

CHC Submission -The Australian Regulatory Guidelines for Complementary Medicines (ARGCM) Part B: Listed Medicines

To:

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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 B: Listed Medicines,* January 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 B of the ARGCM and thanks you for the opportunity to make this submission. The CHC 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 permissible (coded) indications project have progressed through consultation and any applicable legislative amendments are proceeding.

In general, the CHC finds the draft ARGCM Part B 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 B in Attachment A (confidential).

Specific Issues

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 effective date (similar to Health Canada). This information could be incorporated in addition to the version history log currently used in TGA documents.

Definitions for Indication versus Claim

The CHC recommends the TGA provide clear legal definitions of an Indication versus Claim to provide clarity for industry. Currently, the document includes interchanging use of these terms and appears to suggest that an 'indication' and 'claim' have the same meaning. For example, on page eight: "Upon submission of a listing application, a sponsor must certify under section 26A of the *Therapeutic Goods Act 1989* (the Act) that the therapeutic goods meet all applicable legislative requirement, which includes that the applicant holds information or evidence to support any **claim/indication** that the applicant makes relating to the medicine". While under the section 'The sponsor holds evidence to support indications made for the medicine', on page thirteen, "At the time of listing, applicants of listed medicines certify under paragraph 26A(2)(j) of the Act that they hold information or evidence to support any **claim** that they will make about the medicine".

Attachment 9a & 9b: Guidance on the use of the term 'quantified by input' for listed complementary medicines and questions and answers on the use of 'quantified by input'

The CHC recommends that Attachments 9a and 9b not be implemented as currently drafted and that prior to implementation the TGA addresses the issues raised during the 2009 consultation on guidance for Quantified by Input.

The CHC notes that Attachments 9a and 9b are based on the 2009 *Draft Guidance on the use of the term 'Quantified by Input' for Listed complementary medicines* and the related documents, *Questions and answers on the use of 'Quantified by Input'* and *Explanatory note: Draft Guidance on the use of the term 'Quantified by Input' for Listed complementary medicines*. Several issues were raised by the CHC at the time of the 2009 consultation and these have not been addressed in the draft attachments.

The CHC provides additional specific comments in relation to the Guidance for Quantified by Input at Attachments B C and D (**confidential**).

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

Yours sincerely

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