



The Royal Australasian
College of Physicians

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To whom it may concern

Re: The Royal Australasian College of Physicians (RACP) submission on options for reform to the regulatory arrangements for advertising therapeutic goods for the Therapeutics Goods Administration's (TGA)

The objective of this submission is for the RACP to provide comments to the TGA on options for reform on the regulatory arrangements for advertising therapeutic goods. This paper primarily addresses the advertising of therapeutic goods to consumers to allow them to receive accurate information about the benefits and risk of therapeutic goods ensuring that they can safely access these goods without the intervention of a health professional. The College would like to congratulate the TGA on its reform process and looks forward to the next stage where the TGA will identify the preferred package of reforms.

Recommendations:

The College will address the questions posed by the discussion paper as follows:

- 1. Are the current arrangements for advertising of therapeutic goods in Australia known to you?**

The College is aware of these arrangements

Should these be better known or understood?

The College believes they could be better utilised as follows;

- Information is available on the Therapeutic Goods Advertising Code Committee (TGACC) web site¹ and the TGA web site.² However, in order to find out how to submit complaints one must follow a link to the Complaints Resolution Committee (CRP) web site which has a very useful online complaint form and advice³.
- It would be helpful if the TGA web site provided cross-links to the CRP web site and the TGACC & CRP web sites should be consolidated. In addition, the National Prescribing Service (NPS) web site⁴ should also contain information about how to complain about unethical promotion and cross-link to the above.
- The TGA and/or the NPS should also educate consumers and health professionals on the importance of submitting complaints about promotion (as a crucial part of post-marketing surveillance) as the U.S.

2. Do you have comments or complaints about the current advertising arrangements?

The College would like the TGA to consider the following:

- Complaints about the current advertising arrangements should evaluate the “lower risk” listed medicines and devices for efficacy. Sponsors self-certify that they hold the evidence to substantiate the indications and/or claims made for a listed medicine or the intended purpose of a medical device but only a relatively small proportion of sponsor’s new entries on the Australian Register of Therapeutic Goods (ARTG) are checked by the TGA.
- Concerns about sponsor self-certified information on the ARTG can be sent to the TGA and is referred to the Regulatory Review Section. They state, “due to the Privacy and Confidentiality provisions that apply to regulatory investigations the TGA is unable to discuss the progress or outcomes of these reviews.” Occasionally, in response to complaints, a therapeutic good is removed from the ARTG. This is currently notified only in the Government Gazette and promotion and use of such goods invariably continues.

¹

<http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/all/search/F767C1377721F31CCA257291001B8CDA?OpenDocument>

² <http://www.tga.gov.au/docs/html/advcomplaint.htm>

³ <http://www.tgacrp.com.au/>

⁴ <http://www.nps.org.au/home>

- 3. Do you find advertisements for therapeutic goods helpful?**
 - The College believes these are helpful as they have the potential to alert consumers and health professionals to new products or improvements in old ones.

- 4. Should the current pre-approval process be retained?**
 - The College would like to suggest that an improved evaluation and monitoring processes particularly for the pre-approval process be introduced.

 - The College would like to suggest that a more cost-effective process would be to replace the pre-approval process with a less-expensive (but still funded) promotional monitoring program (including industry, health professional and consumer education) with the monitoring program interfaced with a complaint process capable of imposing effective sanctions.

- 5. Should the TGA publish on its web site products removed from the ARTG?**
 - The College believes that the TGA web site should include products removed for any reason, for example when a review finds that the sponsor cannot substantiate indications listed on the ARTG, or when a sponsor de-lists a product themselves rather than face a review.

 - The College believes that the TGA web site should also include details of all complaints (and their outcome) referred to it by other bodies such as the Complaint Resolution Committee (CRP) and the Complementary Healthcare Council (CHC).

 - The College would like to suggest for transparency the TGA web site should list all new products added to the ARTG on a weekly basis and this information be made available by subscription to a TGA email alert system.

- 6. Should the CRP be reconstituted as an independent body?**
 - The College would like to be invited to be a member of the CHC. Currently members are nominated by the Australian Consumers' Association (Choice), the Australian Self-Medication Industry (ASMI), the Australian Traditional Medicine Society (ATMS), the Complementary Healthcare Council (CHC), the Consumers Health Forum Inc (CHF), the Pharmacy Guild of Australia (PGA), the Pharmaceutical Society of Australia (PSA) and the Royal Australian College of General Practitioners (RACGP). The TGA and the Food Standards Australia New Zealand (FSANZ) and have observer status.

- 7. Should the CRP consider complaints about all forms of advertising?**
 - The College would recommend that CRP consider complaints about all forms of advertising. Currently advertisements to consumers delivered as leaflets, brochures, catalogues, shelf talkers, etc have to go to industry self-regulatory

8. Could trivial or straightforward complaints be better dealt with rather than requiring CRP consideration?

- The College would like to suggest that straightforward matters such the lack of a required warning should be dealt with by the CRP (or TGPA) Secretariat and not require consideration by the CRP (or Therapeutic Goods Promotional Authority (TGPA)).

9. Should civil penalties apply for breaches?

- The College believes that the current provision under S42 (DM) of the Therapeutic Goods Act, 1989 is ineffectual as this requires the TGA to put a criminal case to the public prosecutor to get action.
- The College would like to suggest that the CRP and/or the TGA and/or the proposed Therapeutic Goods Promotional Authority (TGPA) need to be able to use civil penalties such as infringement notices and enforceable undertakings involving fines, corrective advertising orders, de-listing products and refusal to list a product substantially similar to one that had been cancelled.⁵

⁵ <http://www.tga.gov.au/legis/enfguidelines.pdf>