

Consultation: Therapeutic Goods Advertising Code

Proposed improvements including proposed framework for Schedule 3 medicine advertising

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) consultation on proposed improvements to the Therapeutic Goods Advertising Code (TGAC), including a proposed framework for Schedule 3 (S3) medicine advertising.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 30,000 pharmacists¹ working in all sectors and locations.

PSA's core functions include:

- providing high quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

Background

Previous reviews and consultations

PSA has made submissions over the years in relation to proposed reforms around arrangements for the advertising of therapeutic goods. The following provides a summary of PSA's understanding and response to past consultations and outcomes of reviews.

¹ Pharmacy Board of Australia. Registrant data. Reporting period: 1 Apr 2017 – 30 Jun 2017. At: www.pharmacyboard.gov.au/About/Statistics.aspx

Date	Activity	Outcome noted or relevant to PSA	PSA's position
2014 – 2015	Expert Review of Medicines and Medical Devices Regulation	Seven recommendations on advertising of therapeutic goods to the public. Two recommendations on reviewing the Scheduling Policy Framework (SPF) including a review of S3 advertising guidelines.	
2016	Australian Government response	Accepted recommendations, noting that the Australian Health Ministers Advisory Council (AHMAC) would need to consider any proposed changes relating to the SPF.	
Nov 2016	TGA consultation on regulatory framework for advertising therapeutic goods	From 1 July 2018, TGA will assume responsibility as a single complaints handling body for therapeutic goods advertising directed to the public. Other measures to help improve compliance with legislation: <ul style="list-style-type: none"> • cessation of pre-approvals of advertisements for certain non-prescription medicines • deliver an advertising compliance education program • broader and enhanced enforcement and compliance powers. 	PSA has long advocated for a single body, and recently supported the option for TGA to assume that role. PSA supported this option but emphasised it would need to be accompanied by measures such as those outlined in the subsequent two dot points. PSA recommended development of pharmacist-specific materials to provide guidance on responsibilities as health service providers and retailers. PSA supported these measures.
Apr 2017	TGA consultation on the SPF and advertising of S3 medicines	Identified the need for further consultation on a possible S3 medicines advertising framework. This has led to the current consultation.	Refer to next section

Review of SPF and S3 advertising

The April 2017 TGA consultation on the SPF and reforms to S3 advertising resulted in the following proposed reforms. PSA's comments and position on the proposed reforms are summarised below.

	Proposed reform	Comments relating to PSA's position
1	Split the SPF into a policy document and a guidance handbook.	<p>PSA notes that this change is intended to: enhance clarity around the legislative nature of requirements; incorporate assessment of benefit in conjunction with risk in applications; improve usability of application templates.</p> <p>PSA advocated for "greater consideration of potential benefits of rescheduling" in order to achieve "an appropriate balance between risk and benefit".</p>
2	Establish a stakeholder working group to provide advice on ongoing reforms to the Poisons Standard and the SPF.	PSA strongly supported this option and advocated its role in this type of forum as the peak body for pharmacists in Australia.
3	Consider changes to allow full public consultation on interim scheduling decisions and to extend the two-week consultation period on a case-by-case basis to four weeks.	<p>PSA agreed with the reported view that interim decisions should be open to full public consultation.</p> <p>PSA also repeatedly raised the issue of the very restrictive consultation timeframes associated with interim scheduling decisions.</p>
4	Create a new appendix in the Poisons Standard to enable additional controls or requirements for S3 substances to be specified, in particular for substances that have been down-scheduled from Schedule 4.	<p>In 2015, PSA recommended the introduction of greater flexibility to the SPF to enable inclusion of appropriate reference to specific conditions or recommendations around the implementation of the scheduling of a substance.</p> <p>In April 2017, PSA welcomed this option being canvassed for substances being down-scheduled to S3. However, PSA also clarified that such controls "need not be limited to the down-scheduling of substances to S3" i.e. it may potentially be appropriate and useful for a substance in any other schedule and for any type of rescheduling.</p>

Current consultation

Comments on the consultation paper

Overall, PSA is pleased to see the progress and direction being taken with regards to the future regulatory framework for advertising therapeutic goods. PSA welcomes the opportunity to comment through the TGA's current consultation on proposed changes to improve the TGAC and a possible framework for advertising of S3 medicines to the public.

For example, PSA understands the TGAC is being revised to provide for more objective tests to determine breaches, given the anticipated introduction of strict liability offences. PSA supports this approach.

Proposed reforms also intend to address inconsistencies between requirements for advertisements for medicines and medical devices. PSA echoes the need to have a level playing field with regards to advertising provisions for all therapeutic goods.

The following table provides PSA's comments on proposed changes currently under consultation. PSA's comments focus on issues or proposed amendments which are relevant to pharmacists.

	Extract of key proposed changes relevant to PSA	PSA's comments
4	Proposed Code changes	
4.1	Changes to support effective sanctions and enforcement of advertising requirements	
	Remove or minimise subjectivity in the interpretation and implementation of specific advertising provisions	<p>PSA agrees with this approach. The proposed change is essential given pre-approval of advertisements will cease in favour of a more self-regulatory regime. Enhanced sanctions and enforcement powers will only be effective if advertisers are assisted in complying with requirements.</p>
4.2	Core objectives for the new Code	
	<p>Include/maintain following objectives and requirements:</p> <ol style="list-style-type: none"> 1. Advertisements must comply with Therapeutic Goods Act 1989, regulations and the TGAC. These will include specific requirements and prohibitions on content, statements, claims and representations. 2. Advertisements must be truthful, balanced and not misleading. Claims must be consistent with ARTG entry and be consistent with approved indications (or intended purpose for medical devices). <ul style="list-style-type: none"> • Must not claim or imply that product is effective for specific demographic groups of patient (particularly where this may be a vulnerable group) without detailing the supporting evidence. 3. All claims must be substantiated. <ul style="list-style-type: none"> • Scientific information referred must also be educationally appropriate. Details must be publicly accessible. • Advertisement must identify sponsor of the scientific study and must also detail if the sponsor of study has or had any direct or indirect commercial interest in the therapeutic good or the ingredients being promoted. • Testimonials – advertisement must acknowledge any valuable consideration provided; person must be accurately identified and not be an employee or related to the sponsor or the advertiser. 4. Adequate and appropriate information must be given on risks, cautions and side effects, and provide balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help. The advertisement: <ul style="list-style-type: none"> • must be consistent with current social expectations for public media, and presentation of claims/content consistent with relevant government campaigns • must not unduly glamorise products or prey on vulnerability of particular consumers • must be consistent with Quality Use of Medicines objectives • must not be likely to create a false expectation in its likely audience that the product will deliver health benefits or improvements to their quality of life • must not discourage consumers from taking medicines 	<p>PSA agrees with the retention of core requirements, including the legislative underpinning.</p> <p>PSA supports the efforts being made to develop a new TGAC containing clearer and more specific details of what is and is not permitted in advertisements.</p> <p>PSA welcomes specific changes flagged, for example, explicit reference in the TGAC to quality use of medicines objectives, enhanced focus on supporting evidence, and inclusion of clear information on risks and benefits.</p> <p>PSA will comment during public consultation on a draft legislative instrument where further detail will be specified.</p>

	Extract of key proposed changes relevant to PSA	PSA's comments
	<p>prescribed by a healthcare professional.</p> <ul style="list-style-type: none"> • If a sponsorship advertisement (e.g. promoting a team, individual or competition), must not include any brand tag-line other than product name, and cannot refer or link to any product advertisement. • Disease awareness campaigns must not identify any specific product or sponsor. 	
4.3	The Council recommendations	
	<p>Include new definitions for “prohibited” and “restricted” representation. Current definitions may be inadequate in light of new diagnostic techniques (e.g. direct-to-consumer genetic testing), advertising of diagnostic tests and proposal to allow enhanced efficacy claims for certain complementary medicines.</p> <p>Include new restricted representations and provisions dealing with scientific information.</p> <p>Testimonials to be subject to clearer more objective conditions.</p> <p>Prohibit offers of free samples of therapeutic goods as part of an advertisement. Examples of exceptions would be: sunscreens, class I medical devices such as condoms and dressings.</p>	<p>PSA agrees amendments as suggested are necessary to ensure the TGAC is contemporary, and scientific information relevant to the advertisement can be readily understood and accessed.</p> <p>PSA welcomes inclusion of clearer advice regarding testimonials.</p> <p>PSA agrees with the continuation of prohibition of free samples with advertisements.</p>
4.4	Consultation comments	
	<p>Possible development of guidelines to clearly and unambiguously communicate requirements of the new TGAC.</p> <p>Suggested inclusion of specific examples of compliant and non-compliant advertising.</p>	<p>PSA is supportive of canvassing different ways of delivering information on requirements to advertisers.</p> <p>PSA would be pleased to assist with the development of tools or information that is tailored for pharmacists engaging in advertising activities.</p>
5	Price Information Code of Practice (PICOP)	
	<p>Better underpinning of the PICOP is proposed in the development of a new TGAC so that communication of price information to consumers can continue to be permitted even where products themselves cannot lawfully be promoted directly to consumers.</p>	<p>PSA agrees with this approach.</p> <p>PSA advocates greater clarity to support compliance by pharmacists accompanied by stricter penalties for non-compliance.</p>
6	An option for an Advertising Framework for Schedule 3 (pharmacist only) medicines	
6.1	Overview	
	<p>A significant majority of stakeholders support the broadening of direct-to-consumer advertising of S3 medicines on condition that there are requirements to ensure consumers are aware that pharmacist advice is required, and that some S3 medicines would not be suitable for advertising.</p>	<p>PSA agrees with a conditional broadening approach as outlined in previous submissions.</p>

	Extract of key proposed changes relevant to PSA	PSA's comments
	<p>Proposed approach could be that S3 medicines can be advertised unless the Delegate determines advertising is not appropriate for medicines containing a particular substance or class of substances.</p> <p>Existing S3 substances could be considered by a working group (consisting, for example, of jurisdictions, medical practitioners, pharmacists, consumers and industry representatives) on a case-by-case basis. Advice from the Advisory Committee on Medicines Scheduling (ACMS) could be sought as required.</p> <p>Retain the existing Appendix H mechanism (i.e. as a positive list of substances that may be advertised to the public).</p>	<p>PSA does not support a default position of permitting advertising of S3 medicines even with a mechanism to determine exceptions.</p> <p>PSA continues to support consideration of S3 advertising on a case-by-case basis.</p> <p>PSA would support the establishment of a working group to consider appropriateness of existing S3 substances to be advertised.</p> <p>PSA supports the retention of Appendix H as a positive list of S3 substances permitted to be advertised.</p> <p>PSA has suggested that consideration could be given to permitting classes of substances being included in Appendix H.</p>
6.2	Product advertising requirements	
	<p>To include prominently in advertisements at the top (print) or as a leading statement (broadcast):</p> <p style="padding-left: 40px;">Your pharmacist <i>must decide</i> if this product is suitable for you.</p> <p>To include prominently in advertisements at the bottom (print) or as the ending statement (broadcast):</p> <p style="padding-left: 40px;">Ask your pharmacist about side effects relevant to you.</p>	<p>PSA agrees with the proposal to standardise messaging through the inclusion of standard phrases at agreed places of advertisements.</p> <p>PSA believes there is scope to consider strengthening emphasis on the outcome of a pharmacist's assessment of product suitability i.e. that the clinical decision may result in non-supply of the product or recommendation of an alternative.</p> <p>PSA will comment further during public consultation on the draft advertising code.</p>
6.3	Substances unsuitable for inclusion in Appendix H	
	<p>Guidance to a working group of wide range of stakeholders assessing existing S3 substances would include a list of criteria of what may not be appropriate for advertising, for example:</p> <ul style="list-style-type: none"> • injectables • substance for use in emergency situations • where safer analogues or therapeutically equivalent medicines are available • where there is potential for inappropriate use, abuse or diversion • where the substances form part of surgical procedures • medicine for treatment of chronic condition that requires a doctor 	<p>PSA supports the establishment of and participation in a working group to assess existing S3 substances and develop a list of criteria or guidance on substances unsuitable for inclusion in Appendix H.</p>

	Extract of key proposed changes relevant to PSA	PSA's comments
	as part of the treatment.	
6.4	Process for adding a substance to Appendix H	
	A process similar to that for rescheduling proposals is suggested, including public consultation. However, referral to the ACMS would be at the Delegate's discretion.	<p>PSA supports the ongoing inclusion of a public consultation process.</p> <p>PSA would however be keen to see amended timeframes with regards to consultations, announcement of outcomes and implementation dates as outlined in previous submissions.</p>

Education program

At a recent TGA workshop to discuss the exposure draft of the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017*, a statement was made regarding TGA's plan to develop an education program for industry, health care professionals and consumers to support implementation of amendments to the advertising section of the draft Bill.

PSA takes this opportunity to reiterate that we strongly recommend inclusion of pharmacist-specific guidance materials in the education program. Pharmacists, as health service providers and retailers, will require clear and appropriate guidance so that they are able to fulfil their responsibilities and support the TGA in meeting its overall objectives. PSA supports the TGA's approach to enforcement encompassing "guidance, education, assistance and warnings".

As the custodian of the *National Competency Standards Framework for Pharmacists in Australia 2016*, PSA welcomes the TGA's indicative proposal that the education program will include competency-based modules and other guidance documents. PSA would welcome the opportunity to work with the TGA to design and implement necessary education materials for pharmacists.

(End of submission)

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