



**HEALTH
WORLD
LIMITED**

**Australia's Leading
Natural Health
Science Company**

A.B.N. 73 010 636 165

*Health World Limited submission on the Consultation Regulation Impact Statement:
Regulating the advertising of therapeutic goods to the general public*

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Introduction

Health World Limited is a leading supplier of natural medicines in Australia and New Zealand.

In principle we support the TGA's efforts to improve the advertising approval and regulation process, because the current system is both inefficient and lacking in certainty.

However we are concerned that some of the options presented in the Consultation document will be highly detrimental to natural healthcare in Australia, and as a consequence to the health of many millions of Australians who choose this option and fund it from their own resources.

Health World Limited is a member of the Complementary Healthcare Council and we support the submission on this consultation by the CHC. Our submission addresses issues where we have a different view or emphasis from the CHC, and in the absence of comment on a specific point in the Consultation document then the CHC response represents our view.

Proposal 1 - Option 4

We support the retention of the pre-approval system for advertising. Without an approval system, the risk of irresponsible or inaccurate advertising claims being broadcast is too high. There are however several problems with the current approval system:

- Approval is split between CHC and ASMI, and is not always consistent
- Approval is no guarantee that the product will not be subject to a complaint and a subsequent adverse decision. As an example refer to the CRP decision and subsequent TGA reviews of our *Urinary Tract Support* product.
- Approval is required on an advertisement, not claims, so each separate advertisement needs to be resubmitted, even if there are no changes to the claims being made.

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We believe that a modified pre-approval system should have the following characteristics:

- A single approval body for all advertising channels
- Approval of claims, not advertisements. Sponsors should be able to submit their advertising claims (which would include statements included on the ARTG plus advertising/marketing statements) for approval. Once approved, these claims should be able to be used in any media without further approval
- Approval of these claims should provide certainty to the sponsor. Should a complaint be made, it will be dismissed with no consequences to the sponsor, so long as the sponsor has represented the claims correctly and accurately. In effect the approval should be binding providing it has been correctly used
- Approval must be provided within a mandated timeline (not more than 2 weeks).

On this basis, we believe the TGA should provide this pre-approval function, rather than having it delegated to external bodies. The TGA has the expertise in-house to assess the evidence supporting claims to provide a binding approval (although would need to increase this resource), and the best consistency in decisions would come from the same body providing approval and handling complaints.

Should it be determined that the TGA cannot provide a reasonable turn-around time for advertising claim approvals, then a second option would be for this responsibility to be delegated to an external body resourced appropriately and working to the requirements outlined above. This would however increase the chances of a difference of opinion between the approval body and a complaints handling body, which is a major issue for industry at present, and is therefore less desirable.

Proposal 2 - Option 2

We support a process that increases the timeliness of complaint handling and also ensures that the group hearing the complaint is correctly constituted with members who have complementary medicine industry experience and the ability to interpret scientific and traditional evidence used to support claims. We do not believe that the options proposed by the TGA solve either of these issues as they are written.

We propose that the body handling the complaints be given a mandatory timeframe in which they need to process and resolve complaints. This group also needs to be correctly constituted with suitably qualified members, selected based on their skills, not on their affiliation to a particular group. Skills required include the ability to appraise scientific evidence and traditional evidence, and to apply this evidence in the same fashion as will be done by the TGA during section 31 reviews using the new evidence guidelines.

To ensure consistency between advertising approval and complaint handling, these functions should be handled by the same body. Our first preference is for the TGA to perform this function, as they will also be carrying out section 31 reviews on product claims.

There also needs to be an appropriate appeal mechanism so that if the sponsor is not satisfied with the initial decision they may request a review which is referred to an independent body (such as the ACCM), rather than being reviewed by other TGA staff. This reduces the likelihood of the reviewer

being influenced by the opinion of the original decision maker. There should also be provision for the advertiser to engage in discussion with the TGA to try to come to a mutually agreed position, to try to reduce costs and time wasted by both sides, as per the Urinary Tract Support issue referred to previously which was ultimately decided largely in Health World's favour by the AAT,

Proposal 3 – refer CHC submission

Proposal 4

We support increased enforcement against repeat offenders. However we are opposed to the proposal to increase penalties for advertising breaches because the TGA regulations are interpretative, not definitive, and are subject to a large degree of interpretation. As currently happens and is likely to continue, sponsors and the TGA (and even different reviewers within the TGA) may interpret these regulations differently and it is unreasonable to subject sponsors to large financial and civil penalties unless there is absolute clarity on what is allowable and what is not. We therefore are opposed to increased penalties as currently proposed.

Advertising which correctly uses claims approved by the pre-approval scheme should be immune from any form of penalty or sanction. Otherwise there is no effective purpose to a pre-approval scheme.

Any funds generated from fines beyond the cost of administering the process, should be diverted back to industry education and support, to help reduce the number of advertisements requiring enforcement.

Proposal 5 – refer CHC submission

Proposal 6 - Option1

We strongly support the maintenance of the status quo with regard to the definition of a health care practitioner. The ability of sponsors to advertise to and educate non-NRAS health care practitioners such as naturopaths, herbalists and homoeopaths would be severely restricted by these proposed changes, as these practitioners would be regarded as lay people under the advertising regulations. These practitioners are generally degree-qualified and highly skilled in the administration of natural medicines. They are also a large group and a popular choice of healthcare provider for many members of the Australian community. Restricting the ability for sponsors to provide technical information to these practitioners would have the following consequences:

- Reduction of the level of knowledge of naturopaths and herbalists over time
- Increased risk of adverse reactions and side effects
- Increased risk of drug/herb/nutrient interactions
- Reduction in the quality use of medicine, and
- Reduction in the amount of products that are provided to Australian consumers from TGA-GMP facilities, as many practitioners are likely to prescribe more imported products, or consumers may choose to bypass practitioners and import products directly.

We understand that the TGA has expressed concerns over their ability to determine which non-NRAS practitioners are able to exercise specialist judgement. We believe that membership of a professional association with the ensuing requirements for continuing professional development and a minimum education standard is a suitable reassurance for the TGA.

We propose that the TGA adopt the AHPRA list of practitioners as the default standard, with special provision for naturopaths, herbalists and homoeopaths who are members of professional associations, to also be included within the definition of health care practitioner, and therefore exempt from advertising controls by the TGA.

Should the TGA consider it is not desirable to have this special provision indefinitely, they should provide a window of time to allow these professions to seek national registration under AHPRA. This would need to be a long period (up to five years) as AHPRA have publicly stated that they are not accepting new applications at present, and this situation may continue for several years.

Proposal 7 & 8 – no comment

About Health World Limited

Health World Limited is a manufacturer and distributor of natural medicines under the brands Metagenics, Ethical Nutrients, Inner Health and Endura. Based in Brisbane, Health World Ltd is a significant employer of Australians and New Zealanders in highly skilled manufacturing, sales and marketing and technical roles.

Yours Faithfully
Health World Limited



Technical Director