

Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Consultation: Complaints handling - Advertising therapeutic goods to the public

This document responds to the call by the Therapeutic Goods Administration (TGA) for submissions regarding design of the new complaints-management process. That process is concerned with the advertising of therapeutic goods, from 1 July 2018, in implementing the Expert Review of Medicines and Medical Devices.

In essence, there is substantive concern among clinicians, pharmacists, consumer advocates, educators and regulatory specialists about the regulatory framework for the advertising of goods that have therapeutic qualities and that are perceived by consumers as having therapeutic qualities. That framework must encompass goods that are harmful and goods, such as homeopathic products, that are inefficacious.

The concern relates to the current formal framework, which (as demonstrated in work by Harvey, Braithwaite et al) is ineffective and can accordingly be improved through the new process outlined by the Department of Health in the Government's response to the Expert Review. Saliiently the concern also relates to administration by the TGA of the new framework. In carrying forward recommendations by the Expert Review (and more broadly giving effect to the consumer protection principles underlying both the Australian Consumer Law and the Therapeutic Goods Act) it is imperative that the TGA as the primary entity concerned with consumer protection in the health goods & devices space deal with complaints about advertising on a basis that is

- timely,
- transparent,
- independent, and
- accountable

That responsiveness requires both adequate resourcing of (and by) the TGA and a sustained commitment to best practice. In doing so the TGA will build its legitimacy, which has been eroded through non-engagement with key stakeholders, and enhance national productivity as highlighted by Arnold & Bonython. Effective regulation is demonstrably beneficial to the national economy and taxpayer through the reduction of preventable harms.

Basis

This submission is made by Dr Bruce Baer Arnold of the Canberra Law School, University of Canberra. It reflects teaching of consumer protection and health law. It also reflects

The submission does not represent what would be reasonably perceived as a conflict of interest.

In providing this document the independent submission by Harvey, Vickers & Rottler is noted and strongly endorsed, consistent with past submissions and publications by Arnold & Bonython.

The role of the TGA

A move to best practice by the TGA assuming responsibility for handling complaints about the advertising of therapeutic goods is commendable. In assuming that responsibility as the specialist body it is imperative that the TGA bears in mind that its paramount responsibility is the protection of Australian consumers. It is not an industry support agency. It cannot leave the hard tasks to the Australian Competition & Consumer Commission (ACCC) under the Australian Consumer Law.

It must be conscious that its performance over the past decade (determined by its misinterpretation of its mission, its resource allocation and its non-engagement with civil society) has resulted in legitimate perceptions of regulatory capture and institutional incapacity. The TGA must also be conscious that enterprises have recurrently shown a willingness to 'game' the advertising regime, with self-regulation under the current regime being demonstrably ineffective. It is important that the TGA take responsibility rather than relying on consumer advocates and the media. Benchmarking against the ACCC is relevant.

Timeliness

It is imperative that the TGA both respond and be seen to respond on a timely basis to complaints about the advertising of therapeutic goods. Timeliness is important in terms of the TGA's legitimacy, appraisal of its effectiveness as a body with statutory powers and funding, the harm attributable to delay and scope for reducing marketer perceptions that particular behaviour is permissible.

That responsiveness involves an acknowledgment to complainants that a complaint has been received and will be addressed within a specific period. As part of improved transparency arrangements (see below) data about the processing of complaints should be published periodically. Systematisation of publishing as an integral part of the complaints process (rather than as an inappropriate regulatory burden) should both reduce costs and enable ongoing publication rather than relegation of data to an appendix within the Department of Health annual report. It is directly relevant to the Commonwealth's stated commitment to Open Government.

Matters should be addressed to the subject of complaints on an ongoing rather than batch basis, with a requirement that responses be required within a specific period. That period should be calibrated to the seriousness (and thus priority) of the complaint. It should also be calibrated to an explicit TGA advertising enforcement strategy modelled on the annual ACCC enforcement strategy statement that is actively publicised by the ACCC through for example speeches by the ACCC Commissioner and statements on the ACCC website.

The TGA should further be analysing complaints regarding advertising in order to identify and thence respond to 'hot spots' in industry practice, complementing the Department's community education initiatives.

The TGA should set, abide by and report against specific targets for dealing with complaints. Those targets include the resolution of complaints rather than merely receipt and acknowledgment of complaints.

Transparency

In any complaint regime it is axiomatic that some complaints will be non-substantive, some will be serious (for example a regulatory response can quickly alleviate a major harm) and some will be less serious.

Consistent with other submissions to the current consultation, it is important that the TGA expressly and clearly identify its prioritisation of responses. That prioritisation can be related to the advertising enforcement strategy statement noted above, with the Department for example having scope to target public education in looking beyond specific complaints.

In avoiding a regulatory 'black box' system, contrary to the Commonwealth's Open Government policy and consistent with the Department's commitment to accountability through fact-based performance appraisal, complainants should be informed on a timely basis of the prioritisation of their complaints. There is no substantive reason why the Department cannot institute an online 'dashboard' that publishes ongoing statistics about complaints received, in process, resolved. is assigned to.

Consumers, businesses, civil society entities and other stakeholders legitimately expect that there will be timely publication of specifics of breaches, including details of what breaches upheld or rejected by the TGA and why. That publication, in a readily accessible form (again consistent with Open Government and FOI initiatives), should include observers to identify advertisers, product names, product types and decision rationales. Such disclosure does not pose intellectual property or confidentiality problems. It is consistent with the practice of the Complaint Resolution Panel.

Best practice in reporting centres on outcomes rather than statistics about paper processing, contrary to the stance in some agencies which confuse 'raising a ticket' with resolving a complaint. In addressing consumer expectations about complaint processing the TGA should emphasise compliance rather than the despatch of warning letters or compliance notices.

Independent

The ACCC provides a model for engagement by the TGA (and more broadly by the Department of Health) with industry, consumers, civil society and other stakeholders. In the past the TGA has been reluctant to take on board feedback or questions from outside industry and has emphasised communication with particular stakeholders rather than with the community at large. That stance fosters perceptions of regulatory capture and incapacity; it is likely to result in substantial costs for the public health system and national economy.

It is important that the Department emulate the ACCC in providing timely public information when serious enforcement action is initiated. In essence, the TGA, consistent with a succession of internal and external inquiries, must adopt a more outward-facing approach. That approach will be welcomed by business and consumers alike.

As noted in other submissions, the TGA should not (and need not) wait until enforcement action is concluded, for example until a Federal Court judgment is delivered.

Accountable

It is imperative that the TGA provide stakeholders with information sufficient for a timely appraisal of the efficiency of performance and of the effectiveness of the advertising complaints regime. That information is of significance for business, consumers, members of parliament and other stakeholders. It is reflected in preceding comments about a shift from the TGA's 'black box' approach, evident in the difficulties experienced by journalists, academics and consumer representatives seeking information from the Department.

The emphasis on outcomes rather than transaction statistics means that the TGA must evaluate and publicly disclose, on a timely basis, whether the regulatory action regarding complaints results in compliance. It is insufficient for the TGA to warn advertisers; effective regulation requires the TGA to follow up warnings regarding all serious complaints to ensure that advertisers heeded that guidance. A preceding paragraph for example noted research by Harvey demonstrating that some advertisers claim compliance but in fact disregard obligations, in some instances systematically gaming the current regulatory framework. Follow-up is of value for potential litigation and for industry awareness.