory statements in a guideline for evidence. The CHC recommends that section 3 should be removed from the document.

Structure and function: the document fails to consider the use of widely accepted evidence, such as pharmacopoeias and government publications, to support generally recognised claims, such as structure- and function statements. Structure-function statements that imply a health benefit should be considered and included in this document.

RDIs: The draft fails to clarify the dose, ie the percentage of RDI, required to permit a vitamin or mineral to carry claims. The CHC recommends the reinstatement of the 10% and 25% levels to permit structure and function and supplementation claims, respectively.

References: The list of reference sources (Appendix 1) has not been updated or expanded to include currently available authoritative works. Please see att. 4, Appendices 1A and 1B, for an expanded list of suggested references.

[2] Baume P. A question of balance: report on the future of drug evaluation in Australia. Canberra: Australian Government Publishing Service, 1991.

Summary of recommendations:

1. The legislated guideline should be a concise, transparent and principles-based document.
2. Guidance material on the application of the guideline should be adopted by reference throughout the ARGCM.
3. The TGA is requested to consider the alternative model, with associated appendices, prepared by industry. Please note: further consultation is requested on the finer detail of these documents.
4. Appropriate and extensive consultation is required and re drafting is recommended with members of the OICG.
5. The current regulatory reform projects, including labelling, coded indications, need to be coordinated with that of the evidence requirements so that Sponsors can incorporate all necessary changes at the same time.
6. The need for any expert review pre listing be removed.
7. Requirements for algorithms and clinical significance should be removed.
8. Provision for the use of acceptable reference works systematic reviews should be added.
9. Advisory statements should be removed.
10. The list of references should be updated and expanded.
11. There should be minimal impact on products already in the marketplace. The new format for the summary of evidence could be so constructed that additional information can be appended to existing summaries.

Suggested timeframes for further consultation with industry

- The CHC insists that after further consultation with industry on the rewrite of this document to develop an appropriate and acceptable document, a commercially realistic implementation period be implemented in recognition that other major reforms are underway and parallel reforms such as the Coded Indications Project are only in developmental stages yet will have a impact upon the implementation of the said document.
- A transition period of a minimum 5 years would be required with reform of this type of magnitude.
- An opportunity for annual reviews should be incorporated so that the TGA and the association bodies could review the impact these changes may have made on Sponsors and on the consumer.
- A significant period of time should be permitted in which sponsors can amend and/or update the Australian Register of Therapeutic Goods (ARTG) at no cost.

The CHC thanks you again for the opportunity to make this submission. The CHC will continue to work proactively in providing feedback to the TGA on key guidance documents, including the priority update of the ARGCM and appropriate Evidence Guidelines for listed medicines. The CHC encourages a closer examination of the intersection between evidence based-industry focused research and robust policy development to achieve lasting outcomes that will provide for improved population health.

Yours sincerely,

Dr Wendy Morrow

Background

The CHC is the peak industry body for the Complementary Medicines (CM) Industry, representing the entire industry supply chain including; manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. The CHC is committed to a high growth and sustainable CM industry. Uniquely placed as the voice of both Industry and consumers we promote industry advancement whilst ensuring consumers have access to CMs of the highest quality, contributing to improved population health outcomes. We are the principal reference point for our members, government, media and consumers to communicate about issues relating to the CM industry.

Complementary medicines and natural healthcare products are vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic 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[3].

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 higher rates than domestic consumption[4]. 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[5].

Production of complementary medicines in Australia is a substantial industry, with 59 TGA approved manufacturing facilities for Listed medicines nationally (including CMs, sunscreens and over-the-counter medicines). Over 75% of Australians use complementary medicines, so it is not surprising that the majority of consumers can name the exact CM product they purchase and why.[6]

Australia's complementary medicines industry continues to lead the world in the development of global benchmark standards in safety, quality and efficacy.

[3] Source TGA, http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm

[4] CHC Complementary Medicines Industry Audit May 2011, available by request

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

[6] My Opinions Research for CHC May 2011.