Pharmaceutical Society of Australia

Consultation: Complaints handling – Advertising of therapeutic goods to the public

JUN 2018

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) on the proposed complaints handling model for advertisements for therapeutic goods directed to the Australian public.

PSA understands this consultation will help inform the design of the new complaints management process which is scheduled to come into effect on 1 July 2018 as an outcome of the **Australian Government's response** to the **Expert Review of Medicines and Medical Devices Regulation**.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 31,000 pharmacists[1] 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.

[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 January 2018 – 31 March 2018. At: **www.pharmacyboard.gov.au/About/Statistics.aspx**

Background

PSA has consistently advocated for a transparent and less complex system to be implemented for the management of complaints relating to therapeutic goods advertising. Complaints management needs to occur within a framework that promotes ethical marketing practices consistent with patient safety and quality use of medicines principles. Overall PSA is pleased to see progress being made in designing the new system.

PSA is supportive of the risk-based compliance approach and the adoption of principles of being ethical, consistent and transparent. We acknowledge likely improvements through parallel measures such as amendments to enforcement powers and sanctions, and the review of the Therapeutic Goods Advertising Code. Further we believe the design of a supportive and educative complaints management system is fundamentally important, not only from a compliance perspective, but also in being able to meet the needs of health consumers and the broader public including vulnerable people who may be hesitant of lodging complaints despite genuine concerns.

Comments on current consultation

Through this submission, PSA provides feedback on specific issues identified and/or contained in the **consultation paper** (with page numbers indicated where relevant). These are outlined in the table below.

Issue	PSA's comments
Commencement date (p. 5)	The TGA will become the single body responsible for the handling of complaints about the advertising of therapeutic goods to the public from 1 July 2018. Taking into account the need for advertisers to be informed and educated about the new arrangements and consumers to be made aware of the new complaints system, PSA has some concerns that this implementation timeframe currently does not appear feasible. The consultation paper also does not mention what arrangements may apply during any transition period.
Approach to compliance (pp. 6–8)	PSA is generally supportive of the proposed approach to compliance, in particular the emphasis on public health and patient safety. We also believe that, for the system to be flexible and responsive, it is necessary to design regulatory actions which are "appropriate and proportionate" with the risk posed by the advertisement – as reflected in the graduated response to advertising non-compliance. One aspect of advertising behaviour that PSA believes is not adequately addressed through the proposed model is where an advertisement or a series of advertisements appear to deliberately target or exploit the consumer's relative lack of knowledge about therapeutic goods. In such cases, while the consumer's ability to use the therapeutic good safely may not be substantially impacted and the potential risk of harm may be low, PSA would have significant concerns if the advertisement is considered to be unethical or inconsistent with quality use of medicines

	principles. In addition, if such advertisements are permitted to occur on an ongoing basis due to a low priority for regulatory action (based on the low potential risk of harm), a wider group of consumers would be exposed to the offending advertisements. Clearly this is highly unsatisfactory and we believe it needs to be addressed appropriately through the new complaints model.
Table 2 (p. 8)	Under the “Accidental Non Compliance” column, the text of the second bullet point is incomplete.
Communication with the complainant	PSA is aware that concerns raised in the past have included the overly long complaints resolution timeframes, lack of transparency about complaints outcomes, and confusion around how / where to lodge a complaint. In order to substantially improve the complainant’s ‘experience’, PSA believes it is particularly important that proactive communication occurs at key stages of the complaints handling process. This should help address the broader feedback regarding transparency and should also contribute to ‘acceptance’ of (rather than frustration over) timeframes even when they may be overdue. It should also enhance satisfaction and trust more broadly. Thus PSA proposes the following: • Receipt of a complaint should be acknowledged formally and promptly. Manual notification of a unique identification number by the TGA is proposed for when the complaint is received outside of the online hub. In addition, the consultation paper states that “online complainants will receive a unique identification number visible on the form at the time of submission”. In all cases, PSA suggests formal acknowledgement of receipt of the complaint must be issued to the complainant from the perspective of transparency and accountability. The formal acknowledgement can highlight the unique identification number, and should also include some indication of next steps and expected timeframes. • The proposed model includes acknowledgement of receipt of the complaint after initial assessment and triaging of the complaint are completed, and a case identification number has been issued. PSA suggests this would become the second step of formal communication with the complainant (PSA has suggested addition of an earlier step as outlined in the previous bullet point) and should be framed as ‘outcomes of initial assessment’ (or similar). This will promote transparency and help the complainant understand and accept that their complaint is being handled appropriately. • If the complaint relates to a matter outside of the remit of the TGA and needs to be referred to another jurisdiction or more appropriate authority, once again, the complainant must be updated on the actions taken by the TGA. This must include information on where and how the complainant can make contact about their complaint going forward. • With regards to when a complaint is referred by the TGA to another body, the consultation paper text (p. 9) states that the complainant

	will be consulted as to whether they wish the TGA to take this action. However, this step does not appear to be reflected in the complaints process diagram (top of p. 9), acknowledging it is intended to present a high level overview rather than all of the detail. • The complaints process diagram includes the step relating to the publication of the outcome of a complaint. Although there is an arrow extending from the "Publish outcome" step to the "Reporter", it is not clear whether this constitutes proactive and informative advice back to the complainant. Once again, PSA would strongly recommend that formal advice on the outcomes of the complaint is provided to the complainant.
Categorising complaints handling	There are suggestions in the consultation paper that the advertiser's attitude to compliance or their awareness of advertising obligations will guide the triaging of complaints. PSA has some concerns that these factors are rather subjective. We believe it may be appropriate to give less weighting to such factors when assessing therapeutic goods advertising complaints.
Outcomes of investigation of complaints (pp. 12–14)	As outlined in this submission, PSA is supportive of the emphasis of the proposed complaints handling system on public health and patient safety, as well as the graduated response to advertising non-compliance based on the risk posed by the advertisement. The complaints process diagram (top of p. 9) shows that the outcome of a complaint will be published once the case is closed. However, the consultation paper lacks clarity around the exact detail of what will be published. Although PSA accepts that a graduated response will mean different requirements or timeframes associated with actions to rectify the non-compliance, we strongly believe there are core elements that must be reported publicly for all complaints that have progressed to the investigation stage (regardless of assigned priority). The report can be in summary format so it is not onerous for the TGA and facilitates communication. This is firmly in the public interest and necessary to fulfil transparency in relation to a robust and accountable complaints handling system. For example, information subject to public reporting must include: • date of receipt of complaint and when case was closed • the therapeutic good reported in the complaint and investigated • the responsible advertiser • what breaches were identified and upheld • details of corrective actions requested and timeframe. PSA seeks confirmation regarding the key elements to be included in a public report of complaint outcomes.

Education and guidance (p. 16)	As indicated earlier, PSA supports educative measures as one aspect of the overall compliance approach. However, advertisers' obligations are legal in nature, and therefore we believe it is appropriate that clear expectations regarding such obligations are presented firmly and as early as possible. The consultation paper indicates that an e-learning program to assist advertisers will be provided on the TGA web site and is expected to be available mid-2018. • It would be ideal for e-learning programs to be made available well in advance of the implementation date so that advertisers can familiarise themselves with new requirements. We believe the current timeframe is inadequate for advertisers to transition seamlessly with there being less than four weeks between the end of the consultation period (4 June 2018) and proposed commencement date (1 July 2018). • PSA is pleased the TGA will discuss specific stakeholder needs around guidance documents. PSA has previously requested that guidance and information materials specific to pharmacist advertisers be considered. Although compliance obligations are the same for all advertisers, the environment or circumstances through which pharmacists may advertise are different to, for example, sponsor companies. As the recognised standards-setting body for the pharmacy profession, PSA welcomes the opportunity to work with the TGA to assist in the design and implementation of resources for pharmacists. • PSA notes the TGA "will raise awareness about the new advertising complaints handling process and the role of the TGA in the regulation of advertising for therapeutic goods". PSA suggests this is a significant opportunity to engage with consumers and promote the new arrangements widely and clearly. Pharmacists are also a key information source for health consumers who may have concerns about the advertising of particular products.

(End of submission)

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