Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

30 May 2018

Therapeutic Goods Administration

RE: ASCEPT feedback to TGA on "Consultation: Complaints handling - Advertising therapeutic goods to the public"

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) thank you for the opportunity to provide comment on the Consultation: Complaints handling - Advertising therapeutic goods to the public.

ASCEPT is the leading professional body in Australasia for clinical pharmacology policy and practice and its members' expertise encompasses experimental and clinical pharmacology and toxicology (including: clinical trial and regulatory issues, pharmacovigilance and quality use of medicines). ASCEPT members serve on most Commonwealth and State committees concerned with medicines regulation or quality use of medicines.

Proposed ASCEPT feedback to TGA on "Consultation: Complaints handling - Advertising therapeutic goods to the public"

Section of Consultation Paper	Background	ASCEPT comments
General	<u>What complaints system is being replaced?</u> The previous system of advertising complaints of therapeutic goods was a combination of co-regulation and self-regulation. The role of the TGA was as the Government's key stakeholder. The complaints process was complicated and involved two separate bodies (the Complaints Resolution Panel and the Therapeutic Goods Advertising Code Council), the membership of both being predominantly industry	The proposed system of a single body approach (with the TGA as the single body) appears to be a substantial improvement on the previous complaints system. In particular, the proposed system of external regulation by TGA (rather than the largely self-regulatory system that is currently in place) appears to be a more robust approach.

	(Medicines Australia [for prescription medicines] and the Australian Self Medication Industry [ASMI] and the Complementary Healthcare Council of Australia [CHCA] (for non-prescription medicines)), some consumer groups, Pharmacy Guild, Pharmacy Society of Australia and RACGP. In only exceptional cases were complaints referred to TGA and/or Australian Competition and Consumer Commission for any action.	
General	Consumer knowledge of the complaints process	It will essential that consumers are adequately informed of the appropriate complaints path, as is will differ from other advertising-related complaints. It is not yet clear how consumers will be made aware this. Should is form part of any approved advertisement?
Section 6 "Our Approach"	Graded approach to compliance with "help and support" for low compliance risk cases, ranging up to enforcement for high compliance risk cases, as outlined in Tables 1 and 2.	ASCEPT agrees with this graded approach
Section 7.2 Triaging of complaints	After a complaint is made, staff within TGA will triage the case into low, medium, high or critical categories (see Section 8 response, below)	Although the categories of severity of the breach are reasonable, there remains some subjectivity. What attributes will the staff within the TGA who are triaging the complaints have (i.e. what degree of clinical knowledge will these staff have)? This is not clear in the current consultation document. Clinically trained staff (e.g. medical practitioners, public health physicians) would be essential, with specialist clinical pharmacologists likely to be best placed to assess the nature of the breach and its severity. ASCEPT believes that this process should be independent of industry representatives. What will the

		process be if the responsible entity disagrees with the TGA's assessment?
Section 8	Hierarchical nature of complaints, with categories of low (isolated, low level breach), medium (ongoing breaches), high (continued or serious breaches) and critical (extensive or targeted advertising breaches that may lead to patient harm or undermine public health messages), as outlined in the figure on page 11	ASCEPT supports the proposed severity grading system and regulatory action approach, as outlined on page 11. As outlined in response to section 7.2, there remains subjectivity in these definitions; it would be difficult to be any more prescriptive which is why clinically-trained staff would be essential in the assessment of the severity of any breach and that the process be independent of industry.
Section 9 Reporting of outcomes of complaints		ASCEPT largely agrees with the proposed publication specifications, as listed on pages 14 and 15. However, in high and critical priority outcomes, is publication on the TGA website sufficient? Should responsible entities be made to publish a retraction (possibly in the same medium that the original advertisement was published) as a means to ensure the erroneous message contained within the non-compliant advertisement does not have continued effects on patient safety or public health.
Section 9 "Time to action complaints" on page 15	The table within this section lists key performance indicators (KPI) targets of 95% time to action complaints in 20 days for high priority and 100% in 10 days for critical priority cases.	These timeframes seem discordantly long, given that for high and critical priority cases, the TGA responses are meant to be an email or telephone call to the responsible entity "immediately".
Section 9 "Time taken to close complaints" page 15		ASCEPT believes the "Time taken to close complaints" KPIs are reasonable.
10 Governance	A new non-statutory committee, the Therapeutic Goods Advertising Committee, will be formed. This	Although ASCEPT agrees that a broad group of stakeholders is necessary to provided governance of

	committee will have wide representation across stakeholders involved in therapeutic goods advertising and will include representation from: • patient and health consumer representative bodies • therapeutic goods industry • publishers and broadcasters (including social media and internet) • healthcare practitioners, and • advertising and other parts of the media industry. The committee will act as a forum for engagement on advertising issues and will provide advice on thematic issues in advertising complaints, compliance priorities and education plans. The committee will also advise on the policy settings for therapeutic goods advertising, including for products such as medical devices that were formerly not completely included within the advertising regulatory framework.	the advertising complaints process, it is important that the independence of the TGA as the regulator (and patient safety as its sole objective) is not compromised by excessive industry involvement in decision making. ASCEPT believes that it is essential for a clinical pharmacologist, representing ASCEPT, be a member of the committee.
11 Education and Guidance		ASCEPT agrees with the focus on education and guidance being a key strategy in support of compliance and welcomes an e-learning program to help with this.

Submission prepared in consultation with ASCEPT expert members. Please do not hesitate to contact the ASCEPT Secretariat [redacted] at ascept@ascept.org for any further information.

Yours sincerely,

[redacted]