The Royal Australian College of General Practitioners

RACGP submission to Therapeutic Goods Administration

Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public.

RACGP details

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1. About RACGP

The Royal Australian College of General Practitioners (RACGP) thanks the Therapeutic Goods Administration for the opportunity to respond to this consultation.

The RACGP is the specialty medical college for general practice in Australia, responsible for defining the nature of the discipline, setting the standards and curriculum for education and training, maintaining the standards for quality clinical practice and supporting general practitioners in their pursuit of excellence in patient care and community service.

This submission has been prepared by RACGP members Dr Justin Coleman and Dr Jane Smith.

2. Introduction

The RACGP takes a keen interest in the regulation of advertising of therapeutic goods. General Practitioners (GPs) are responsible for most of the medical prescriptions in Australia and are regularly involved in discussions with patients around over-the-counter medications whose advertising and promotion may well have influenced the patient's purchasing decision.

We note that very few, if any, of the proposed reforms would directly or indirectly result in any financial gains or losses to the average GP, and as such we can confidently argue that our position is free of any pecuniary 'vested interest' and that our sole concern is the health and safety of our patients—in effect, the Australian public.

3. Our concerns for consumers (our patients)

Currently, consumers are frequently being misled by direct-to-consumer advertising claims**.** Misleading claims include some for which the TGA has already completed its decision (e.g. reprimand for 'Nurofen targeted relief')**.** Many other alleged misleading claims remain incomplete in the 'slow-grind' TGA process (for example, the majority of complaints referred to the TGA by the Complaints Resolution Panel (CRP) over the past three years have not been finalised.)

The 'vitamin and supplement' industry thrives on claims of therapeutic efficacy which can be shown to be false or exaggerated. This industry is so lucrative that it is more profitable to make a false claim to increase market share for as long as possible, and then deal with any TGA complaint at a later stage. The time course for a complaint, including the pre-complaint sales, the first complaint, the drawn-out TGA case and appeals, the eventual reprimand and finally the delay in taking any action on that reprimand, can be years. Meanwhile, the profits far outweigh any financial penalty and by the time the company complies by withdrawing the claims, it is time to move onto a new advertising campaign.

Although consumers are free to spend their money in whatever way they see fit, we believe that people are particularly vulnerable when it comes to products which purport to promote health or relief from suffering. False advertising claims for health

products have potentially far more serious consequences to individuals than do false claims for most other consumer goods purchased.

Purported weight-loss agents and relief from chronic painful conditions such as arthritis are particularly prone to fanciful claims.

Advertising claims using evidence-based terms such as 'scientifically shown to', 'clinical evidence' or 'tests have proven', should require the company to demonstrate that the understood, scientific meaning of these words actually applies in each case. Besides any direct misleading, this lazy appropriation of scientific terms by marketing divisions also waters down the public's understanding of the meaning of such terms when they are applied correctly. This is particularly important in light of the ongoing struggle of the medical profession to continually 'clean up its own back yard' by debating and applying evidence to its own therapeutic interventions.

4. Our concerns with the current TGA code

The RACGP strongly affirms the regulatory role of the TGA, and we believe that role requires strengthening.

The current Therapeutic Goods Advertising Code 2007 was developed six years ago and is in great need of revision. The complex set of regulations and codes require updating, simplification and strengthening.

Broadly speaking, the code and the process of handling complaints under the code, is considered almost 'toothless'. The long delays, the light punishments and the lack of timely, firm action when reprimands are ignored, have led to a situation where large companies can merely 'factor in' a potential TGA complaint into their promotional budget.

TGA code revisions should be more frequent and in each case designed to reduce the 'wriggle room' for companies who aim to avoid sanctions. The upper limits on penalties for confirmed breaches of the code should be increased. In particular, penalties for ignoring or unreasonably delaying compliance with a reprimand should be severe. Penalties for companies who repeatedly breach the code should also be severe enough to make them fastidiously avoid subsequent breaches.

The media is rapidly changing, and advertising regulations must be extended to include all forms of media including online and subscription media, pay TV and social media (where sponsored campaigns are concerned).

5. Comments on the specific TGA Proposals for Reform

Proposal 1: Alternatives to the pre-approval scheme

We support BOTH **option 2** (inclusion of medical devices) AND **option 4c** (TGA to undertake the pre-approval function). Medical devices are every bit as important as medications when it comes to the need to ensure accuracy in advertising. Their non-inclusion is an accident of historical regulatory boundaries which should be rectified.

The TGA should be adequately funded to undertake both the pre-approval and the complaints resolution function. An economy of scale would suggest both of these

should come ‘under the one roof’, but this must be accompanied by more efficiency and faster turnaround times—particularly for complaint resolution.

Proposal 2: The complaints handling process

We support **option 2a** (TGA to handle complaints). Again, with the proviso of adequate resources to ensure timeliness!

Proposal 3: Provision of advice in relation to advertising matters

We support **option 2** (expert advertising advisory committee). We want to maximise efficiency and effectiveness, and it appears from your description of this proposal that option 2 would be more likely to achieve this outcome.

Proposal 4: Investigation and enforcement powers

We very strongly support **option 2** (Enhance investigation and enforcement powers). We see this, alongside streamlining the complaints process, as the main point of the whole reform process.

We support each of your ‘dot point’ changes to the legislation and are delighted that they have been proposed. We believe they are much needed to protect consumers against unscrupulous product promotions.

Proposal 5: Advertising of higher risk medical devices

We support **option 2** (Prohibit the advertising of higher risk medical devices). As per *proposal 1 option 2*, we see the TGA’s role as including medical devices and, by extension of the same logic which disallows advertising of prescription medications, we consider dangerous the direct-to-consumer advertising of higher risk devices.

Proposal 6: Advertising directed to health professionals

We support 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.)

As it stands, the Therapeutic Goods Advertising Code 2007 categorises complementary and alternative medicine (CAM) practitioners such as naturopaths and homoeopaths, alongside medical practitioners and other health professionals who are registered with AHPRA. Thus, the advertising exemptions which apply to AHPRA-registered practitioners (who are considered to have sufficient expertise to judge each claim on its merit) also currently apply to CAM practitioners.

It is very common—usual practice for some groups—for companies to promote products with no evidence of efficacy (supplements, herbal and homeopathic remedies) to CAM practitioners who in turn dismiss the need for ‘scientific evidence’. Such practitioners then on-sell the product to consumers. This relationship is substantially distinct from that between AHPRA-registered health professionals and their patients, and is more akin to wholesalers advertising to direct-to-consumer distributors. We believe that CAM practitioners should therefore not be exempt from the Code, but should instead be subject to the same regulations as concern direct-to-consumer advertising.

We have noted current social media campaigns and petitions against this option by CAM practitioners and at least one company which sells vitamins and 'natural therapies'. We would point out that both groups have significant financial interests in this matter, although it is not entirely clear why those CAM practitioners who signed the petitions feel so strongly about their right to receive advertising which is exempt from the TGA safeguards against false claims.

We also believe the wording of the petitions themselves inaccurately reflects the actual TGA reforms proposed and has instead been deliberately distorted so as to gain maximal outraged support. For example the title of the most-signed proposal is '*Stop the proposal that may delete Naturopathy'* [1]an outcome which is an entirely unsustainable claim. In all the petitions we have seen, no reasonable reader could guess that the issue at hand is limited to the advertising of goods; instead, the petitions warn about encroachments on the interaction between the CAM practitioner and their client.

Proposal 7: Advertising of Pharmacist-Only medicines

We support **option 2** (Transfer from the scheduling framework the responsibility for approving advertising of Pharmacist-Only (Schedule 3) medicines to the general public). This implements a recommendation from the 'Galbally Review' (2001) and allows all therapeutic goods advertising functions to be administered by the area within the TGA responsible for overseeing the advertising regulatory framework.

Proposal 8: The Price Information Code of Practice

We support **option 2** (Provide legislative underpinning to the Price Information Code of Practice.) Anything which increases clarity in the quite confusing code is likely to improve compliance, which is a high priority for the RACGP.

[1] http://www.change.org/en-AU/petitions/therapeutic-goods-administration-tga-australia-stop-the-proposal-that-may-delete-naturopathy