Consumers Health Forum of Australia

Submission to TGA Consultation on Proposed improvements to Therapeutic Goods Advertising Code

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Consumers Health Forum of Australia (2021) *Submission to the TGA Consultation on Proposed improvements to Therapeutic Goods Advertising Code.* Canberra, Australia

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Overview

The *Therapeutic Goods Advertising Code (No.2) 2018* (the Code) is the compliance standard that prescribes the minimum requirements for the lawful advertising of therapeutic goods to the public in Australia. It is an important instrument for a range of stakeholders including advertisers, manufacturers, suppliers and retailers; relevant industry associations; health professionals and peak bodies; and consumers and consumer representative groups. With the potential for serious consequences for non-compliance, it is important that the Code is contemporary and clear.

In this consultation the Therapeutic Goods Administration (TGA) was seeking feedback on options to improve the Code. The proposed improvements were aimed at increasing advertisers' understanding of the requirements of the Code, ensuring provisions work as intended, and improving advertising compliance. The proposed improvements considered the need to minimise unnecessary compliance costs while continuing to ensure that advertising does not contribute to any unsafe or improper use of advertised products.

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health consumer affairs, including health-based research. We have over 260 members reflecting a broad spectrum of organisations including state-based consumer peaks, condition-specific groups, volunteer patient groups, professional associations, Primary Health Networks (PHNs) and the research community.

We work in collaboration with our members, national partners and research collaborators to influence policy, programs and services to ensure they are in the consumer and community interest. This includes our role on the TGA Advertising Consultative Council (TGACC) as consumer representatives.

CHF is pleased to make this submission in response to this TGA Consultation.

CHF Submission

General comments

Overall, we are supportive of the proposed changes and believe that they improve the clarity of the regulations and protect consumers, as can be seen in our responses to the consultation questions for each section. The exception to this is the proposals for Section 16 Endorsement and Section 17 Testimonials, which are detailed in our responses to those consultation questions.

We note that page 9 of the consultation paper states that "all information to support the claims being made must be substantiated before the advertising occurs". This does not match with our understanding of how the post-market surveillance model of regulation operates. Further detail needs to be provided as to how this "substantiating before advertising" occurs. In particular, who does the 'substantiating' and what the regulatory response or penalty will be for a 'substantiator' who approves advertising that leads to complaints that reveal that claims were made without evidence.

Upon review of the Code, we have concern at the narrow definitions it has in regards to specifying 'radio' and 'television' as the specific mediums to which parts of the Code applies. We would strongly urge that these be broadened to use terms such as 'audio' and 'video' respectively to clarify that the Code applies to other mediums that use these formats such as podcasts or internet videos where advertisements can be hosted.

However, more broadly we note our primary concern is that this consultation does not address the 'elephant in the room' problems of the new therapeutic goods advertising regulatory scheme: compliance and enforcement.

The TGA Advertising Annual Reports published so far (2018/19, 2019/20) reported nearly 4000 complaints over the first two years of the new regulatory system. From our discussions with the TGA since 2018, including as part of the TGACC, such an overwhelmingly large number of complaints was not expected when the system was designed, and it has been a struggle for the system to cope.

We note that this volume of complaints is occurring despite the generally low awareness of the general public of: the rules with which advertisements must comply, the TGA's role in regulating therapeutic good advertisements, the process for complaining and the existence of the TGA in general. This suggests to us that if awareness of these components was higher, the already overwhelming number of complaints received by the TGA would be even larger.

Most of these advertising complaints are not investigated by the TGA by design of the system, with only an advisory letter sent to the advertiser requesting they review their advertisement for compliance. There is no follow up required by either party to ascertain if there was a breach and if so, what changes were made or penalties incurred. This lack of action can be discouraging to consumers who complain and can lead them to believe the TGA has dismissed their concerns as unimportant.

Of the fraction of complaints that are investigated, the vast majority appear to be in breach of the Code or the Regulations according to the TGA Annual Reports. Across the first two years of operation of the current regulatory scheme, it appears that only 137 complaints were found to not be breaches (2018/19 report page 18, 2019/20 report page 20).

Despite this incredibly high proportion of investigations confirming breachers, the regulatory response for these confirmed breaches as publicly reported contains zero instances of financial penalty being levied against those advertisers (2018/19 report page 18, 2019/20 report page 20). The vast majority of TGA actions were the provision of a letter to the advertiser.

Additionally, there is no evidence of follow up efforts by the TGA to see if compliance was subsequently achieved in a timely manner following regulatory action. It is perhaps unsurprising then that external research done in this area, in particular by Professor Ken Harvey AM, has found that advertisements that have complaints lodged with the TGA are still non-compliant after the TGA has 'resolved' the complaint.

Given all of this, it is hard to take the position that the TGA is effectively regulating these advertisements and fulfilling their mission to protect public health or that advertisers are respecting and observing the regulations. While some misunderstanding of nuances of the code by some advertisers, especially new and small operators in the sector, is plausible it seems unlikely that the totality of the above-described situation can be entirely attributed to the poor clarity in some sections of the Code this consultation is seeking to address.

More broadly, the TGA states that it takes a 'risk-based approach' to advertising compliance, and regulation in general, where the priority for an advertising complaint is determined by the 'risk posed' (which we take to mean 'danger') by the product advertisement. However, we believe this is a fundamentally flawed approach to risk-based management. While the danger posed by a product is a key component to determining its risk, an equally important metric is the likelihood of that danger being realised and the volume of people it effects. A 'low' danger that affects one million Australian's is as equally "risky" as a one-in-a-million' critical danger that affects one Australian.

As CHF has expressed previously, greater clarity is needed around the process the TGA follows regarding regulatory compliance. In particular

- The process by which not only the *severity* or *danger* of the risk but the *likelihood* of the risk and the *volume affected* are considered in categorizing the "level" of reported breach (i.e. a low severity but high likely risk is "as risky" as a high severity but low likelihood risk).
- The process by which 'repeat offenders', whether it be multiple complaints for one advertisement or multiple complaints for one advertiser across a range of advertisements, are escalated up to a higher breach. In particular around potential 'bundling' of the extreme number of currently "low risk complaints into targeted higher risk categories.
- The process by which the appropriate regulatory action to be taken for a breach is decided, in particular for 'repeat offenders' and in regards to the levy or non-levy of financial penalties.

- The process by which compliance following regulatory action is ensured.
- The process by which an escalated regulatory action is determined should non-compliance be observed following prior action, again in particular for 'repeat offenders'

Without a more rigorous and well-defined system that addresses the above, it is our view that no amount of rule changes or improvements to improve clarity in subsections of the Code will have any meaningful effect on improving the situation for consumers. If the rules are not effectively enforced, the rules might as well not exist.

Finally, should appropriate and effective regulation through post-market surveillance not be logistically feasible given TGA resources, given the failure of the previous "Complaints Resolution Panel" system that preceded the current system, consideration should be given to whether a general ban on direct to consumer advertising of medicines (such as biologicals, goods containing a Schedule 4 or Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons, and goods containing a Schedule 3 substance not included in Appendix 8 of the Poisons Standard) be extended to simply cover all therapeutic goods.

Responses to Consultation Questions

Section 4: Additional definitions

1.Do you support the clarifications in relation to 'claim', 'indication' and 'intended purpose'?

Yes. Although we would suggest additional clarity needs to be inserted around the appropriate language that can be used in advertisements for uses or purposes that are not supported by evidence but by 'traditional usage claims.

We would also suggest that 'non-therapeutic claims' have some a Note inserted or guidance generated that gives an explicitly non-exhaustive list of examples to provide clarity around what such claims may be e.g., 'natural', 'Australian made', 'popular', the process by which the product was formulated/created, how effective it is, contains X% of, 'leading brand', 'best seller.

2.Do these measures assist in understanding how relevant Code requirements should be applied in relation to an advertisement?

Yes, we believe so.

3.What additional guidance, if any, is needed?

Unsure, although we would suggest more worked examples of what therapeutic and non-threptic claims can and cannot be made and what evidence is sufficient or insufficient to support those allowable claims.

Page 8 notes that complementary medicines based on traditional use do not need robust evidence to be able make therapeutic (and potentially non-therapeutic claims). Clearer guidance about what evidence they require to make claims, how that evidence is assessed and how this affects the types of claims they are and are not able to make should be produced.

Section 10: Prohibition on causing fear or distress

4. Do you support strengthening section 10 to expressly prohibit advertising that may cause fear and distress?

Yes

5.Is the form of words proposed above suitable for the purpose of prohibiting advertising that may cause fear and distress?

Yes, the suggested statement "*Advertising for therapeutic goods must not exploit consumers' lack of knowledge or contain language that could bring about fear or distress*" seems appropriate.

Potentially guidance could be produced with examples of such statements that are prohibited on these grounds, including ones that are about a condition rather than a specific product and ones that describe the potential effects from *not* using a therapeutic good.

Section 11: Introduction of a mandatory statement for therapeutic goods that cannot be purchased by the public

6. Do you support the inclusion of a new statement for advertisements for goods only accessible through services offered by health professionals/ practices, or only available for purchase by health professionals/ practices?

Yes

7.Which of the suggested statements best convey the intended message?

Generally, we support the iterations suggested that prompt the consumer to speak to their health professional and do not support the ones that only advise the consumer they cannot purchase the product. For example:

"THIS PRODUCT IS/THESE PRODUCTS ARE ONLY AVAILABLE FOR PURCHASE BY HEALTH PROFESSIONALS AND HEALTHCARE FACILITIEIS. TALK TO YOUR HEALTH PROFESSIONAL ABOUT WHETHER THIS PRODUCT WOULD BE RIGHT FOR YOU"

Where appropriate, we would also support the statement being amended to suggest a specific health professional who would be best placed to provide advice to the consumer e.g., "Talk to your pharmacist about whether this product would be right for you" for pharmaceutical or 'Talk to your dentists about whether this product would be right for you" for dental products.

We would also support the amendment of 13(1)(d) as suggested to read 'an advertisement or *therapeutic goods* to which section 11 applied"; where the broader term 'therapeutic goods' has replaced the narrower term 'medicine'.

8.Do you support a general obligation that when advertisers have the ability to 'hide' health-professional directed advertisements from the general public they should do so? How could this obligation be enforced?

Yes.

We would suggest enforcement of this obligation with significant financial penalties and/or prohibition from being able to advertise products in the future.

Section 12: Streamlining requirements for mandatory statements in advertisements for the purchase of therapeutic goods without prior physical examination.

9.For advertisements that facilitate the purchase of a therapeutic good without prior examination, do you support requiring advertisers to reproduce the relevant health warnings in the advertisement wherever possible?

Yes.

10.When advertisements are genuinely limited by physical space or character count, do you support providing the option for consumers to click on a prominently displayed and appropriately named hyperlink to access the health warnings (similar to the example above)?

Yes, in principle, but we would like to see some clarity on how 'genuineness' is arbitrated and the limits on 'genuineness', as we cannot think of any legitimate circumstances where such limitations exist AND there is no capacity for a visual/image components as noted in the Code (Section 13, subsections 5 and 8).

For example, an advertisement on Twitter would be genuinely limited to 280 characters, however the advertisement could include a promotional image. That image which would then be able to have the warning statements imposed over it. The supply of a link to read the warnings in detail could be done in addition to the warnings via imposed words on the image.

Similarly we can envision a scenario where a space limitation is a budgetary ones due to the additional costs of buying the extra space to include the warnings in a legible manner e.g. extra inches in a newspaper or longer time in a radio advert. However we are strongly of the view this is *not* a genuine limitation as the Regulator should not be prioritising the profitability of industry over its duty to adequately protect the public.

11.If you support the inclusion of health warnings in this way, when do you consider it would be appropriate to permit this option?

Where there is both an unavoidable physical/space/time limit in the advert and, in the case for digital advertisements, no visual or image component of the advert over which the warning can be imposed.

12.For advertisements that facilitate the purchase of a medicine without prior examination, do you support advertisers having the option of conveying the necessary warnings and contraindications through a reproduction of the appropriate parts of a medicine label?

Yes. Although this may require the TGA to review the requirements for medicine labels, in particular any requirements around plain language and consumer testing of labels, to ensure consumers can comprehend the medicine label contents without having a health professional to question.

13.What risks are involved with relying on the medicine label in an advertisement in this way? Are there any other conditions that would need to be imposed to address these risks?

As previous, the main risk would be whether medicine labels are written in a way that is intended to effectively inform the consumer as to how and when use of the medicine is appropriate rather than to provide liability protection for the supplier.

Section 13: Requirements for mandatory statements in other types of advertisements

14.Do you support any of the options for replacement mandatory statements in tables 1, 3, 5, 7, 8, 9 or 12? Would the replacement mandatory statements achieve the stated objectives?

Yes. They all appear to be appropriate conditions of mandatory health warning statements into a single statement in circumstances where multiple statements are required.

Although we would query why the warning statement "Ask your health professional/provider as to if this product is right with you" is not also required. We would advocate for this to appended onto all the warning statements provided in Tables 1-12.

15.What alternative formulation of these statements would be better to achieve the objective?

As previous, the statement "Ask your health professional/provider as to if this product is right with you" should be appended to all the existing and revised consolidated health warning statements.

16.What alternative mandatory statements could be used in the circumstances set out in tables 2, 4, 6, 10, 11, 13 and 14?

As previous, the statement "Ask your health professional/provider as to if this product is right with you" should be appended to all the existing and revised consolidated health warning statements.

17.Do you support the option for amendments to subsection 13(2A)?

Yes, this seems an appropriate way to apply mandatory warning statements for an advertisement that of for multiple therapeutic goods in any combination of medicine, medical device or other good.

However, as in the previous response we believe the statement should be amended to include "Ask your health professional/provider as to if these products are right for you".

18.Do you support the option of a new statement for advertisements that meet the requirement of the new subsection 13(2A)?

Yes, as previous the statement should include the sentence "Ask your health professional/provider as to if these products are right for you".

19.What are your views on the current 'symptom' mandatory statements?

They seem appropriate, although we do not believe the exemption for adverts under a specific character length (text only), or length (radio, noting previously expressed concerns about the narrowness of 'radio' for the purposes of the Code) is appropriate.

We would argue that this is not an unavoidable or 'genuine' limitation but a budgetary one. Advertisers should be required to factor into their budgets the expense of including the mandatory waring statements rather than being allowed to not give consumers all the information they need when considering the product.

Schedule 1: Option to amend the approach to the identification of health warnings.

20.Do you support the above approach for determining the relevant health warnings to be included in an advertisement of a relevant medicine?

Yes, presuming that the three step Table structure produces a process that catches all the various sources of mandatory warning statements noted across pages 29+30 of the consultation. However, industry groups would be in a better position to provide a response to this question.

21.How could the above procedure be improved, or made simpler or clearer to follow?

It is not clear to us how the contents of Table 1, Table 2 and Table 3 will be determined initially and then kept up to date over time. Clarity in this area would assist in making sure that the procedure is simple and effective in comparison to the current procedure.

22.Do you have any suggestions or concerns in relation to any of the above tables?

No

23.This option relies heavily on the label of the medicine that is available to the advertiser. Is this appropriate?

Yes. There is no reasonable objection we can conceive of to making medicine labels available to advertisers, or just generally available to anyone who wants or needs access for any reason.

Section 16 Endorsements and Section 17 Testimonials

24.Do you support either Option 1, Option 2 or Option 3?

We do not support any of the options.

Our position is there should be a complete prohibition of testimonials and endorsements for therapeutic goods in all circumstances. There is no benefit to consumers being given health advice from those who are neither health professionals (such as their doctor) nor familiar with the consumers personal circumstances (such as their family or close friends).

The only benefit of this proposed amendment is a commercial one to the supplier's bottom-line and maximising business profits is not the purpose of TGA regulations.

The exception to this is Government public health campaigns, where general action not tied to a specific product, good or supplier for the purpose of generating sales is being promoted. In this case testimonials and endorsements are appropriate, if not encouraged

25.For Option 1: •What elements of the new provision do you support? •What elements of the new provision would you change, and how? •Is there another requirement that should be included?

We do not support Option 1.

26.Do you support Option 2, which allows those involved in the marketing of therapeutic goods to provide testimonials in advertising?

No.

27.Do you support the inclusion of new mandatory statements under Option 2?

No. We do not support Option 2 in any capacity.

28.Do you support Option 3, which allows direct sellers to use their own testimonials in advertising? Please state reasons for supporting or opposing this approach.

No.

29.Do you have any alternative suggestions for the endorsement and testimonial provision?

A complete prohibition on testimonials and endorsements, except for designated Government Public health campaigns.

Section 20 and Schedule 3: Clarification of samples requirements and additional eligible goods

30.Do you support amending subsection 20(1) to make it clear that both the offer of a free sample of therapeutic goods, and the provision of the sample itself, in advertising are prohibited (other than for those goods included in Schedule 3)?

Yes.

31.The proposed amendment to subsection 20(1) seeks to clarify that it is both the offer and provision of a sample of therapeutic goods in an advertisement that is prohibited. Other goods that are not therapeutic goods that are given as free samples, even when connected to the therapeutic goods, would not be captured by the prohibition. Is this appropriate?

No. The provision of a free sample of a non-therapeutic good with a therapeutic good is an incentive to buy and use a good that is not based on the health status of the consumer nor the appropriateness of the therapeutic good in their circumstances. The prohibition of such incentives should thus extend to non-therapeutic good free samples too.

32.Do you support the proposal that other therapeutic goods can be considered for inclusion in Schedule 3?

In general, yes, but there would need to be a rigorous process for approval.

33.Do the guiding principles listed above provide an appropriate guide for the assessment of new goods for Schedule 3? Are there any additional 'principles' to be considered?

Yes, these seem appropriate. At this stage we do not have any suggestions for additional guiding principles.

Sections 28 Restricted representations – serious form of disease, condition, ailment or defect; and 29 Restricted representations – public interest criteria: clarifications

We note there are no specific question for this section of the consultation, but we support the adding of the five "Notes" across the two sections for increased clarity.

Section 30 Prohibited representations: clarifications

We note there are no specific question for this section of the consultation, but we support the adding of the five "Notes" across Section 30 for increased clarity.

Sections 15 Scientific and clinical representations; and 9 Accuracy

While there are no questions regarding these Sections in the consultation paper, on pages 52-54 of the consultation, the TGA states that it does not believe any amendments to Section 15 and/or Section 9 of the Code are unnecessary as the problems observed are to do with compliance issues not Code issues.