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To whom it may concern

The RACGP welcomes many of the reforms to the regulatory framework for advertising therapeutic goods. However, it makes little sense to replace the current system of mandatory vetting and pre-approval of advertisements with an industry self-regulation approach as per Recommendation 55.

Pre-approval is our first line of defence against the public harms caused by false and misleading claims in medicine advertising. Reports indicate that many advertisements vetted during the pre-approval process require revisions before publication because they are in breach of the *Therapeutic Goods Advertising Code*.<sup>1</sup>

A retrospective policing system leaves regulators to clean up the damage caused by such claims, a task that is not only inefficient but also fiendishly difficult. Moreover, the high rate of Code non-compliance discovered on audit suggests that industry self-regulation is a fraught system with which to replace the pre-approval process. TGA data shows that of the compliance reviews conducted between July 2015 and June 2016, 80 per cent (327 out of 408) were verified breaches.<sup>2</sup>

New, more transparent complaint-handling processes (Recommendation 56) and stronger powers of enforcement (Recommendation 57) are welcome measures.

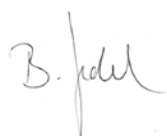
However, targeted education programs for sponsors and advertisers as per Recommendation 58 are likely to be costly and ineffective in comparison to the pre-approval arrangements already in place.

While imperfect in that it does not apply to advertisements published on the internet or pay television, the pre-approval process helps maintain the integrity of the promotion of therapeutic goods. The RACGP believes that the need to protect Australian consumers should come before the need to reduce the regulatory burden on sponsors and advertisers.

Finally, the RACGP would like to restate its concern over the resourcing of the TGA Complaints Resolution Panel (TGACRP). The RACGP wrote to the TGA in October 2013 and again in August 2016 with regard to this matter. While the RACGP had been invited to participate on the TGACRP, no funding was allocated to the position, effectively meaning that any GP representative would be required to attend meetings and complete the associated administrative work on a voluntary basis.

Ignoring this issue signals the perceived worth of clinical representation on the TGACRP is low. Furthermore, it tells a worrying tale of broader resourcing woes that may undermine implementation of the current recommendations.

Yours sincerely



Dr Bastian Seidel  
President

#### References

1. O'Reilly B. Advertising reform: watering down consumer protection [Electronic article]. 2016 [Available from: <http://www.doctorportal.com.au/mjainsight/2016/38/advertising-reform-watering-down-consumer-protection/>].
2. Australian Government Department of Health Therapeutic Goods Administration. Performance statistics report: July 2015 to June 2016. Canberra: TGA; 2016.