







Technical Alert

Call for Industry Comment

Australian Regulatory Guidelines for Complementary Medicines ARGCM: Part B- Listed Medicines

Dear Members,

The TGA is currently progressing through a phased consultation process for the revised Australian Regulatory Guidelines for Complementary Medicines (ARGCM). The revisions are to ensure these key regulatory guidance documents are reflective of current regulatory requirements, they have also been restructured to increase their usability. Part A: <u>General Guidance</u> was revised in November 2012, consultation now continues with <u>Part B: Listed medicines</u>.

Members are encouraged to review the consultation document and send comments and proposed changes to Emma Burchell at: submissions@chc.org.au by COB, **Monday 11 February 2013** for submitting to the TGA by 18 February 2013.

Part B of the ARGCM aims to provide guidance on the regulatory framework for listed 'low risk' complementary medicines and reflect current regulatory requirements for complementary medicines

Feedback is sought on the following areas, particularly on the usability, relevance, and clarity and where more or less information may be required:

- Medicines and ingredients that have been approved for use in listed complimentary medicines
- Legislative requirements for listed medicines
- The listing process *via* the electronic listing facility
- Product variations
- Post-market compliance matters

The consultation draft for the proposed regulatory requirements can be found here.

The CHC welcomes enquiries regarding this consultation. Please contact Emma Burchell on 02 6260 4022 or 0451 681 663.

Complementary Healthcare Council of Australia

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PO Box 450 Mawson ACT 2607 | Tel: +61 (0)2 6260 4022 | Fax: +61 (0)2 6260 4122 | Website: www.chc.org.au