
AMA submission to the Therapeutic Goods Administration – Proposed improvements to the Therapeutic Goods Advertising Code

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Introduction

The AMA supports, in principle, changes to the Therapeutic Goods Advertising Code (the Code) that clarify the rules around the advertising of therapeutic goods to ensure compliance. The AMA does not support proposals to ease regulation on advertisers to advertise in a broader scope than is currently permitted. The AMA supports a complete ban on all endorsements and testimonials, except for their use in government public health campaigns.

Direct to consumer advertising of medicines may increase use, but not necessarily effective or rational use in line with quality use of medicines principles. While advertising may potentially increase awareness of certain health conditions and medicines, its primary purpose is to increase demand and sales for the advertiser's product and is therefore unlikely to be objective or unbiased. Advertising to the public is about profits, not improving patient care. This should be kept front of mind when considering any changes to the Code.

The AMA believes that pharmaceutical or other commercial industries should not be the main suppliers of patient information and education regarding health, disease, and treatment options. Patients should consult a registered medical practitioner so they are provided with the most appropriate therapeutic options to suit their individual medical situation. Any changes to allowing specific therapeutic goods to be advertised should be led by government public health campaigns and strategies.

Section 4: Additional definitions

The AMA supports the Code being as clear as possible to ensure compliance. Therefore, the AMA has no issue with including definitions for 'claim' and the associated notes, 'indication', and 'intended purpose'. The AMA understands that there is current confusion from the industry around these meanings in this context.

Section 10: prohibition on causing fear or distress

The AMA agrees that advertisements should not cause fear or distress in consumers and therefore supports the re-addition of the requirement that *Advertising for therapeutic goods must not exploit consumers' lack of knowledge or contain language that could bring about fear or distress*.

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

The AMA supports the option to include a mandatory statement clarifying that the advertised product is only available through a health professional/healthcare facility, or can only be purchased by a health professional/healthcare facility. The AMA believes it is still important to advise consumers that they should talk to their medical practitioner/pharmacist about whether the therapeutic good is suitable for them and so this messaging should not be lost when broadening the scope of section 11.

This is particularly important because while advertisements may be directed to healthcare facilities/health professionals and may be accessed through a restricted website, this can be difficult to monitor/maintain in an online environment and so the public may still be able to view the advertisement. The AMA agrees that there should be a general obligation for advertisers to hide health-professional-directed advertisements from the public wherever possible. For instances where this is not possible, mandatory statements would provide a safety net.

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

An alternative way to access health warnings in online advertising

The AMA understands that advertisers have issues around the space required for mandatory statements and health warnings in online advertising. The AMA believes that health warnings and mandatory statements are important messages to potential consumers and should be clearly displayed in advertisements. How the TGA determines whether an advertisement is genuinely limited by space or character count may require further clarification, as these parameters can be manipulated through the design of the online material. Health warnings should be prioritised in the design.

The AMA understands that there are requirements for certain advertisements to provide information about where health warnings can be found. However, the AMA does not believe it is appropriate to place health warnings in a website link instead of in the main advertisement. Health warnings and mandatory statements should remain directly on the advertisement. A link to all other information is appropriate.

Accessing health warnings through the image of a medicine label

The AMA agrees that the same objective of the use of health warnings can be achieved by the advertiser reproducing the warnings and contraindications from medicine labels on to the advertisement. Therefore, the AMA does not oppose advertisers doing this. However, the health warnings must be displayed in an appropriate size to ensure consumers with visual impairments can still read them.

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

The AMA does not agree with advertisers that mandatory statements should be removed from the main advertisement via a link. Mandatory statements are important for consumer awareness and decision making and should remain on the advertisement.

Sections 12 and 13: Wording of mandatory statements

Generally, the AMA does not oppose the replacement options outlined in the consultation paper tables if the same objective is achieved and the statement is clear and concise. The objectives should not be compromised for the convenience of fitting within an arbitrary advertising space. The AMA agrees that existing statements are already clear and concise and in some cases and do not require further change.

To ensure the replacement option conveys the same message as the existing statement, the replacement option should state: *Always read the label and follow the directions for use*. There could be other 'directions' on the packet not related to the use of the actual product and so this distinction should be specified. This applies to the replacement options in Tables 1, 5, 7, 8, 9, and 12.

The AMA does not oppose the TGA's proposed combined mandatory statement for advertisements of one or more medicines with medical devices and/or other therapeutic goods.

The AMA believes that symptom mandatory statements provide important prompts for the consumer to seek medical advice for their condition. Exemptions for these mandatory statements should not be expanded.

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

The AMA refers to users of the Code to determine the best method to assist in determining which warning labels need to be included in the advertisement.

Section 16: Endorsements and Section 17: Testimonials

The AMA supports aspects of Option 1: clarifications to testimonial and endorsement provisions, where inconsistency between the Code and the Act is clarified regarding endorsements in public health campaigns. However, the AMA would support a complete ban on endorsements and testimonials in all other cases.

Endorsements and testimonials are by their very nature subjective, biased, and anecdotal advice intended to increase the sales of a therapeutic good. The AMA believes endorsements and testimonials inhibit informed consumer choice and may result in an increase of patients requesting/purchasing therapeutic goods that are not appropriate for their individual circumstances. Patients should pursue advice on their medical concerns and subsequently the use of therapeutic goods from their medical practitioner, who is able to tailor treatment based on the patient's medical history and individual circumstance.

An advertisement with a testimonial from a consumer saying that a therapeutic good worked for them, followed by a mandatory statement stating the 'this product may not be right for you', is counterproductive and detracts from the message that consumers should be consulting health professionals for their health needs.

The AMA believes that doctors' relationships with medical, health care or other industries must be accountable and transparent and must not compromise, or be perceived to compromise, the doctor's professional judgement, capacity to care for their patients or the community's trust in the integrity of the medical profession¹. This should apply to all health professionals.

The AMA understands the intention behind prohibiting former health professionals from making endorsements in advertising is to protect consumers who may attach undue importance to a former health professional's statement.

However, without a complete ban on endorsements and testimonials, it is essential that the TGA consult on what constitutes a 'former' health professional for the purposes of the Code. Does it mean that if an individual was registered as a health professional at any point in their lifetime, regardless of how long ago they stopped practising, they should be considered a 'former' health care professional for the purposes of the Code? For example, what if the former HCP stopped practising 10 or more years ago? What if they only practised for a very short period of time before they stopped? What if they are (or were) registered but not practising (e.g., a non-practising registration for medical practitioners).

Should the TGA decide to proceed with Option 1, it is important to engage with the registered health care professions and other relevant stakeholders on defining a 'former' health professional. Should the TGA consider allowing certain 'former' health professionals to make endorsements in advertising, it is important to consult on how such endorsements can be undertaken appropriately to protect vulnerable consumers; for example, by not allowing individuals to refer to their former role as a health professional or use their relevant qualifications when advertising.

The AMA does not believe that broadening the range of people that can provide testimonials is in the best interests of patients because the individuals as listed in the consultation paper have a direct conflict of interest, whether it be financial or personal, that could bias their testimonial. Therefore, the AMA does not support options 2 and 3.

¹ Australian Medical Association (2020) [Advertising and Public Endorsement](#).

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

The AMA supports amending subsection 20(1) of the code to clarify that providing and offering therapeutic good samples is prohibited. The use of therapeutic goods should be based on the therapeutic needs of the patient, as directed by their medical practitioner, and not by marketing strategies.

The AMA opposes advertisers and sponsors being able to apply for additional therapeutic goods to be included in Schedule 3 of the Code. As above, the AMA believes that patient use of therapeutic goods should be based on the therapeutic needs of the patient as directed by their medical practitioner, not by marketing strategies. Any exemptions under Schedule 3 should be led by government public health strategies based on reliable, evidence-based research with robust conflict of interest management strategies in place.

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

The AMA does not oppose the proposed changes to sections 28 and 29 as the addition of Notes in these sections aim to clarify the intention of the sections to enhance understanding and compliance with the Code.

Section 30: Prohibited representations: clarifications

As above, the AMA does not oppose the proposed changes to section 30 as the addition of Notes in this section aims to clarify the intention of the sections to enhance understanding and compliance with the Code.

Conclusion

The AMA supports methods to clarify any areas of confusion that inhibits advertisers from complying with the Code. However, methods should not ease advertising regulation and expand the scope of advertisements. Advertisements in themselves are designed to influence a consumer's purchasing decisions and as a result are inherently biased and subjective. There should be a ban on endorsements and testimonials except for public health campaigns. Consumers should obtain their health information and treatment options from their medical practitioner to ensure their health care is safe, of high quality, and effective.

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