
AMA submission – TGA regulatory framework for advertising therapeutic goods

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The AMA supports most of the changes to the regulatory framework for advertising over-the-counter (OTC) medicines that are proposed in the consultation paper released in November 2016.

What we support

Complaints management

The AMA fully supports the proposals to implement a more transparent and efficient complaints management process. The AMA is regularly contacted by members of the public seeking assistance because they are confused about where and how to report concerns about OTC medicines advertising. A single agency responsible for receiving and managing complaints will go a long way to simplifying the process for consumers.

Retaining the complaints handling function within the TGA seems a sensible approach because it already has technical expertise relating to therapeutic goods and as well as understands the regulatory framework. It would be the simplest and least costly model to implement and the most logistically efficient to ensure a seamless process from reporting to sanctions. The AMA is confident in the TGA's independence from industry or other sectional interests.

The AMA is also pleased to see that the system proposed would allow non-compliant advertisements to be dealt with even if they are not the subject of an independent complaint.

Sanctions and penalties

The AMA also fully supports the proposals to broaden and strengthen the TGA's investigation and enforcement powers, so that it can take swift and effective action to address breaches.

We commend the proposals to increase the level of penalties and sanctions; introduce corresponding civil penalty provisions; and introduce powers to serve infringement notices and injunctions.

In particular, the power to apply penalties for ignoring directions to withdraw advertisements in breach of the regulations is welcomed.

Therapeutic Goods Advertising Code

The AMA supports the intention to improve the Advertising Code itself, such as:

- prohibiting reference to a serious medical intervention
- ensuring that any ‘scientific’ information in an advertisement is identifiable and accessible to consumers
- prohibiting the use of testimonials in advertisements; and
- prohibiting the offer of free samples as part of the advertisement.

We look forward to the opportunity to comment on the specific proposals in a separate consultation as flagged in the consultation paper.

What we don’t support

The AMA does however have concerns regarding the shift from the current regulatory framework requiring pre-vetting of OTC medicines advertised directly to consumers to one which essentially relies on industry self-regulation.

Given that complementary medicines are not required to meet the same standards of efficacy as registered medicines, it is particularly important to ensure that the public is protected from misleading and fraudulent claims about the therapeutic benefits of scientifically unproven products.

Some regulation is essential so that clear and true statements are made regarding the efficacy and standards of evidence relied on.

The AMA supports a regulatory framework that ensures direct-to-consumer advertising of complementary medicines does not:

- exploit patients’ vulnerability or lack of medical or health-related knowledge;
- attempt to induce unjustified fear or concern in patients/consumers regarding their own health in order to increase demand for the advertiser’s products or services;
- encourage inappropriate self-diagnosis or treatment or in any way discourage patients from seeking the advice of their medical practitioner;
- attempt to promote an unreasonable expectation as to the applicability or efficacy of the advertised product or service;
- create inappropriate use of the goods or services;
- make unsubstantiated claims; or
- be false, misleading, or deceptive.

The AMA is not confident that a self-regulatory approach would provide sufficient protection to the public.

Given this, we strongly support the Government’s decision that the pre-approvals system remains in place while stronger compliance and enforcement powers are fully implemented.

Recommendation

As noted above, the AMA has concerns about proposed industry self-regulation of the advertising of OTC medicines. However, if the Government allows industry self-regulation sometime in the future as indicated in the consultation paper, the AMA strongly recommends that an evaluation should be undertaken of the impact of this change on advertisement compliance.

If a self-regulatory model is implemented, after two years the Government should:

- commission an independent review of the self-regulatory model which assesses advertisements of OTC medicines for breaches of the regulations and analyses the number and type of complaints made to the new complaints handling body;
- publish a report of the review; and
- reassess its position on industry self-regulation based on the review findings.

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