

ADVERTISING TO THE PUBLIC: COMPLYING WITH THE TGA CODE 2018

Response to the Consultation Draft

October 2018

ABOUT RESEARCH AUSTRALIA

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our role:

Engage

Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect

researchers, funders and consumers to increase investment in health and medical research from all sources.

Influence

government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes.

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TABLE OF CONTENTS

INTRODUCTION	4
ACCURACY, TRUTHFULNESS AND THE CODE	5
PUFFERY AND THE GUIDANCE.....	6
INFORMED DECISIONS, HEALTH LITERACY AND PUFFERY	7
CONCLUSION	9

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RESPONSE TO THE CONSULTATION DRAFT

Introduction

Research Australia welcomes the opportunity to make a submission to the TGA's consultation on the draft Guidance (Guidance) for complying with the Therapeutics Goods Advertising Code 2018 (the Code).

Research Australia is the peak body for Australia's health and medical research and innovation sectors. Our members strive to create new knowledge and develop new therapies, technologies and interventions that can deliver better health outcomes and improve human health and wellbeing. Ultimately this depends not just on the availability of products to people, but the decisions they make as consumers in respect of these products.

This is the interest and perspective we bring to this consultation- enabling consumers to make decisions about therapeutic products that will enhance their health and wellbeing.

Health literacy is a critical issue in relation to consumer decisions about health products, and it is well recognised that health literacy levels in Australia vary widely and are, overall, inadequate. This makes it difficult for some consumers to make informed decisions, and to distinguish false and/or exaggerated claims from true statements and information when evaluating whether to purchase a therapeutic product.

The importance of our health and low levels of health literacy are the primary reasons why the advertising of therapeutic goods is subject to restrictions not applied to most consumer goods.

Research Australia's submission addresses a single element of the Guidance on the Code. This is the section in Attachment B dealing with 'puffery'- claims in advertising so exaggerated that a reasonable person would not believe them. This section implies that there are circumstances in which puffery is permitted in the advertising of therapeutic goods.

Research Australia submits that the advertising of therapeutic goods is a special case where the correct position is that puffery should not be permitted, and the Guidance should be amended to make it clear that puffery is not permitted under the Code.

Accuracy, truthfulness and the Code

The draft Guidance which relates to the TGA Advertising Code 2018, which takes effect from 1 January 2019. Section 5 of the Code sets out its Object.

5 Object

The Object of this Code is to ensure that the advertising of therapeutic goods to consumers is conducted in a manner that:

- a) promotes the safe and proper use of therapeutic goods by minimising their misuse, overuse or underuse; and*
- b) is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance; and*
- c) supports informed health care choices; and*
- d) is not inconsistent with current public health campaigns.*

Section 9 of the Code specifically addresses the issue of accuracy of information contained in advertising, which is critical to all the Objects, but especially to not misleading or deceiving consumers, and to supporting informed health care choices.

9 Accuracy

Advertising for therapeutic goods must satisfy the following:

- a) any claims made in the advertising are valid and accurate, and all information presented has been substantiated before the advertising occurs; and*
- b) it is truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons; and*
- c) any comparisons made in the advertising between therapeutic goods or classes of therapeutic goods do not directly or indirectly claim that the goods or class of goods being used as the comparator are harmful or ineffectual; and*
- d) if the goods are included in the Register— it is consistent with the entry for the therapeutic goods in relation to that inclusion.*

Research Australia notes the requirement in a) above that any claims are valid and accurate, and in b) above that the advertising is truthful.

Thus, the draft Guidance in respect of Section 9 is consistent with the Section. The guidance on section 9(a) states in part that ‘you (the advertiser) *must hold evidence that can demonstrate the accuracy of every claim (including non-therapeutic claims) made in an advertisement. ...*’. The guidance makes it clear that this applies to both therapeutic and non-therapeutic claims.

In respect of section 9(b), the Guidance states that ‘*In addition to being substantiated, advertising for therapeutic goods must be truthful, balanced and not misleading (including any implied claims)....*’

Research Australia supports this approach in the guidance, which emphasises the importance of providing accurate and truthful information to support informed decision making while avoiding statements that are misleading. The obligation to be able substantiate all claims made is critical to the integrity of the Code.

Puffery and the Guidance

Attachment B of the Guidance provides 'Other guidance on the application of the Code'. Except for the text on the prominence of mandatory information, precisely how this guidance relates to the guidance in the body of the Guideline is unclear.

Attachment B includes a section on 'puffery'. This section explains the concept of puffery as defined by the Australian Consumer and Competition Commission; essentially, puffery is a claim made in advertising that is so exaggerated no reasonable person could believe it – an obvious lie.

The discussion in Attachment B around puffery gives examples of possible claims of puffery that could be made in respect of a therapeutic good, and where such a claim would not be exaggerated enough to be considered to be puffery. It then states

It should also be considered (by the advertiser) whether puffery has a place in ethical and responsible advertising of therapeutic goods to consumers. If you (the advertiser) are unsure whether a particular statement that you consider puffery will be seen in the same way by the public and that it might therefore mislead the public, you should remove the statement. [Page 74]

The inclusion of this section on Puffery in Attachment B to the Guidance indicates the TGA believes that if a statement is puffery, it is not misleading and is therefore permissible under the Code in an advertisement for a therapeutic good.

Research Australia submits that this is not the case. Such a position is inconsistent with Section 9b) of the Code which require not only that advertising not be misleading but that claims in the advertising are valid and accurate, and that the advertising is truthful. By definition, a claim that is so exaggerated as to be unbelievable is not valid, accurate or truthful.

It is Research Australia's view that puffery is prohibited by the Code, and that the Guidance in relation to puffery is inconsistent with the Code.

Research Australia submits that the Guidance should retain the explanation of Puffery, but state that notwithstanding that Puffery may not be misleading it is nonetheless not valid, accurate or truthful; as a consequence, such statements cannot be made in an advertisement covered by the Code, and Puffery is not a defence to a breach of the Code.

Informed decisions, health literacy and Puffery

Quite apart from the prohibition of puffery under the Code, there is another strong argument for why puffery should not be permitted in the advertising of therapeutic goods to the public, even if it is permitted for other consumer goods.

The Guidance make the case for why the advertising of therapeutic goods is a special case:

‘Therapeutic goods are not usual items of commerce - there are potential adverse consequences to individuals and the broader public from their accidental or deliberate misuse. In addition, the relative merits of products may not be apparent to consumers. As a result, there is particular legislation that applies to the advertising of therapeutic goods to consumers. This legislation reflects the importance of consumers being fully informed so that they can select treatment options appropriately for use in the care of themselves or their family.’ [Code, p.6]

Therapeutic goods are not a cosmetic or a fashion item, or a food stuff. A therapeutic good should only be taken for the therapeutic benefit. The only information that is relevant to a consumer’s decision about whether to purchase a therapeutic good, is their knowledge of their own health and accurate information about the product; the therapeutic benefits it might provide and the possible side effects.

The inclusion of puffery does not support informed decision making. Even for a consumer who recognises the claim as false it may have the effect of influencing their decision making. It may distract them from the information they should be assessing in deciding or reduce the weight they attach to it. The existence of spurious claims about the product may even create the impression that the purchase of this product that should not be taken more seriously than other consumers goods, leading to a failure to adequately consider the decision being made.

The Guidance recognises that Australians generally have low health literacy levels. [P.11] Perhaps of even greater significance when designing advertising for a general audience is the wide variation in the health literacy levels in the Australian community.

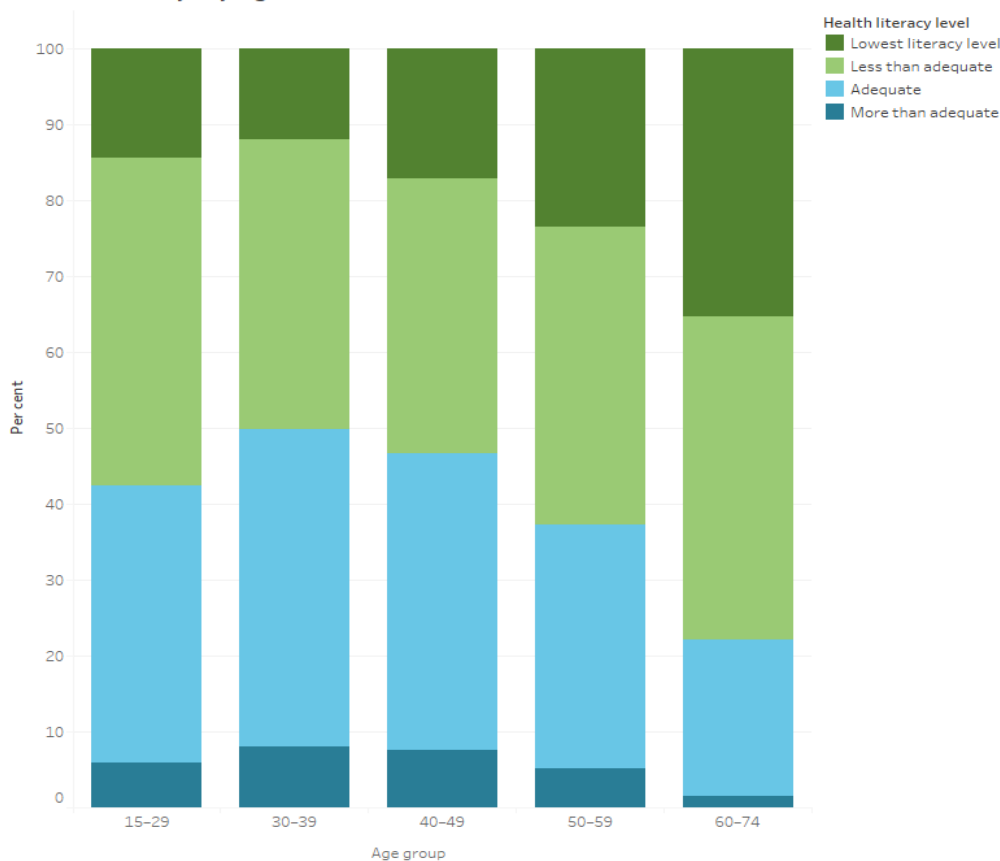
The Australian Institute of Health and Welfare (AIHW) reports that in 2006, (the latest date for which data is available):

- 41% of Australians aged 15–74 were assessed as having adequate or more than adequate health literacy skills.
- Half (50%) of all people aged 30–39 had health literacy skills that were adequate or better. Less than one-quarter (22%) of people aged 60–74 had health literacy skills that were adequate or better.
- Levels of health literacy skills were similar for males and females—40% of males and 41% of females had adequate or better health literacy skills.¹

The degree of variability by age is illustrated in the following table.

¹ AIHW, <https://www.aihw.gov.au/reports/australias-health/australias-health-2018/contents/indicators-of-australias-health/health-literacy>, accessed on 1 October 2018.

Health literacy, by age, 2006



The wide variation in health literacy was reflected in several other dimensions apart from age, including income level, educational attainment, occupation, and country of birth.

The variation in health literacy is significant because it has implications for the treatment of puffery. The Guidance in relation to Puffery states that *'Whether a part of an advertisement can be considered puffery needs to be considered through the eyes of the reasonable person to whom the advertising is directed.'* [page 74]

A reasonable person would be assumed to have a 'reasonable' or perhaps 'average' level of health literacy. When levels of health literacy vary so significantly, what a reasonable person might consider to be puffery and thus unbelievable, could still be both believable and influential to a significant proportion of the population. Typically, these will be the people who are generally seen as Australia's more vulnerable populations when it comes to misleading consumer practices- the elderly, the poorly educated, and those on low incomes.

Research Australia submits that this is not an acceptable outcome when it comes to therapeutic goods and that the appropriate course is to prohibit puffery in the advertising of therapeutic goods. Doing so will enhance the ability of consumers to identify and evaluate the appropriate information needed to make an informed decision.

The section on Puffery in Appendix B of the Guidance, which currently invites the advertiser to consider if *'puffery has a place in ethical and responsible advertising of therapeutic goods to consumers'*, should instead state clearly and unambiguously that puffery has no place in the ethical and responsible advertising of therapeutic goods to consumers

Conclusion

Research Australia submits that the Guidance should be amended to make it clear that Puffery is not allowed in the advertising of therapeutic goods.

As outlined above, Research submits two arguments for this position. The first is that the Guidance is inconsistent with the Code. A statement that is so exaggerated as to be unbelievable cannot simultaneously be truthful and accurate, as the Code requires all claims to be.

The second argument is that because of the wide variation in health literacy of Australian consumers, a statement that might be perceived to be puffery by a 'reasonable' person could still be misinterpreted as accurate by a proportion of the Australia population and thus be misleading.

The special nature of therapeutic goods and, to quote page 6 of the Code, the '*potential adverse consequences to individuals and the broader public from their accidental or deliberate misuse*', warrants the separate and more restrictive treatment of therapeutic goods when it comes to advertising these products to consumers.

The Advertising Code reflects this higher standard expected by the community, and this should not be undermined by the treatment of puffery in the Guidance.

Research Australia is pleased to have had the opportunity to make this submission and is willing to contribute further information and use its convening power in the health and medical research and innovation sectors to respond to any further questions the TGA may have.

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