Response to the Consultation: The regulatory framework for advertising therapeutic goods - November 2016

Introduction

In October 2014, the establishment of the Expert Review of Medicines and Medical Devices Regulation (the Review) was announced. The Expert Panel delivered two reports that assessed the regulatory framework for medicines and medical devices in Australia, and made 58 recommendations for reform.

A similar review was conducted over 20 years ago, this led to significant transformations to the regulatory approval process for medicines in Australia. Since then while there have been some business reforms within the TGA, there have not been any notable changes.

The world has evolved immensely during this time, in particular, the digital and social media platform which has led to easy access to obtaining and transmitting up to date information via the Internet. The type of information available includes various topics and health is very high on the list. According to Ultrafeedback survey, August 2011, 84% of Australians say they looked for health information online in the past year. This indicates the public are much more interested, more educated, well informed about their health and their responsibility to improve their health outcomes than ever before.

Sponsors are also using this new digital space to advertise their products through direct advertising or through the third party such as blogging. The benefit of using this media for the sponsors is the advertisements are now published faster, more varied choices of medium can be used to promote their products through Instagram for example. Most importantly, these advertisements published on the internet are permanent even when the product is no longer available either due to recall or delisting from the ARTG (Australian Register of Therapeutic Goods).

The demographics has also changed since the last TGA review, people are living longer. The focus of delivery of healthcare will also change in the next 20 years. Currently, the focus of healthcare is cure for acute sickness and individual patient oriented. In the future, however, there will be more focus on prevention for diseases, more consumer orientated, more on wellness care and for maintaining chronic medical conditions. Therefore in light of this, healthcare will focus more on self-care. The advertising of Complementary Medicines (CM) e.g. vitamins and over the counter (OTC) medicines need to cater for the changing environment and evolving consumers' needs. The suggested reforms proposed by this Review will need to keep these changes in mind in order to address the future healthcare needs of the nation.

This invitation sent from TGA on 9 November 2016 regarding the handling of complaints under a new complaints-management system for therapeutic goods advertisements directed to the public and other recommended reforms to the advertising regulatory framework is very timely. This response is to TGA's proposals specifically recommendations 52 to 58, covering advertising and handling of advertising complaints.

Recommendation Fifty Two
The Panel recommends that advertising of therapeutic products to the public continues to be regulated by the [TGA] under a legislative framework which includes an advertising code.

This task should remain with TGA, as a national regulatory agency, they hold the key information and have the expertise in this area. However, the framework in which this is administered needs to be updated to cater for the changed environment, for reasons as cited in the introduction. The public are now more health conscious and wanting more options to improve their health outcome than ever before in the world history. The life expectancy of an average Australian has also increased in the last 20 years. Increasingly, there has been a greater reliance on health supplements to improve people's wellbeing. In addition, the ease of access to the latest health information and the public's eagerness to obtain health resources means the new legislative framework for advertising needs to be authoritative and dependable to prevent adverse outcomes for the aging population. Therefore if this task is to remain with TGA, there is a need to address these issues to ensure that this framework can withstand these demands.

Currently, the framework is complex and not transparent. While the public do not need to be aware of how advertisements are vetted, they need to have the assurance that there is a statutory body which is not only dependable but also has the power to administer punitive action which will deter irresponsible advertising.

Recommendation Fifty Three
The Panel recommends that advertising to the public continues to be prohibited for Schedule 4 and 8 prescription medicines, and the advertising of medicines in Schedule 3 of the Poisons Standard continues to be prohibited except those products containing ingredients set out in Appendix H (Recommendation Twelve refers).

The prohibition of advertising S3 of the Poisons Standard was legislated a number of years ago. As cited in the above responses, the world has evolved significantly in the last 20 years and most importantly, the advent of the internet. The public can readily access health information while this may sometimes lead to inappropriate self-diagnosis of medical conditions, this does help to educate the public regarding their health and how to improve or maintain it. A number of websites which are government initiatives such *as Better Health Channel,* a Victorian government sponsored one, National Prescriber Service (NPS) website together provide medicines and health information including specific consumer information on medicines which can be accessed easily. These websites are consumer friendly and educational. They often provide treatment solutions to minor ailments. The social media also plays an impactful role in educating or alerting the consumers on the availability of treatment for minor ailments.

If the information on these products is readily available in the public domain, then advertising of these products should not be restricted. While advertising S3 may appear to be adding to the bottom line for the sponsors, it does in many ways, educate the public on whether these options are appropriate to treat their minor ailments. Being able to purchase S3 medicines to alleviate their symptoms of minor ailments would save money and time for them as well as the burden of

consulting a medical practitioner. This would lead to reduction in the health care cost to the federal government.

In addition, this further supports the future focus of healthcare delivery which is turning it from acute care to a self-care model.

Advertising S3 medicines could be achieved successfully by placing caveats or certain requirements on these items. This may include wording such as “medically diagnosed” or strictly enforcing sponsors only advertise TGA approved indications. The use of specific and succinct wording would assist the general public in their product choice. Furthermore with the proposed new critical health information panel on all OTC medicines, consumers can more readily self-select appropriate medications to treat their conditions.

It is worth noting that S3s are pharmacist only medicines. This means that a pharmacist would be involved in assisting the public in their choice of therapy and they can provide further counselling to achieve a better health outcome.

In fact, this practice of advertising over the counter medicine is common in major markets around the world such as the US and the UK. While these countries have different advertising frameworks to the public and healthcare professionals, they have permitted the advertising of S3s or similar medicines to the general public.

Quality Use of Medicines (QUM) is one of the central objectives of Australia’s National Medicines Policy. Permitting the advertisement of S3s does not compromise Australia’s National Medicines Policy but rather enhances it and allows improvements in the focus of delivery of healthcare. If S3 advertising is implemented, change in the advertising framework will be required.

Recommendation Fifty-Four
The Government accepts that the ***future requirements for advertising therapeutic products to the public should be made consistent for all medicines and medical devices****, noting that increasing consistency of approach could help reduce complexity for advertisers. The Commonwealth also notes that the differences between medicines and medical devices means that consistency may not be appropriate in particular circumstances.*

While we agree unreservedly that stronger penalties and sanctions framework has to be implemented, an efficient and effective complaints resolution process in medicines and medical devices advertising is long overdue. Improving efficiency does not necessarily mean a consistent approach but it does mean removing complexity.

There are many different types of medicines targeted to different audiences and sponsors of these products have variable level of understanding of their regulatory responsibilities. Consequently, the level of risks varies markedly. Using one system that is self-regulatory across all sectors is inappropriate and dangerous for the following reasons:

- Level of risks associated with registered medicines as opposed CM e.g. vitamins are different. With prescription medicines, the target audience are prescribers who have medical training and they can interpret information such as clinical data that may be presented to them. While CM are often low risk, the target audience is the general public. They are more likely not trained to critically evaluate claims presented to them in advertisements and can easily be swayed by colourful, glossy posters or celebrity personality recommendations.

Since the data used to list CM are not reviewed by the TGA, it is possible that claims based on sponsor's interpretation of data may be inaccurate or erroneous. These inaccuracies may not be identified unless the health authorities have conducted an audit. The TGA does not routinely conduct audits which means these errors could go unnoticed until an issue arises.

Herbal products, for example, can vary markedly depending on how the active ingredient is extracted. This can lead to inconsistent dosing and inappropriate product claims.

- Level of education amongst sponsors of CM is highly variable. When listing medicines, sponsors have used inappropriate names e.g. Caruso's Cough Stop and Caruso's Kids Cough Stop. The names of these two products are in breach of the Therapeutics Goods Advertising Code 2007, as their brand name implies that these products have the unreal expectations that they are capable to stop all coughs.

Refer: Therapeutic Goods Advertising Code 2007, Section 4:

> *General principles*
> *No 2 where it states that an advertisement (which in this case is the label) must not*
> *(a) be likely to arouse unwarranted and unrealistic expectations of product effectiveness;…*
> *(g) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;*
> *(h) contain any claim, statement or implication that it is effective in all cases of a condition;*
>
> *In addition, the name of Caruso's Kids Cough Stop is directed to minors which is in breach of the same section part*
> *(j) be directed to minors, except the therapeutic goods listed in Appendix 5.*

Removing complexity by amending legislation to make advertising consistent should only be done if this results in less risk to the general public.

The general public have limited to no understanding of the difference between registered and listed medicines, therefore when they see a medicine which contains the claim "cough stop" they will likely take this to mean that "it will stop their cough". Very few people would appreciate that while cough is innocuous, it can also be the first sign of serious illness such as carcinoma of the lungs. If the member of public believes and trusts the claim "Cough Stop" and persists taking the product, it may lead to a delay in diagnosis of a more serious disease and ultimately the difference between potential cure to a more life threatening health outcome.

The current “Complaint Review Process” is ineffectual. Despite clear breaches of the Therapeutic Goods Advertising Code being brought to TGA’s attention, no action is taken to stop misleading and inappropriate advertising.

Recommendation Fifty-Five

The Government accepts that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public should be stopped in favour of a more self-regulatory regime. The implementation of Recommendations Fifty-Seven (enforcement powers) and Fifty-Eight (sponsor education) are critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation. Removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers, and is consistent with the Government’s commitment to minimising unnecessary regulatory burden.

Similar to what is cited above for Recommendation 54, reducing unnecessary complexity is important however if this is done at the expense of the public interest then this should not be considered. Pre-approval and vetting is not a complex process, this framework is adopted elsewhere in the world most notably the UK PAGB (Proprietary Association of Great Britain). PAGB is a trade association which represents the manufacturers of branded over-the-counter medicines, self-care medical devices and food supplements. This association provides a pre-publication approval system for consumer advertising of over-the-counter medicines that are subject to a Marketing Authorisation, registered traditional herbal medicines (THMs) and food supplements. While there are no other similar authorities in Australia, we can adapt some of their practice and adjust it to meet our needs.

In Australia, we have a fragmented approach to dealing with the advertisement of OTC and CM. For OTC, we have ASMI (Australia’s Self Medication Industry), and for CM, we have Complementary Healthcare Council. To reduce complexity, one organisation should be responsible for pre-approval or vetting an advertisement. This will reduce the unnecessary complexity for advertisers and sponsors. A non-government organisation such as ASMI could potentially take on this role of reviewing CM advertising.

Of course training needs to be provided to whichever organisation that takes on the role of vetting advertisements. If pre-approval was conducted by one agency, the approach would still need to be consistent and transparent. A new framework and guidelines would need to be set up and written.

If stringent advertising framework is legislated to ensure sponsors and advertisers are clearly aware of their responsibility and obligation to the Australian public then the government’s concern for unnecessary regulatory burden is unfounded. Currently, the pre-approval of advertisement and the complaints management systems are both complex. In addition, the latter lacks punitive powers to ensure the advertising code is adhered to. Similar organisations in the world have greater punitive powers and are far more transparent in the manner in which these matters are dealt with.

Recommendation Fifty-Six

The Government accepts that current mechanisms for managing complaints should be disbanded and a new mechanism established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. A single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, thereby benefiting consumers.

To progress this recommendation, the Department of Health will consult with stakeholders on the appropriate design of the new complaints-management process and consider whether to establish the function within the TGA or another existing Commonwealth agency; or to call for tenders from external organisations to undertake the function.

We agree that the current complaints management system needs to be reviewed and disbanded. A hybrid system should be considered, the complaints may be triaged through one organisation which can be a non-government organisation such as ASMI. The complaints can be lodged via a website. This website could also be an educational portal for sponsors. The complaints need to be allocated a number and then divided into either administrative non-compliance or more technical non-compliance. The latter could be referred to the TGA for further review as they hold the registration dossier. For CM, this may entail robust information to be submitted with the complaint as no data is submitted with listed medicines. ASMI or similar organisation through the website can provide updates to the complaints. It is important to consider providing a website where all complaints are lodged and timeframes and penalties are legislated so offending sponsors can be seen by the public, this is not dissimilar to "Name and shame concept" for restaurants. This will deter sponsors from producing irresponsible and unsubstantiated advertisement.

Recommendation Fifty-Seven

The Government accepts the need for stronger compliance powers against misleading advertising, noting that broadening enforcement powers will benefit consumers by ensuring appropriate compliance with regulatory requirements and deter inappropriate and misleading advertising of therapeutic goods.

We agree there be stronger compliance powers against misleading advertising as cited above. In addition, the public should readily be able to access this information. The public need to be aware of inappropriate and irresponsible sponsors of OTC and CM. This will further support the future healthcare focus that is self-care.

Recommendation Fifty-Eight

The Government accepts that the TGA should develop a formal education programme to provide sponsors and advertisers with appropriate information and tools to assist them in understanding their obligations and achieving compliance with advertising requirements. This will be particularly important once the reforms to the advertising regulatory framework are in place (particularly implementation of Recommendation Fifty-Five).

A formal education programme is important not only for advertisers and sponsors but also for the general public. Sponsors need to be educated so as to improve their ability to use their data to promote their products. As cited in Recommendation 54, there is a disparity in sponsors' ability to interpret data and follow the advertising code. This is very important as the level of clinical evidence is variable with CM. In addition, TGA currently do not review listed medicines. Any listing based on unsubstantiated data would only be identified through an audit. A formal education programme if appropriately structured should diminish unnecessary risks to the public.

While formal education programmes for sponsors and advertisers is important, it should be designed in such a manner that the level of understanding can be documented and assessed at the end of the learning module not dissimilar to Medicines Australia's approach. Medicines Australia have learning modules through University of Tasmania where sponsors can register and complete their learning and receive a certificate or acknowledgement of completion.

Formal education should also be directed to the public. This type of information should be available through TGA website or other government funded health websites. More appropriately, there should be a more self-care focus as cited in the introduction. Governments should not create obstacles but partner with the public to embed the importance of self-care into everyday life.