

Consultation Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public

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Background

Previous advertising reform consultations held by the Therapeutic Goods Administration (TGA) have highlighted several areas of the current system that are in need of reform, including the pre-approval of advertising claims, the complaints handling process, and the penalties offered for breaches of the *Therapeutic Goods Act 1989*. [1, 2] Throughout this process, the TGA have invited submissions on these issues from all members of the community, including industry, academia, and consumer organisations. The emphasis placed on engaging the community around these issues is to be commended, and we welcome the opportunity to comment on the reforms put forward in the present regulation impact statement (RIS) on the advertising of therapeutic goods to the general public.

Our specific research interests have been focussed on a particular aspect of the therapeutic goods market, namely direct-to-consumer breast cancer imaging devices. These new devices, including electrical impedance scanning, digital infrared thermal imaging, and electronic palpation imaging, are funded out-of-pocket, do not require a referral from a doctor, and are promoted directly towards consumers as safe and effective solutions for breast cancer screening and diagnosis - applications for which they have not received Australian Register of Therapeutic Goods (ARTG) certification. Considerable attention has been drawn to these devices since 2010, following a series of complaints raised to the Complaints Resolution Panel (CRP) about inappropriate and misleading advertisements.[3-9] Following these complaints, it was discovered that little was known about the devices' effectiveness for the indications that they were being advertised for.

In 2011, we conducted a systematic review that aimed to assess the evidence base to support these devices for breast cancer screening and diagnosis. The findings of our review indicated that there is currently insufficient evidence to recommend the use of these technologies for breast cancer screening, and the high level of variability among studies of symptomatic women limits their utility as diagnostic tools as well.[10] Despite having limited, variable quality evidence for screening and diagnosis, these devices are advertised for these indications in Australia, the United States, Canada, and the United Kingdom.[6, 11-13] The main potential harms of such advertising material come from receiving a false-positive or false-negative test results from these devices.

The reforms outlined in the present RIS offer the potential to amend the current system, and provide an increased degree of protection from such inappropriate advertising in the future. This consultation also presents a unique opportunity for members of the breast cancer community to provide input into the manner in which advertising for new breast imaging devices may be regulated in the future. In order to ensure that the breast cancer community is represented in this reform

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process, we conducted semi-structured interviews with members of national and state-based, not-for-profit organisations involved in breast cancer imaging (n=5), consumer advocacy (n=7), and research (n=4) between January and March 2013. In total, we interviewed 16 stakeholders from within the breast cancer community around the TGA's proposed changes to the regulation of therapeutic goods advertising, as outlined in May 2012 document 'Advertising regulations for medical devices; options for reform'.^[1] Within these options we sought perspectives from stakeholders around the pre-approvals process, specifically targeting the three proposed options:

1. Extend the current pre-approvals process to include medical devices.
2. Remove the pre-approvals process in favour of active monitoring.
3. Only require pre-approval for repeat offenders.

Since holding the stakeholder interviews, the options for reform to the arrangements for therapeutic goods advertising have been updated and refined by the TGA. While the responses we received went into detail around the available options presented above, the key principles guiding the options outlined in Proposal 1 of the present RIS were similar enough that we can offer comment based on their feedback. In this submission, we summarise the responses provided by participants around the proposed changes to the regulation of therapeutic goods advertising outlined in the present RIS.

Proposal 1: Alternatives to the pre-approval scheme

Option 1: Maintain the current system

Option 1 was not part of our interview process, as we focussed around the three proposed changes to system outlined in May 2012. However, throughout the interview process participants stated a range of concerns with the current system, which would preclude option 1 from being recommended as an appropriate course of action. The current lack of pre-approval for medical device advertising has a series of flow-on affects, which have had an impact on the quality of advertising material for emerging breast imaging devices:

1. Firstly, the current system allows devices to be advertised directly towards consumers for indications that they did not receive ARTG certification for.[10] This practice appears in contrast to the stated principles of the Therapeutic Goods Act 1989.
2. Secondly, there has been a history of inefficiency in the current system of self-regulation for Complementary and Alternative Medicine (CAM) advertising,[14] and a steady increase in the number of complaints raised about advertising within the medical devices industry.[1] This option would do nothing to improve the quality of CAM or medical device advertising, as it offers no alternative to industry self-regulation.
3. Thirdly, the inefficiency of industry self-regulation, coupled with the current lack of pre-market approval of medical device advertising, has led to a reliance on the general public and competitor companies to identify inappropriate advertising. Participants suggested that this is an unnecessary impost on the general public, as the purchasers of these products are unlikely to have the skills or resources needed to adequately differentiate between appropriate advertising claims and false or misleading advertising claims.
4. Finally, medical devices are often not limited to use by medical practitioners, and are often accessible to consumers without a referral from a registered healthcare practitioner. In cases where a consumer can access a product without input from a registered practitioner, such as an emerging breast imaging device, consumers are reliant on the accuracy of the information provided in the advertising material which may be unreliable.

Recommendation for Option 1

The current system does not include provisions to pre-approve medical device advertising, and instead relies on industry self-regulation and consumer complaints to ensure the quality of

advertising claims. Given the highlighted issues with this arrangement, maintaining the status quo is not recommended as a suitable option.

Option 2: Extend the current system to include pre-approval for devices, and cover subscription broadcasting.

Option 2 aims to extend the current pre-approval system to include medical devices, including in-vitro medical devices, and subscription broadcasting. Stakeholders expressed both advantages and disadvantages of option 2, but were largely in favour overall (n=11/16). However, 3 participants needed clarification about the proposal before offering comment, and 2 participants did not support the option.

Advantages of Option 2

Participants indicated a range of advantages for option 2:

1. This proposal would lead to the greatest increase in consumer confidence of advertising claims compared to the other proposed options.
2. This option would provide a standardised process across all advertising of therapeutic goods, and allow for a greater level of consistency to be applied to regulatory decisions.
3. Assuming that this process is effective at adequately approving advertisements for therapeutic goods, it would lead to a degree of cost-recovery by reducing the burden on the complaint handling system.
4. Stakeholders representing consumer advocacy groups also noted that this option places the impetus of discerning the accuracy of advertising claims on the regulator instead of the consumer.
5. Advertisements have less ability to present false or misleading information to the general public.

Disadvantages of Option 2

The main disadvantage of option 2 identified by stakeholders was the increased cost and resource requirements for the expanded pre-approvals process. These associated costs would be born predominantly by the regulated industries, but would also require a significant increase in resources for the TGA in order to carry out the approval process. This would also have a flow-on effect of slowing down the time-to-market for advertisements of new and innovative therapeutic goods, which may slow their uptake within the community. One participant also questioned how the Consultation regulation impact statement: Advertising of therapeutic goods to the general public

pre-approvals process would affect government-funded health services, such as a national screening campaign, which are promoted to the public. A final disadvantage of this option comes in relation to the issue discussed in bullet point 1 of option 1; devices are often advertised for indications that they did not receive ARTG certification for. In this instance, the perpetrators of false or misleading advertising may not be the sponsor or manufacturer of the product, but a local distributor or small business within the community. It may be the case that, as these sole-practitioners may not be members of a regulated industry body, that they may not be aware of their obligation to submit their advertising for pre-approval. Overall, the general consensus towards this approach is summarised succinctly by Participant 1:

“My doubt is not whether this is the best arrangement, my doubt is about the extent to which it can be successfully introduced.”

Recommendation for option 2

In the interest of increasing public safety from false or misleading advertising, option 2 is recommended as the most suitable approach. This option was most favoured by interview participants, and will ensure the highest level of consumer confidence in therapeutic goods advertising from the proposed options. However, serious concerns were raised about the capacity of the TGA and the cost to industry required to carry out this proposal.

Option 3: Limit the current pre-approvals scheme to cover only “higher risk” categories of advertisements.

The option to limit the current pre-approvals scheme to only cover “higher risk” categories of advertisements was not explicitly discussed with participants as an option for reform, however it was highlighted by two participants as a potential alternative to the other options outlined in the May 2012 report.[1] The following views on this option are the result of in-depth discussion between the interview participants and the principal author (TV), and may not be representative of the broader stakeholder community.

Advantages of Option 3

Assuming that option 3 would also be expanded to include advertisements for medical devices, this option has the benefit of being more resource, time and cost-efficient than option 2, as the number of advertisements requiring approval would be significantly fewer, while maintaining a higher level of consumer protection from false or misleading advertising than option 1 or option 5.

Under this arrangement, new and innovative therapeutic goods that pose little risk to public safety can be accessed sooner by consumers, while higher-risk products will receive adequate assessment of their advertising claims.

Disadvantages of Option 3

There are a number of disadvantages and qualifications to be made around this proposal in order for it to be recommended as the most appropriate course of action. Currently, the risk-category that determines the level of pre-market evaluation a medical device faces during conformity assessment is determined by the manufacturer of the device when applying for ARTG certification.[15] However, as we have observed in the case of emerging breast imaging devices, the intended use of a listed device on the ARTG is often different from the practical application of the device. If the TGA plan to use this same risk classification system to determine which products require advertising pre-approval, then emerging breast cancer imaging devices would not be covered under this scheme as they are currently certified by their manufactures as “low risk”. We previously raised the issue of risk-classification for these imaging devices in the TGA consultation for the pre-market assessment of medical devices, and this issue is equally relevant here.

Interview participants did offer comment on the classification of a ‘repeat offender’, as this provision was included under option 3 of the May 2012 options for reform.[1] If an advertisement is to be labelled as ‘high risk’ on the basis of the sponsor having repeatedly breached advertising regulations, three key considerations that need to be taken into account:

1. How many times would a company have to breach regulations before it is labelled as a ‘repeat offender’?
2. This system will be open to exploitation, as smaller companies can re-register under new trading names to void their ‘repeat offender’ status.
3. There is the potential for harm to occur before a company is labelled as a ‘repeat offender’.

Recommendation for option 3

It is the opinion of the authors and two of the interview participants that option 3 could be a suitable alternative to the current system, under the condition that medical devices were included in the pre-approval system, and risk-classification for diagnostic devices were revised accordingly so that they would be covered by the pre-approval system. This approach would be less resource

intensive for both industry and the TGA compared to option 2, and will offer a greater amount of consumer protection from fraudulent advertising than options 1 or 5.

Option 4: Retain pre-approvals (modified or not as per option 2 or 3) and: maintain current pre-approval delegations to industry associations, such as ASMI and CHC, or: appoint an independent statutory office holder to undertake pre-approval function, or: TGA to undertake the pre-approval function.

The main benefits and disadvantages of this option are outlined in our response to option 2 and 3. However, the options for reform discussed with participants did not include arrangements for who should be tasked with carrying out the pre-approvals, and as such we have no stakeholder comments to offer to this option.

Option 5: Remove the pre-publication approval scheme.

Although we didn't put this forward as an option exactly as presented in the current RIS, it was similar in principle to the "monitoring system" option discussed during the stakeholder interviews. There was little support (n=3/16) for a proposal that would remove the pre-approval scheme in favour of industry-self regulation, with the majority of participants indicating that they did not support this type of arrangement (n=12/16). One participant did not offer a response on this proposal.

Advantages of Option 5

Participants noted three key benefits of this option:

1. This option would reduce the resources required for pre-approval for both the TGA - by removing their responsibility to pre-approve advertisements - and for industry bodies - by removing the fees required for TGA approval.
2. This option would decrease the time-to-market for companies to broadcast their advertising for new therapeutic goods.
3. This option may prove to be an appropriate deterrent against false and misleading advertising if it is coupled with appropriate increases in penalties for misconduct.

Disadvantages of Option 5

In contrast to the proposed benefits, stakeholders highlighted a number of key disadvantages that ultimately diminished their support for this option. The most commonly regarded disadvantage of this proposal was the history of ineffectiveness of industry self-regulation of therapeutic goods advertising in Australia. Participants pointed out examples of deficiencies in the self-regulation of advertising in the CAM industry, as have been highlighted in peer-reviewed literature.[14] The authors would also like to point to the large rise in complaints in the medical devices industry, including complaints targeted towards breast cancer imaging devices,[3-5] raised to the Complaints Resolution Panel as an indication of ineffectiveness of industry self-regulation.[1] Given the track record of advertising self-regulation in the CAM industry, and increasing evidence of deficient self-regulation in the medical devices industry, participants did not have confidence that this arrangement would be effective at preventing misleading advertising claims.

It was also noted that the regulation of therapeutic goods advertising should aim to minimise the potential harm to the general public, by limiting their exposure to false or misleading advertising claims. On this point, it was suggested that by removing the requirement for pre-approval there is less impetus for companies to adhere to the relevant codes of conduct (legislated or industry-nominated), as any breaches and penalties would be administered after profits had been garnered. This would likely lead to three follow-on effects for consumers:

1. It will likely increase consumer exposure to inappropriate advertising due to advertising breaches being detected retroactively.
2. It places a large burden on consumers and health activists to identify and differentiate between inappropriate and appropriate advertising, a task which they likely lack the capacity for as even trained professionals can find this difficult.
3. It requires consumers to identify and complain about inappropriate advertising after a harmful event has occurred that could have otherwise been avoided, such as receiving a false-positive test result from an emerging breast imaging device.

Recommendation for Option 5

Based on the responses from participants, we suggest that the highlighted disadvantages of this option are not justified by the proposed benefits in terms of cost-saving and time-saving. In particular, this option allows for the potential of undue harm to come to the community, which can be otherwise prevented if an efficient pre-approval process was in place. Removing the role of the TGA as the principle regulator of therapeutic goods advertising places the main burden of

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monitoring advertising claims on the general public, as industry self-regulation is unlikely to be an effective means for ensuring appropriate advertising. It is therefore recommended that this arrangement not be considered as a worthwhile option for reform.

Summary

After consideration of the views of 16 individual participants, option 2 was most favoured by stakeholders from breast cancer imaging, consumer advocacy, and research. Of the options proposed in the present RIS, participants indicated that option 2 provides the greatest amount of consumer protection from false or misleading advertising, however they acknowledged that this option would incur a significant increase in resource allocation and financial costs to both the industry and TGA. Concerns were raised by stakeholders about the capacity of the TGA, or any individual body for that matter, to pro-actively screen advertising material for all therapeutic goods prior to broadcast or publication.

The authors suggest that option 3 should also be considered as a viable option, as it is less resource intensive than option 2, while offering a higher level of consumer protection than option 1 or option 5. However, this option should only be considered under the condition that medical devices be included in the pre-approval process, and that the risk-classification for emerging diagnostic imaged devices be revised to adequately reflect their risk to public health.

We would like to extend our appreciation to the TGA for providing the opportunity to contribute the views of the breast cancer community to the proposed options for reform, as they relate to a contemporary issue of concern. We look forward to the opportunity to participate in future discussions around regulatory reform of therapeutic goods in Australia.

Sincerely,

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