CHC Submission -The Australian Regulatory Guidelines for Complementary Medicines (ARGCM) Part C: Evaluation of Complementary Medicine Substances for use in Listed Medicines

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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 consultation draft: *Australian Regulatory Guidelines for Complementary Medicines (ARGCM) Part C: Evaluation of Complementary Medicine Substances for use in Listed Medicines*, April 2013.

The Complementary Healthcare Council of Australia (CHC) is the peak industry body for the complementary medicine industry and is unique in representing the entire supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers.

Complementary medicines and natural healthcare products include vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products and natural cosmetics using herbals and botanicals. The term 'complementary medicines' includes traditional medicines: Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines.

The CHC provides comment to Part C of the ARGCM and will continue to work proactively with the TGA to enhance the complementary medicines regulatory framework.

General Comments

The CHC, in general, supports the restructure of the ARGCM from parts 1,2,3,4 & 5 to parts A,B,C & D (with attachments) to increase the useability of the guidelines and to ensure the information provided is reflective of current regulatory requirements. The CHC notes that further, more comprehensive reviews of the ARGCM are expected in the next 12-18 months to reflect changes through progression of reforms, including changes to the Electronic Lodgement Facility. With the suite of complementary medicine reforms underway, it will be essential to review the individual sections of the ARGCM again, in consultation with industry, particularly when the evidence requirements for listed medicines and the permitted (coded) indications project have progressed through consultation and any applicable legislative amendments have taken place.

In general, the CHC finds the draft ARGCM Part C is relevant to the needs of industry and, in the main, is clear and easily understood.

The CHC provides detailed comment to the draft ARGCM Part C in Attachment A (confidential).

Specific comments

1. **Determination on the application** (flow chart page 12 & page 15). The CHC understands the determination process may involve others within the TGA after the conclusion of the evaluation phase. These 'decision points' should be clarified in the document to assist industry expectations with regard to timeframes and transparency of process, especially as no statutory timeframes currently apply to the evaluation of a complementary medicine substance for use in listed

medicines. Suggested amendments have been provided in the word version of the guidance document attached to this submission.

2. **Determination on the application** (flow chart page 12 & page 15). 'If the application is unsuccessful, the applicant will be advised as soon as practicable and provided the reasons why the application was not successful. If the applicant is dissatisfied with the outcome, they may arrange a meeting with the TGA to discuss the matter'. The CHC suggests that guidance on appeals mechanisms and review of decisions should be provided in this section of the document and relevant links to the TGA webpages provided.

3. **Overview of the evaluation process** (page 11, 15 & flow chart page 12). The TGA should allow for an expedited evaluation pathway for new substances that have been approved by other regulatory bodies for example, Health Canada, EU etc. The evaluation time for these substances should be shorter and more predictable. The CHC suggests that not all new ingredients should go through the full process as described on Page 12.

4. **Provide timeline for approval.** Uncertainty over timelines for approval of a new substance application is a barrier to brining new complementary medicines to the Australian community. The TGA could adopt a model similar to that used in the pharmaceutical and OTC (over-the-counter) sector where the approval process proceeds through a statutory timeframe, with certain exceptions commensurate to the unique complexities of complementary medicines.

5. **Compositional guidelines for complementary medicine substances.**

A key priority in the CHC Strategic Plan is to encourage innovation for industry growth. A Compositional Guideline is provided as part of a new substance application that has undergone evaluation and approval by the OCM, with advice generally being sought from the Advisory Committee on Complementary Medicines (ACCM). Once this process has been completed, the Guideline is currently required to undergo broad industry consultation, which allows amendments to be made to the original compositional guideline.

The CHC propose a variation to this process. That is, when a sponsor applies to the TGA for evaluation of a new complementary medicine substance and a compositional guideline is generated that defines the substance that has been evaluated and approved for use in Australia, the compositional guideline should be published on the TGA website as a final version. This proposal does not change transparency of either the process or information, with the CHC supporting that all compositional guidelines be published to enable industry to refer to the approved specifications as necessary.

If another stakeholder wishes to amend the final compositional guideline, they can still do so by applying to the TGA. The amendment would need to include justification and would be evaluated by the TGA and would include a still-to-be-determined evaluation fee. The original sponsor of the substance should be invited to comment before any decision is made, to ensure that the amended compositional guideline accurately reflects the substance that has been evaluated. If the amendment is considered to be appropriate, the final compositional guideline would be updated to reflect the

change and re-published on the TGA website. This would not prevent another sponsor from submitting a closely-related but distinct substance with its own specific compositional guideline, for separate assessment.

A compositional guideline for a pre-existing complementary medicine substance.
Where a substance is already used in a medicine in Australia, but there exists neither a default Standard nor a compositional guideline to define the substance, issues of identity and quality can become problematic. To remedy the situation, the TGA may generate a compositional guideline for the substance in question. In this case it is appropriate for the regulator to issue a draft compositional guideline and call for public consultation as this enables the TGA to ascertain the precise substance and test methods in current use.

Once the consultation period has closed, the draft should be amended and a final version published on the TGA website within 8 weeks. In instances where the TGA do not adopt the suggested changes the CHC suggest that to ensure transparency, the TGA publish the reasons for not adopting industry recommendations.

Procedure for amending compositional guidelines (page 25). Compositional guidelines should be living documents that can be amended for a prescribed fee when necessary. The industry associations, sponsors, or TGA officers, may request an amendment to a compositional guideline, for example to allow or include the use of new or better test methods. In each case, justification must be provided to support the amendment.

Industry requires an efficient process whereby the original applicant can apply for a change to a compositional guideline as a result of changes in manufacturing process or specifications. This process would be reflective of the approach taken of the various pharmacopoeias where regular updates to monographs are routine practice. There is also a need to include a detailed process map of the review process for an existing draft or finalised compositional guideline in the document.

The CHC and its members agree that a change to the consultation process for compositional guidelines would enhance and streamline the new CM substance process for the benefit of the industry and the regulator. We strongly feel that sponsors who have paid for the evaluation of a new substance have the associated compositional guideline published as a final version on the TGA website. As previously stated these documents would remain as 'living documents' as industry can call for an amendment when needed.

6. **Inclusion of a Change Log**
The CHC recommends the inclusion of a change log at the beginning of each revised guidance document as part of good administrative practice. This change log should identify the sections removed, added or changed and the rationale for the change as well as an effective date (similar to Health Canada). This information could be incorporated in addition to the version history log currently used in TGA documents.

We thank you again for the opportunity to make comments on this guideline and look forward to further discussions in the near future.