



From the President

18 December 2017



Dear Sir/Madam

Re: The regulatory framework for advertising therapeutic goods

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to respond to the Therapeutic Goods Administration (TGA)'s consultation on the regulatory framework for advertising therapeutic goods. The RACP welcomes the Government's acceptance of and commitment to delivering the majority of the recommendations of the Review undertaken in 2015.

As has been recognised, the impact of therapeutic goods advertising on patients, providers and our whole healthcare system can be comprehensive, ranging from impacts on consumer information and decision-making to impacts on physician prescribing behaviour and public health. The regulation of advertising is a critical consumer protection measure and, in substance, an important aspect of the TGA's regulatory regime. The RACP strongly supports the implementation of recommendation 56 – that is, *current mechanisms for managing complaints be disbanded and be superseded by a single agency responsible to receive and manage complaints on advertising of therapeutic products to the public.*

As it stands, regulation of the advertising of therapeutic goods to consumers falls under the broad oversight of the TGA. In the view of the RACP, the TGA should be the centralised agency dealing with complaints about inconsistent and irresponsible therapeutic goods advertising. The TGA has the most appropriate expertise on which to shoulder this responsibility in the best interest of consumers and patients. This will not only enhance the timeliness of considering complaints, but, most important, improve consistency and efficiency in its decision-making, which is part of the core mandate of the TGA. However, the method by which it is implemented will be critical.

The RACP considers that the development of a detailed transition plan will be needed to successfully implement and support the changes, to ensure a smooth transition from the current co-regulatory system governing the advertising of therapeutic goods to a centralised

one. This transition plan should identify specific processes, activities and resources required, as well as including appropriate workforce planning, to facilitate the transition. This will be necessary to ensure there are no delays to the resolution of existing complaints being handled during that time and that a sufficient number of experienced staff are available to implement and manage the changes required.

In addition to this, the single agency should have the characteristics of being

- timely in responding to and resolving complaints made as well as withdrawing the advertisement of concern for a given therapeutic good from the market.
- explicit in its communication plan to inform manufacturers or companies in violation of the relevant Acts, Regulations, and the Codes.
- empowered to impose sanctions and heavy penalties on non-compliant advertisers or sponsors, particularly in cases of repeated contravention of the advertising requirements.

To further strengthen the capability of the complaint handling unit and safeguard the public, the RACP recommends that:

- The relevant overseeing Committee must have experience and include at least two members representing consumers.
- The 'training' for companies must include face-to-face elements and not only be via printed resources or online.
- It must be made expressly clear to companies that inappropriate advertising will lead to heavy penalties, such as having their products taken off the market, in particular for repeated offences.

The RACP also supports the development of a formal sponsor education programme but the development of such a programme should be conducted and overseen by the TGA. It is important that those contracted to develop it must not be affiliated to companies which manufacture and/or sell therapeutic goods.

We look forward to hearing further details on the proposed outcomes, but should you require any further information regarding this response, please do not hesitate to contact [REDACTED]

Yours sincerely

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Dr Catherine Yelland PSM