

CHC Submission -The Australian Regulatory Guidelines for Complementary Medicines (ARGCM) Part D: Registered Complementary Medicines

To:

Diane Wilkinson

Office of Complementary Medicines

Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

ocm@tga.gov.au

From:

Emma Burchell

Head, Regulatory Affairs

Complementary Healthcare Council of Australia

PO Box 450

MAWSON ACT 2607

Date:

22 July 2013

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 D: Registered Complementary Medicines*, June 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' also includes traditional medicines for example: Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines.

The CHC provides comment to Part D 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 recent changes to the Electronic Lodgement Facility. With the suite of complementary medicine reforms underway, it will be essential to review the individual parts 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 D is relevant to the needs of industry and, in the main, is clear and easily understood.

Specific comments

1. Overview of registered complementary medicines (page 5).

    a. This section provides guidance to applicants in determining if a medicine is eligible for registration. The August 2011 (version 4.2) of Part I to the ARGCM included additional guidance around when, under certain circumstances, indications/claims could be made for Registrable diseases. The CHC recommends reference to the "Registrable Disease List" be included in the guidance document, as per the suggested wording below:

"Indications / claims for Registrable diseases may be made under certain circumstances, but only after the safety, quality and efficacy of the product and the claim(s) have been evaluated by the Advisory Committee on Complementary Medicines (ACCM) or other relevant evaluation committee. Where a sponsor seeks to mention a Registrable disease in what would otherwise have been categorised as a medium or general level claim, that claim would become Registrable and the product would require Registration (that is, evaluation by the TGA with the advice of the ACCM, ACNM, or ACPM). The 'Registrable disease' list is shown in Table 6. The Registrable Disease List, which applies to medicines but not devices, is contained in the TGA document Guidelines for Levels and Kinds of Evidence to Support Indications and Claims, currently under review".

b. The CHC considers the following statement from previous guidance documentation be included in the overview of registered complementary medicines 'it is possible to gain provisional approval of a substance for use in Registered complementary medicines before the substance is included in a product'.

2. The process for application for evaluation of a new registered complementary medicine (page 6). This section highlights that there is currently no statutory timeframe for the registration of a complementary medicine. The CHC recognises the complexities that are unique to complementary medicines, however, for those applicants that utilise the TGA pre-submission meeting process and the application is screened and considered 'effective', specified target timeframes should be established at this point of the process.

3. New Registered complementary medicine application process flow chart (page 8).

a. The CHC notes that at the conclusion of the administrative and technical screen, the application is considered either effective or not effective. Whilst the CHC supports applicants utilising the pre-submission meeting process, not all applicants will do so. A third option, to have an application considered 'pending' and the sponsor advised of deficiencies would assist those who do not make use of pre-submission meetings with the regulator. These applications should not prevent the evaluator from commencing another application or lead to a backlog of applications.

b. During the Evaluation Phase (phase 4) clarification on submitted data may be requested during the evaluation. The CHC suggests that as there is currently no set maximum number of requests for information (RFIs), due to the complexities of complementary medicines, a consolidated list of questions be prepared and sent to the applicant to assist with streamlining the registration pathway. In addition a maximum number of requests for information could be determined at the pre-submission stage and reviewed at the Screening stage to assist with industry expectation of timeframes.

c. The flow chart on page 8 and guidance on page 11 advises that during the Evaluation Phase issues may be identified that require advice from a TGA Statutory Advisory Committee. The CHC consider additional detail in guidance would assist industry for

example, 'For complementary medicines, advice is normally sought through the Advisory Committee on Complementary Medicines (ACCM), while the Advisory Committee on Medicine Scheduling (ACMS) may be consulted about the scheduling of substances and ACCM may consult with other TGA advisory committees for some applications'. The CHC considers this additional detail on how the expert committee phase works be included in the guideline to assist with industry understanding and expectation of timeframes.

d. The CHC recommends that the following section be reworded: "Applicant advised that committee advice will be sought and the applicant may choose to provide comment." To "Applicant advised that committee advice will be sought and the applicant provided with a copy of the Committee briefing paper and given the opportunity for comment.

4. The CHC suggests the following statement (efficacy, page 11) be amended to include reference to the evidence guidelines. 'Where the evidence is considered not likely to support the proposed indication, the applicant will be advised in writing and asked whether they wish to amend the indications in line with the available evidence'. To 'it will be determined whether or not the evidence provided to support the proposed indication matches the requirements set out in the 'Guidelines for levels and kinds of evidence to support indications and claims (*update when reviewed*). If not, the applicant will be advised in writing and asked whether they wish to amend the indications in line with the available evidence'. Without reference to the guidelines, this statement may be considered to subjective.

5. Table 4, nonclinical data addressing safety and efficacy (page 18). The CHC questions the inclusion of primary and secondary pharmacodyniamics – in vitro and in vivo. Pervious guidance in relation to safety of complementary medicines has stated: 'Safety may be established by detailed reference to the published literature and/or the submission of original study data. Where there is sufficient evidence based on human experience to support safety, conventional studies involving animal and in vitro studies are not necessary'.

6. The CHC notes minor amendments required to the document such as updating the name for the Australian Quarantine and Inspection Service (AQIS) to Biosecurity or DAFF Biosecurity. The Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) has moved away from referring to the name AQIS. The change means that the AQIS name will be superseded by the Australian Government crest followed by Department of Agriculture, Fisheries and Forestry, Biosecurity - or *DAFF Biosecurity* for short.

7. The CHC notes that further work is to be completed on the relevant attachments relating to various sections of the ARGCM. At this stage the attachments referred to under each respective consultation do not appear to make a complete set and should be reviewed for consistency when completed.

We thank you again for the opportunity to provide comments on this guideline and look forward to assisting with the review of relevant attachments once completed.

Yours sincerely,

Emma Burchell
Head, Regulatory Affairs