SUBMISSION FROM THE AUSTRALIAN TRADITIONAL MEDICINE SOCIETY (ATMS)

TGA Consultation: Complaints handling - Advertising of therapeutic goods to the public

The TGA Consultation Document, version 1.0, May 2018 (document) makes the following requests:

1. We are seeking your views on the TGA's proposed new complaints handling model and graduated responses to advertising non-compliance.

2. We seek the views of stakeholders on our proposed complaints handling model.

Response

As the TGA is requesting general commentary on the model outlined in the document, ATMS will comment on the elements of the process outlined in the document.

The complaints process

This is acceptable.

Accepting your complaint lead

The document states, "Leads will be assessed for validity as we can only legally action complaints about advertisements for therapeutic goods". Given that the TGA has jurisdiction over devices, reference to the advertising of devices should be included in the process. Otherwise, this is acceptable.

Triaging of complaints

This is acceptable.

Priority based complaints handling model

ATMS notes that the 4th priority driver listed here is, "the advertisers' awareness of their advertising obligations." It may be more instructive for advertisers and other stakeholders to reword this to more closely reflect the notion that this driver relates to the advertisers' upheld complaint history, as that appears to be the intent of this driver. If this is not the intent of this

driver, then this should be added as a 5th driver. The reason for suggesting this is that a safe and efficient therapeutic goods industry cannot operate effectively in the presence of serial advertising offenders. Where there is such a history, the importance of this should be reflected in the priority driver terminology. This would also be consistent with the priority levels process referred to in section 8 of the document.

Investigation phase

This is generally acceptable but ATMS would like to see time frames specified for this phase.

Low priority cases

ATMS supports the principle of educating advertisers who've been found guilty of a low-level breach of the Therapeutic Goods Advertising Code (Code). However, as has been the practice of the TGA Complaints Resolution Panel (CRP), under the new process the TGA should subject all advertisements about which complaints have been made to an assessment of compliance with all elements of the Code, including but not limited to, compliance with the evidence requirements for therapeutic claims.It's of note that in the majority of cases where the CRP has called for evidence to justify the claims made for therapeutic goods that are involved in an advertising complaint, that evidence has not met TGA requirements. Such assessments, if included in this new process, or applied routinely to all advertising complaints, would be useful for sponsors, consumers, the regulator and the therapeutic goods industry. This suggestion also applies to all other priority levels.Otherwise, this is acceptable.

Medium priority cases

Apart from the comment made above, this is acceptable. ATMS welcomes the publication of the details related to medium and higher priority cases.

High priority cases

Apart from the comment made above under the heading, Low priority cases, this is acceptable.

Critical priority cases

Apart from the comment made above under the heading, Low priority cases, this is acceptable.

Monitoring and trend analysis

This is generally acceptable, although ATMS would like to see more detail on this element of the process, such as the criteria for selecting past complaint cases and the number to be selected over a given period.

Reporting outcomes and measuring performance

ATMS is of the view that, as is the current practice with the CRP, detailed outcomes, including the product name, advertiser, the nature of the complaint, the findings and sanctions where applicable, should all be made publically available within a reasonable period of time after a determination of a complaint has been made. This should apply to low priority and all other complaints. Such publications are a valuable resource for consumers, advertisers, sponsors,

prescribers and regulators operating in other jurisdictions and provide a similar level of transparency to that which exists under current CRP processes. Otherwise, this is acceptable.

Other Comments

Responsible Advertising

The ATMS is the peak professional body for complementary and alternative medicine (CAM) healthcare practitioners. As such we form a critical element in the CAM sector, and also the broader healthcare sector. Another critical element in this sector is retail therapeutic goods. ATMS are committed to ethical, responsible, patient-centred healthcare, and the desire for an ethical healthcare sector extends to the advertising of therapeutic goods. The ATMS is of the view that the advertising of therapeutic goods should be done in an ethical and responsible manner, it should comply with all relevant legislation, and any claims made by sponsors or advertisers should be supported by appropriate evidence. In this way, healthcare consumers, prescribers and regulators can be assured that the therapeutic goods that are made available at a retail level in Australia can be trusted to do what they say that they'll do, and public trust in the healthcare sector can be maintained.

Advertising Pre-Approval

The ATMS note that the TGA intends to cease the requirement for pre-approval of therapeutic goods advertising, after the current extension to this process expires. The ATMS is of the view that pre-approval should continue, as it is the only means by which advertising Code compliance can be assessed before being published so consumers can be protected from non-compliant advertising practices. While the ATMS support the current practice of post-market surveillance, we are of the view that both pre-approval and post-marketing surveillance should be utilised in the advertising monitoring process.

Resourcing

For many years the CRP has dealt with complaints related to the potential breaches of the Code. It has done this very effectively, largely because of the individuals who comprise the Panel itself and the breadth of experience across the Panel, comprising as it does of representatives from CAM, consumers, advertising clearance agencies, pharmacy, and other relevant stakeholders. The ATMS has concerns that the TGA will not have the same capacity to bring this breadth of experience to the task of complaint assessment, and so suggests that the TGA engage representatives from relevant organisations for this purpose.

More broadly, the ATMS note that it's the TGA's intention to form a Therapeutic Goods Advisory Committee. The ATMS would be happy to contribute a delegate to this committee.

Retractions

The ATMS notes that in cases of Code breaches involving the potential for serious risk to consumers, that the CRP has issued advertisers with retraction notices, compelling public retractions of previously published advertising. ATMS would be interested to know what the status of retractions is in the proposed process and what role if any they'll play in this process,

and what sanctions will be imposed upon advertisers who fail to comply with a retraction notice. If it were the TGA's intention to replace retraction notices with the " Public Warning Notices" referred to in sections 4 and 9 of the document, the ATMS would like to see more detail on these.

Ends

Approved and authorised by ATMS
Monday, 28 May 2018