Technical Alert

Urgent Call for Industry Response

Australian Regulatory Guidelines for Complementary Medicines

Dear Member,

The TGA is currently progressing through a phased consultation process for the revised Australian Regulatory Guidelines for Complementary Medicines (ARGCM), commencing with **Part A: General Guidance**.

It is imperative that all Members review the consultation document and make proposed changes within the document to be returned to Emma Burchell at submissions@chc.org.au by **COB, Thursday 1st of November.**

The current review of the ARGCM forms part of the Complementary Medicines Regulatory Reforms package and is in response to the Auditors Generals recommendations following the ANAO audit of TGA regulation of Complementary Medicines and the release of the TGA reforms: A blueprint for TGA's future.

The ARGCM was first published in 2001. ARGCM revision 5 (2012) is a restructure of the original document in order to increase the useability of the guidelines and to ensure the information provided is reflective of current regulatory requirements. The revised ARGCM comprises four parts with technical information provided in Attachments.

Part A: Provides an overview of the regulatory framework for therapeutic goods in Australia. Information is provided on: the regulation of different types of complementary medicines including but not limited to; active and excipient ingredients, medicine terminology; exempt medicines, practitioner products; and medicine/ food interface issues.

Part B: Provides guidance on the regulatory framework for listed 'low risk' complementary medicines.

Part C: Provides guidance on the evaluation process for a new complementary substance to be approved for use in listed medicines.

Part D: Provides guidance on the registration process for complementary medicines. Attachments: Provide technical details and requirements relevant to the procedural information provided in the main body of the document.

The TGA's draft document for **Part A** is now out for consultation with a short turn around for comment.

Accordingly, the CHC is calling on Members for assistance in ensuring that the consultation document reflects the interests of the complementary healthcare industry:

Please provide feedback **directly onto the Part A document** (using the Microsoft Word version) and return via email. To access the Part A document for editing **click here**

The focus of the ARGCM reforms

The reforms will initially focus on the recommendations from the Auditor-General's report; the recommendations will be implemented through the following projects:

1. Key regulatory guidance materials
2. Standard indications
3. Publishing outcomes of listing compliance reviews
4. Using risk profiles in listing compliance reviews
5. Investigation processes for advertising breaches

Additional recommendations included in the Blueprint also impact upon complementary medicines regulation and will lead to further projects in the future.

CHC feedback on key issues

Changes to the original document include formatting, corrections and clarification of information. The changes do not introduce any new procedures or procedural change.

Please note: further revisions of the ARGCM are expected in early 2013, which will reflect changes through progression of reforms, including changes to the Electronic Lodgement Facility.

The CHC welcomes enquiries regarding this document. Please contact Emma Burchell at submissions@chc.org.au or call 02 62604022.