

**AUSTRALIAN COMMISSION  
ON SAFETY AND QUALITY IN HEALTH CARE**

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**Consultation Response on  
Therapeutic Goods Advertising  
Code: Submission to Therapeutic  
Goods Administration**

**Response from the Australian Commission on  
Safety and Quality in Health Care**

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## Summary

The Commission has prepared this response to the Therapeutic Goods Administration's *Consultation: Therapeutic Goods Advertising Code – Proposed improvements including proposed framework for Schedule 3 medicine advertising* (August 2017).

Safe and quality use of medicines is supported by clear medicines information. Unclear or confusing presentation of medicines information can increase the opportunity for medication errors. Medication errors in community settings contribute to patient harm and increase hospital admissions.

Information presented to consumers in the form of advertising is a major contributor to the information available for a particular medicine. The Commission supports the continued regulation of advertising as integral to patient safety.

## Introduction

The Therapeutic Goods Administration (TGA) is redrafting the Therapeutic Goods Advertising Code. This includes provision for advertising medicines containing substances listed in Schedule 3 of the Poisons Standard. The Australian Commission on Safety and Quality in Health Care (the Commission) acknowledges the opportunity to participate in the consultation.

## Discussion

Health professionals are best placed to provide reliable health information to their patients. Advertisements are not likely to provide complete and unbiased medicines information to patients.<sup>1</sup> A systematic review by Gilbody et al<sup>2</sup> reported that medication advertisements can influence patient demand and prescribing behaviour.

Direct-to-consumer advertising of medications can increase consumer expectations and can diminish the doctor-patient relationship when a doctor declines to prescribe the advertised drug.<sup>3</sup> This is also relevant in a community pharmacy setting. The pharmacist-patient relationship may be compromised when the pharmacist bases their advice on evidence-based practice over the direct-to-consumer advertising messages to which a consumer may have been exposed.

The Commission recommends the advertisement of pharmacist-only medications is kept to a minimum. In particular the proposed alternative TGA recommendation '*a negative list of substances not permitted to be advertised to consumers, with anything off the list authorised to be advertised by default*' may not be in the best interest of patients.

## Commission's recommendations

The Commission supports the continued regulation of therapeutic goods advertising.

The consultation document has been reviewed and the Commission makes the following overarching recommendations:

1. Create appendices in the Poisons Standard to enable additional requirements for Schedule 3 substances to be specified. This includes substances that have been down-scheduled from Schedule 4 (prescription-only) and substances for which direct-to-consumer advertising is inappropriate.
2. The impact of granting market exclusivity for one brand could be assessed further to this consultation. Market incentives for down-scheduling may have the potential to increase access to medicines. However, this may have limited benefit as patients will only have access to one brand.

Table 1 describes the Commission's comments and recommendations on the TGA document *Consultation: Therapeutic Goods Advertising Code: Proposed improvements including proposed framework for Schedule 3 medicine advertising*.

**Table 1:** Recommendations on the Consultation: Therapeutic Goods Advertising Code: Proposed improvements including Schedule 3 medicine advertising

Section	Page No.	Paragraph	Finding	Recommendation
1. Introduction	4	4	Limited emphasis on product labelling and packaging and which are used as advertising tools	Reference packaging and labelling within the regulations
2. Review recommendations	5	1	The Review first mention	Define 'the Review'
		2	The Panel first mention	Define 'the Panel'
		2	Therapeutic products vs. therapeutic goods	Use consistent terms
		All	Numbered recommendations described in words	Use digits for numbers ten and above
		Rec. 55	Agree, but refer to MHRA blue print (4) and the circumstances where vetting may be required  <i>(i) where a newly authorised product, subject to additional monitoring, is placed on the market;</i>  <i>(ii) where a product is reclassified, such as from POM to P; or</i>  <i>(iii) where previous advertising for a product has breached the Regulations.</i>	TGA should retain right to request advertising for review if the self-regulation process is a risk to the consumer

Section	Page No.	Paragraph	Finding	Recommendation
		Rec. 55	This is also dependent on recommendation 56	Note Recommendation 55 is dependent on acceptance of 56, 57 and 58
	6	2 and 3	TGA responsibility as single body is repeated	Consolidate paragraphs 2 and 3
	6	4	Recommendation 28 referenced with no detail	Expand on Recommendation 28
	6	Rec. 58	Reference made to National Regulatory Authority	Consistently refer to either NRA or TGA
	6	Final	Recommendation 11 referenced with no detail	Expand on Recommendation 11
3. Background	8	2	Recommendations 38 and 39 referenced with no detail	Expand on Recommendations 38 and 39
	8	5	Reference to nonalignment with other countries	Expand on the requirements in other countries which may address this issue
	8	6	Reference to schedule 3 substances not appropriate for Direct to consumer (DTC) advertising. If this distinction is made, how are schedule 3 medicines further categorised?	Define categorisation for schedule 3, DTC and non-DTC
4. Proposed code changes	9	2	How will TGA work with Medicines Australia and other stakeholders to minimise subjectivity and enhance compliance and enforcement powers for non-compliance?	Supported but needs further detail on how this will be achieved
5. Price information code of practice (PICOP)	15	Bullet 2	Should PICOP remain in new code or as separate legislation?	Pricing is important information but should be separated from medicines information
6.2 Product advertising requirements	16	Highlight 1	'Your pharmacist must decide if this product is suitable for you' contradicts consumer centred medicines management	Suggest 'You and your pharmacist must decide together if this product is suitable for you'

## References

1. Woloshin S, Schwartz LM, Tremmel J, Welch HG. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? *The Lancet*. 2001;358(9288):1141-6.
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4. Medicines and Healthcare products Regulatory Agency (MHRA) Third Edition of the Blue Guide, September 2014 [www.lmi.no/wp-content/uploads/2017/01/vedlegg\\_5-blue\\_guide.pdf](http://www.lmi.no/wp-content/uploads/2017/01/vedlegg_5-blue_guide.pdf)