Complementary Healthcare Council of Australia

Technical Alert

Call for Comment: Regulation Impact Statement for Regulating the Advertising of Therapeutic Goods

Dear member,

The CHC invites you to comment on the TGA Consultation regulatory impact statement (Consultation RIS) for regulating the advertising of therapeutic goods to the general public. Submissions are welcome to the CHC **before Friday, 28 June 2013** for submission to the TGA by the 12 July 2013.
The CHC cover sheet and submission form can be found here.
Full details of the TGA Advertising Consultation can be found here.

This consultation
The purpose of this Consultation RIS is to seek comment from you to help inform the decisions of the Government on proposed regulatory reforms to improve the management of public health risks in relation to the advertising of therapeutic goods to the general public.
The Consultation RIS:

- describes the existing regulatory framework
- documents problems associated with the existing regulatory framework
- outlines the objectives for reform
- suggests proposals for reform
- invites comments on likely impacts of implementation of the suggested proposals.

After consideration of public comment on this Consultation RIS, the TGA intends to prepare a final RIS to assist Government consideration of the next steps.

Content of Submissions may address any, or all, of the proposed amendments to the advertising regulatory framework or other identified issues. In addition you may wish to consider in your comments whether the proposals will:

- Change the number or type of products that businesses can offer as a result of complying with a proposal
- Alter consumer demand for products as a result of:
  - increasing prices brought about by regulatory requirements
  - changing public information to ensure compliance with regulation.

- Alter the ability or incentives of businesses to compete in the market.

The CHC would welcome estimates of likely regulatory impacts and compliance costs relating to the proposals. All RIS information received will be treated as commercial- in-confidence and a summary of industry estimates will be provided to the TGA as part of the CHC submission.

Compliance costs can include costs relating to:

- Collection and reporting of certain information
- Keeping abreast of certain requirements and training staff
- Changing operating procedures or purchasing patterns
- Cooperating with audits or inspections
- Engaging lawyers, accountants or other advisors

Proposals include

- Proposal 1: Alternatives to the pre-approval scheme (5 options outlined)
- Proposal 2: The complaints handling process (2 options outlined)
- Proposal 3: Provision of advice in relation to advertising matters (2 options outlined)
- Proposal 4: Investigation and enforcement powers (2 options outlined)
- Proposal 5: Advertising of higher risk medical devices (2 options outlined)
- Proposal 6: Advertising directed to health professionals (2 options outlined)
  Specifically affects those professions not currently regulated under the *Health Practitioner Regulation National Law* such as Naturopaths, Homeopathic practitioners and Herbalists (other than Chinese herbal medicine practitioners registered by the Chinese Medicine Board of Australia). Under option 2, advertising to groups of practitioners who are not registered with NRAS would be regulated in the same way as advertising to the general public.
- Proposal 7: Advertising of Pharmacist-Only medicines (2 options outlined)
- Proposal 8: The Price Information Code of Practice (2 options outlined)

Scope of consultation
This consultation does not propose reforms to processes within the self-regulatory schemes administered by industry peak bodies through their respective codes of conduct for resolving complaints about advertisements for therapeutic goods directed to health professionals. It does not cover health claims made about foods, changes to the regulatory schemes administered by health practitioner registration boards and other goods that are not regulated under the Act.

This Consultation RIS does, however, consider advertising-related issues relating to the intersection between the TGA's responsibilities, National Registration Accreditation Scheme (NRAS) and the self-regulatory schemes administered by industry peak bodies.

Background
In May 2012 the TGA set out a series of options for reforms to the current advertising framework for therapeutic goods - *Advertising regulatory framework – options for reform* (May 2012). That paper indicated that an improved regulatory framework could be achieved if changes were made to the pre-approvals arrangements, to the complaints handling processes and to the sanctions and penalties that apply to advertising breaches. This consultation RIS expands on those options and provides an opportunity for feedback on their likely impact.

Amendments to the advertising regulatory requirements may be recommended to Government for consideration following review of public submissions made in response to this Consultation RIS.

- **In 2008** - the Productivity Commission, in its Review of the Regulatory Burdens on Business: Manufacturing and Distributive Trades (2008), recommended (4.4) that: *after further consideration of the most appropriate model, the Australian Government should streamline and clarify advertising rules and work with state and territory governments to ensure reforms also address the need for a simplified system for complaints about national advertising.*

- **In 2010** - A consultation paper, *Improving advertising arrangements for therapeutic goods*, was released for public comment and submissions were considered by the TGA.
- The former Parliamentary Secretary for Health and Ageing, hosted a roundtable in November 2010 for discussion of this feedback and how the regulation of therapeutic goods advertising could be improved. Key areas identified for further review included: pre-approval of advertisements; complaints handling; sanctions for non-compliance; and transparency of decision-making by the TGA.

- **In 2011** - The *Transparency Review of the TGA* examined the transparency of advertising decision-making and recommended that access and quality of information on the processes for regulation of the advertising of therapeutic goods (including complaints) be improved in a report published in June 2011.
- The ANAO Performance Audit Report No 3 (2011) *Therapeutic Goods Regulation: Complementary Medicines* recommended that procedures for undertaking and reporting advertising complaint investigations be implemented.

- **In 2012** - The report, *Advertising regulatory framework – options for reform* - *May 2012*, identified possible options to enhance the operation and effectiveness of the advertising regulatory framework. It was based on previous advertising reviews and addressed pre-approval arrangements, the complaints handling process and sanctions and penalties available for advertising breaches.
- Advertising reform activities proposed in the Transparency Review, the ANAO Audit Report and the Advertising Report have been included in the implementation plan for *TGA reforms: a blueprint for TGA's future*, published in July 2012.

For further information contact:

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