

### Proposal 1: Alternatives to the pre-approval scheme

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Extend the current system to:
  - a) include pre-approval for medical devices
  - b) cover subscription broadcasting ('narrowcasting') (pay-TV).
- **Option 3:** Limit the current pre-approvals scheme to cover only "higher risk" categories of advertisements.
- **Option 4:** Retain pre-approvals (modified or not as per option 2 or 3) and:
  - (a) maintain the current pre-approval delegations to industry associations, such as ASMI and CHC (with an appropriate medical devices industry group if option 2(a) is endorsed); or
  - (b) appoint an independent statutory office holder to undertake pre-approval function; or
  - (c) TGA to undertake the pre-approval function.
- **Option 5:** Remove the pre-publication approval scheme.

The CHC supports option 4a), with modification so that all complementary medicine advertisements are pre-approved by a single body.

The CHC position is to maintain mandatory pre-approvals. For complementary medicines, pre-approvals of advertisements should be delegated to a single body regardless of the type of media across an advertising campaign, including online advertising. This single body should have the capacity to service the peak times for approvals required by industry and for costs to remain competitive. The CHC believe that with on-going legal training, Advertising Service Managers, as a Delegate to the Secretary for Health, should continue to provide the pre-approval function incorporating an industry support component. For example, a presence at industry seminars and provision of generic guidance in relation to advertising matters.

We recommend the CHC be the single body for pre-approvals of complementary medicine advertisements. Should this function be delegated to an independent statutory office holder, the CHC recommends that there be complementary medicine specific expertise represented.

Members supported the idea of a system where all claims for a product are pre-assessed and an approval number generated for a set of claims for a product, rather than a specific advertisement. Once these claims have been verified they could be used in all mediums of advertising. Pre-approved claims under this system could still be subject to a complaint but the pre-approval should carry weight in the decision making process.

The CHC recommends additional delegated authority to companies (as recognition of compliance) in addition to Advertising Service Managers (ASMs). This additional authority would be to carry out minor variations to the already pre-approved set of claims only. Advantages of this option would be a reduced number of advertisements requiring pre approval outside the company and therefore reduced costs to businesses. These delegated approval agents would require industry accredited training and delegation may be revoked under yet to be defined circumstances.

Having an industry-led, self-regulatory component in ensuring compliance with the Advertising Code would engage industry to a higher degree than is currently experienced. In the development of industry accredited training, the single body (the CHC), would liaise with the TGA to ensure an appropriate training program.

### Proposal 2: The complaints handling process

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** All complaints about advertising of therapeutic goods to the general public to be handled by a single body, either:
  - **a.** the TGA; or
  - **b.** an independent statutory office holder.

The CHC supports Option 1, with modification, for the reasons outlined below.

The CHC believes that all complaints about advertising of therapeutic goods to the general public be handled by a single body. The basis of this single body could be the Complaints Resolution Panel (CRP), only if this body is constituted correctly. The vast majority of people assessing the complaints should have specific expertise in the complementary medicine field and in the complaints handling process. This is not the case with the current CRP. When a person leaves the committee a replacement should be based on individual skill set and not an agency or organisation being represented on the committee. Specific complementary medicines expertise would strengthen consistency in decision making.

While the CHC is supportive of enhanced enforcement strategies, it is imperative to note that the Advertising Code is subjective and while penalties for breaches of law are justified, areas that are open to subjectivity are better dealt with by the existing framework of consumer protection laws.

The CHC strongly recommends that the Government require sponsors to subscribe to a Code of Marketing as a requirement of listing on the Australian Register of Therapeutic goods (ARTG). This would enable associations to better enforce sanctions against non-compliant companies. While this recommendation was not supported by Government in 2011, the [Blueprint Reforms](#) state that if further encouragement is required for non-members to nominate a code, the Government will consider further legislative measures including the TGA seeking this information.

### Proposal 3 Provision of advice in relation to advertising matters

- **Option 1:** Status quo - maintain the current system.

Retention of CRP and Therapeutic Goods Advertising Code Council (TGACC) in their current form.

- **Option 2:** Establish an expert advertising advisory committee.

Establish one statutory advisory committee to replace the Panel and Council to provide advice to the Secretary (delegate).

The CHC supports option 1, with modification, for the reasons outlined below.

The CHC supports the TGA seeking advice from a statutory committee in relation to advertising matters in addition to maintaining a single body to handle complaints, such as the reconstituted CRP described in proposal 2. The [TGA Advisory Committee on Complementary Medicines](#) (ACCM) could be used as the basis for this proposal and be referred to for advice on CRP recommendations. The recent [call for expressions of interest](#) to the expert committee should ensure a greater number of complementary medicines specific expertise, are represented on the committee, including from the consumer point of view, than is currently the case.

### Proposal 4 Investigation and enforcement powers

- **Option 1:** Status quo - maintain the current system

- **Option 2:** Enhance investigation and enforcement powers

The CHC in principle supports option 2, TGA increasing the power to enforce rulings, especially for 'repeat offenders'.

The CHC calls for more detail on the TGA risk profiling system, in particular the criteria for higher risk categorisation and the process for removal from the high risk category.

While the CHC is supportive of enhanced enforcement strategies, it is important to note that the Advertising Code is subjective and while penalties for breaches of law are justified, areas that are open to subjectivity should be dealt with by the existing framework of consumer protection laws. Where fines are enforced by the TGA any surplus should be diverted back into industry education.

## Proposal 5     Advertising of higher risk medical devices

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Prohibit the advertising of higher risk medical devices (applicable to Class III, Active Implantable medical devices and Class 4 in vitro diagnostic devices).

The CHC in principle supports option 2, prohibit the advertising of higher risk medical devices (applicable to Class III, Active Implantable medical devices and Class 4 in vitro diagnostic devices).

This advertising recommendation does not affect IVD devices that complementary medicine health professionals may use in clinical practice. As a separate reform process that has already occurred, the TGA In-Vitro Diagnostic devices regulations will require all commercial IVDs and Class 4 in-house IVDs for therapeutic use to be included in the ARTG from 1 July 2014. The future availability of these and other innovative devices to complementary medicine health professionals may be impacted due to the greater scrutiny of the devices and indications on the ARTG but this is not part of this consultation. As such, the CHC will not be making any specific comment in relation to it.

## Proposal 6 Advertising direct to health professionals

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the *Health Practitioner Regulation National Law*.

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.

The CHC strongly supports option 1, maintain the current system for the following reasons.

The proposed changes to advertising of therapeutic goods means that complementary medicine practitioners will not be able to access advertising and educational material from Practitioner-Only complementary medicine companies, as they currently do, as our healthcare professionals would all be treated as if they were consumers.

The CHC position is to maintain the current exemption for health professionals in section 42AA of the Act. The Consultation RIS fails to provide evidence of risk for the professions that are marginalised as outlined on table 3 page 44, that being the profession of naturopathy, homoeopathic practitioners and herbalists. Regulatory reform must demonstrate a need for change including supporting evidence of public health risk.

The Australian Register of Naturopaths and Herbalists (ARONAH) is one of a number of systems for registration for complementary medicine health professionals currently available. ARONAH's system of registration mirrors the principle criteria of the national registration process. Such processes do provide confidence that there is a level of oversight and minimum education criteria applicable to these professions. The CHC position is for the TGA to maintain status quo for the following reasons.

1. The Australian Health Ministers' Advisory Council (AHMAC) has referred the task of developing a process for the management of requests for registration to its Health Workforce Principle Committee.
2. Following advice from the Committee, the Australian Health

Ministers' Advisory Council (AHMAC) will determine a suitable process for managing requests for inclusion of additional professions in the National Scheme.

3. No applications are currently being considered until this process is complete with no defined timeframes detailed.
4. The Australian Health Practitioner Regulation Agency (AHPRA) is, in addition, undergoing a 3 year review of the operation of the National Scheme. This will largely impact any efforts the industry is making towards National registration.

The [Lin Report](#) supports the registration process, however previous efforts to register the profession under AHPRA have met with feedback that Naturopaths and Western Herbal Medicine Practitioners (WHMP) practice did not pose a significant health and safety risk and therefore was not suitable for registration under AHPRA.

The CHC is actively working on the issue of Statutory Registration of Naturopaths and (WHMP), however any submissions seeking a decision to register professions would be considered by the AHWMC and thus actual timing of our campaign efforts are not known at this stage.

The CHC recognises the qualifications, the education and training of complementary health professionals and questions how the Government could propose restrictions on specific CM health professionals when their qualifications are earned by a Government accredited process. We respect the right of all Australians to choose their healthcare modality. In Australia, the demand for complementary and alternative medicine (CAM) and healthcare is increasing with 1 in 6<sup>iii</sup> Australians using complementary therapists as their primary healthcare practitioner, of which Naturopaths are by far the dominant complementary medicine modality – accounting for 8.7 million<sup>iii</sup> health consultations per year. The CM health professional must be kept abreast of critical data.

Complementary medicine health professionals must be able to access technical and scientific information including contraindications around the medicines they prescribe. The CHC strongly believes that if health professionals were not able to access this information, as would be the case under option 2, that this would increase the potential for harm to consumers. Further, this would encourage a greater use of the Internet for product knowledge, which would likely increase the illegal purchase of non-TGA registered products to be used for patient care, thus placing the population at an even higher risk.

Not related to the Advertising Consultation but for members information

## Statutory Registration of Practitioners

For the purposes of advertising, currently Naturopaths and Western Herbal Medicine Practitioners are classified as health care practitioners and excluded from advertising regulations.<sup>1</sup>

In June 2013 the TGA released a regulatory impact statement on proposed changes to advertising regulations, which proposes changing the definition of health care practitioner to those practices registered under the Australian Health Practitioners Registration Agency (AHPRA). This would see non-AHPRA practitioners treated as lay people with all advertising to health professionals requiring compliance with the Therapeutic Goods Advertising Code, currently applicable to advertising to consumers. This will significantly impact the ability of these practitioners to receive education and advertising from practitioner-only supplement manufacturers.<sup>2</sup>

It is the belief of the CHC that these proposed changes have the ability to seriously impact the scope of practice of Naturopaths and Western Herbal Medicine Practitioners. We believe that these practitioners are very important to the complementary medicine industry and the health care of Australian consumers.

The CHC is planning to promote and lobby for the inclusion of Naturopaths and Western Herbal Medicine Practitioners under AHPRA as registered health professions. The CHC is not planning to replace the role of professional organisations which represent natural therapists currently.

It is acknowledged that Naturopaths and Western Herbal Medicine Practitioners have successfully practiced in our community for many generations without statutory registration. However, recently, there have been many signs of negative impacts upon the ability for these professionals to effectively continue their contribution to primary healthcare. Of great concern is the number of regulatory changes that have been proposed or introduced by the TGA and the Federal Government. These changes have the potential (unintended or not) to severely limit the scope and the viability of practice for these professions. Additional information can be found in the

<sup>1</sup> Section 42AA, Therapeutic Goods Advertising Code <<http://www.tga.gov.au/industry/advertising-schedule1-explained.htm#att1>>

<sup>2</sup> TGA Consultation Regulation Impact Statement, Regulating the advertising of therapeutic goods to the general public Version 4.6, May 2013 <<http://www.tga.gov.au/pdf/consult/consult-advertising-ris-130531.pdf>> page 28



*CHC White Paper – Registration of Naturopaths & Western Herbal Medicine Practitioners: Protecting Public Health and Rights*, which can be located [here](#).

All interested individuals and organisations are encouraged to register their interest and/or support for the Registration of Practitioners Campaign, which can be achieved by clicking [here](#) or by visiting <http://chc.org.au/Registration-of-Practitioners>. This webpage will be updated regularly with information about the progress of the campaign.

In addition, the CHC has formed an Advisory Group of professional and industry stakeholders that wish to be directly involved in driving the campaign for statutory registration of Naturopaths and Western Herbal Medicine Practitioners. We would like to invite expressions of interest from those stakeholders that are willing to join the steering group and ask that you email [shanna.choudhary@chc.org.au](mailto:shanna.choudhary@chc.org.au) or phone 02 6260 4022 to register your interest by **20 July 2013**. It should be noted that other forms of support are welcome, and we would be keen to hear from any individuals or organisations willing to contribute to this vital cause.