Australian Government
Department of Health
Therapeutic Goods Administration

Proposed improvements to the Therapeutic Goods Advertising Code

Consultation paper

Version 1.0, May 2021

TGA Health Safety Regulation

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Introduction

Purpose

The Therapeutic Goods Administration (TGA) within the Department of Health is seeking feedback on options to improve the use and application of the Therapeutic Goods Advertising Code (No. 2) 2018 (Code). The proposed improvements are intended to increase advertisers' understanding of the requirements of the Code, ensure provisions work as intended, improve advertising compliance, and minimise advertising compliance costs, while continuing to ensure advertising does not inadvertently contribute to any unsafe or improper use of advertised products.

Feedback from this consultation will be taken into account when implementing any changes to the Code. In addition, feedback will be used to inform changes to guidance and education resources designed to assist with understanding the Code's requirements.

Scope

This paper is structured to seek feedback on options for improving the clarity and performance of provisions of the Code that have been identified by stakeholders as being unclear, inconsistent or otherwise difficult to work with.

Feedback on the appropriateness of the proposed options will assist the TGA in improving the Code.

The paper also summarises issues raised by stakeholders for which the TGA proposes that no changes are warranted at this time. This is because, on balance, the provisions remain appropriate for their intended purpose. However, where appropriate, new and/or revised guidance material will be developed to explain the purpose of those requirements and how advertisers can ensure compliance.

Background

Regulation of therapeutic goods in Australia

The TGA regulates therapeutic goods in Australia through the administration of the *Therapeutic Goods Act 1989* (Act), the *Therapeutic Goods Regulations 1990* (Regulations), the current Poisons Standard, and other relevant subordinate legislation. These instruments establish a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods. A general rule is that therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG), or otherwise subject to an exemption, approval or authority, before being lawfully supplied in, imported to, exported from or advertised in Australia.

Regulation of therapeutic goods advertising in Australia

The advertising of therapeutic goods in Australia is controlled by a combination of measures prescribed under the Act and Regulations. This is complemented by self-regulation through codes of practice administered by relevant therapeutic goods industry associations.

The regulatory requirements relating to the advertising of therapeutic goods to the general public are principally set out in Part 5-1 (Advertising and generic information) of the Act; Part 2 (Advertisements) of the Regulations; and in the Code.

The Code is the compliance standard that prescribes the minimum requirements for the advertising of therapeutic goods to the general public. Advertising in the public domain is permitted for the majority of medical devices, as well as most medicines available for over-the-counter sale. The advertising of prescription-only and certain pharmacist-only medicines to the public is prohibited; however, price information for these medicines can be advertised, with the Code setting out the conditions under which this may occur.

The regulation of advertising contributes to the safe use of therapeutic goods by ensuring the general public receives accurate and balanced information about the quality, safety and efficacy of those goods. It is essential that consumers receive credible information in advertisements so that they can make informed decisions regarding the suitability of the goods for their health needs, and do not delay seeking care from a health professional when appropriate.

Why are changes to the Code being considered?

The Code 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.

The TGA publishes guidance and provides education to assist advertisers to comply with the Act and Code, and can investigate and take enforcement action in relation to advertisements that are non-compliant. With the potential for serious consequences for non-compliance, it is important that the Code remains contemporary and clear.

The Code has been in force for just over two years, with the current version representing a major overhaul of the previous version. Experience with the current Code has provided information on opportunities for improving some provisions.

Therapeutic Goods Advertising Consultative Committee

The Therapeutic Goods Advertising Consultative Committee (TGACC) is a forum through which the TGA consults with industry, and media, publishing and broadcasting bodies involved in the advertising of therapeutic goods to the public. The TGACC also includes membership from government, and consumer and health professional representative bodies. Via its broad representation, the TGACC is able to alert the TGA to problems with the operation of the Code, including any unintended consequences, and where improvements could be made.

In 2020, the TGACC established working groups to identify and consider specific areas where the Code could be improved and where new and updated guidance could be developed to increase advertisers' understanding of their obligations. Many of the proposals included in this consultation paper are the result of work undertaken by the TGACC and its working groups.

The TGA's own experience in investigating breaches of the Code also provides information on opportunities for improvements, or alternatively, where further guidance is needed.

Sinclair Review

In 2020, an independent review of the therapeutic goods advertising framework conducted by Ms Rosemary Sinclair AM (the Sinclair Review) recommended that the TGA increase the clarity and objectivity of the Code by developing additional educational resources and maintaining a log of Code issues that stakeholders have identified as being unclear, inconsistent or difficult to work with. The TGA has implemented these recommendations and the log of issues has been used to inform the proposals in this paper.

Making a submission

To provide feedback on this consultation, please take the Online Survey on the consultation page and provide your submission using the file upload function.

We have posed questions within the paper to help structure your submission. You do not have to answer all questions, none are compulsory. However, when responding to a question, please clearly identify the question number you are responding to. You can also provide us any additional comments you wish to make.

Publication of submissions

The TGA will publish all submissions on its website unless otherwise requested or directed by the author(s). If you do not wish to have your submission made public, please advise at the time of submission.

Guidance material

In addition to referring to the Code, the Act and the Regulations to inform your submission, you may also wish to consult the following material published on the TGA website:

- Advertising Hub
  The Advertising Hub brings together guidance and education resources for advertisers, along with updates about the regulation of therapeutic goods advertising.
- Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG)
  The Guidelines inform advertisers (including sponsors, manufacturers, importers, pharmacists and health professionals) of their responsibilities when advertising therapeutic goods.
- Advertising to the Public: Complying with the Therapeutic Goods Advertising Code
  This guidance provides further information to assist with understanding, interpreting and applying Code provisions and is designed to be read in conjunction with the Code.

Unless otherwise stated, the Act and the Code apply to all types of advertising to the public in relation to therapeutic goods, and all claims made in advertisements for therapeutic goods, including both therapeutic and non-therapeutic claims.

Contacts

If you would like to discuss any aspect of this consultation, please email advertising.consultation@tga.gov.au. Please include the words 'Public consultation – Improvements to the Therapeutic Goods Advertising Code' in the subject field.

Options for improvement

The TGA, TGACC members and other stakeholders have identified the following sections of the Code for possible improvement. Included in the discussion below is one or more options for resolving the identified issues that we are consulting on through this paper.

Stakeholders may also wish to identify areas of the Code not included in this paper where improvements could be made.

Section 4: Additional definitions

Issue

Some stakeholders have identified that the Code could be improved by the addition of new definitions in section 4 for 'claims' and 'indications', with the definitions clearly distinguishing between the two terms.

Stakeholders have also suggested that a definition for 'endorsement' is needed to differentiate between an 'endorsement' and a 'testimonial'. A definition for 'endorsement' is proposed for section 16 of the Code, which deals with requirements for the use of endorsements in advertising (see Section 16 Endorsements and Section 17 Testimonials).

Description

Section 4 sets out a number of important definitions used in the Code. Some terms are defined by reference to another legislative instrument, for example, 'patient information leaflet' has the same meaning as in clause 13A.3 of Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (Medical Devices Regulations). A number of expressions used in the Code are defined in the Act (subsection 3(1)), for example, the definitions of 'advertise', 'current Poisons Standard', 'health practitioner', and 'directions for use'.

Options

Include a definition for 'claim'

Claims made in an advertisement may relate to either a therapeutic or a non-therapeutic quality of the product, its manufacturer or sponsor.

Therapeutic claims for a medicine include such things as 'clinically' or 'scientifically proven', or provides 'fast' or 'rapid action'. The concept of 'therapeutic claim' also includes the approved indications or purposes of the product. Non-therapeutic claims in advertising include such things as 'leading brand', 'best seller', or 'contains 30% more'.

The TGA is particularly concerned that therapeutic claims are supported by high quality data from robustly designed and peer reviewed clinical trials or scientific studies (other than for complementary medicines supported by traditional use evidence). As with the label of the product, therapeutic claims that are inconsistent with the information included in the ARTG entry for that product are not permitted in an advertisement.

An appropriate basis to support non-therapeutic claims is also required to ensure the advertising is not misleading.

It is proposed to move the existing content in section 4 to a subsection and then include an additional subsection relating to ***claim***, as follows:

(2) Without limiting the ordinary meaning of ***claim***, any reference to claim in this Code includes the indication or intended purpose of the therapeutic goods and includes any non-therapeutic claims made about the therapeutic goods.

Note 1: It is a breach of the Act to advertise medicines or other therapeutic goods included in the Register for an indication that is not an indication accepted in relation to the inclusion of the goods in the Register (see sections 21B and 22 of the Act).

Note 2: It is a breach of the Act to advertise medical devices for an intended purpose that is not consistent with the intended purpose accepted in relation to the inclusion of the device in the Register (see sections 41ML and 41MLB of the Act).

Given the breadth of the concept of 'claims', including the various ways in which a claim can be communicated to consumers (including through statements and images), the subsection proposes an inclusive definition, providing clarity on what we consider a claim includes, rather than being an exclusive or absolute definition of claim.

This new subsection would complement other existing provisions of the Code, such as:

- Section 9 Accuracy: requires that any claim made in an advertisement must be valid and accurate, and all information presented to support the claim must have been substantiated before the advertising occurs. Claims must not mislead, or be likely to mislead. There can be no claim that a therapeutic good, or class of therapeutic good may be harmful or ineffective compared with the advertised good.
- Section 10 Effect: prohibits certain claims from being included in advertisements. Under section 10, an advertisement cannot include a claim that the goods are safe and have no side effects; or will be effective in treating all cases of a condition; or that the goods are in any way infallible, unfailing, magical or miraculous; or that there will be harmful consequences if the goods are not used.

In addition, there are requirements for claims made in relation to testimonials (section 17), complementary medicines (section 23), vitamins and minerals (section 25), therapeutic goods for weight management (section 26), and sunscreens (section 27).

Include a note referring to the definitions for 'indication' and 'intended purpose'

'Indications' and 'intended purposes' are claims that relate to the purpose or therapeutic benefit of a medicine or medical device respectively. It is proposed to include a note in section 4 reproducing the legislative definitions of 'indications' and 'intended purpose', as follows:

> **Note**: ***Indications*** is defined in section 3 of the Act to mean, in relation to therapeutic goods, the specific therapeutic uses of the goods.
>
> ***Intended purpose*** is defined in the Medical Devices Regulations to mean, in relation to medical devices, the purpose for which the manufacturer of the device intends it to be used, as stated in:
> (a) the information provided with the device; or
> (b) the instructions for use of the device; or
> (c) any advertising material applying to the device; or
> (d) any technical documentation describing the mechanism of action of the device.

Indications are included in the ARTG entry for medicines and other therapeutic goods. The intended purpose of a medical device is certified in an application for inclusion in the ARTG.

When used in an advertisement, the 'indications' and 'intended purposes' are claims made in relation to the goods and must accurately reflect the uses that the TGA has accepted for those goods. In the case of 'listed medicines', for example, an advertisement of the therapeutic benefit of the medicine must reflect the permitted indication(s) included in the ARTG entry.

The risk of reproducing the definitions of 'indication' and 'intended purpose' in the Code is that the Code may become inaccurate if the definitions were to change. A Code update would be required to ensure that advertisers were not misled by the definition in the Code. This risk can be mitigated by including a reference to the definition rather than reproducing the definition.

Questions

1. Do you support the clarifications in relation to 'claim', 'indication' and 'intended purpose'?
2. Do these measures assist in understanding how relevant Code requirements should be applied in relation to an advertisement?
3. What additional guidance, if any, is needed?

Section 10: Prohibition on causing fear or distress

Issue

A concern raised by some stakeholders about section 10 is that it does not adequately prevent an advertisement from causing 'fear and distress' in some consumers. For example, advertising, which includes 'evidence' that suggests that a condition will lead to disability or pain could cause consumers to worry and create or reinforce a need for the advertised product. There have been instances where advertising has played on the fear of consumers contracting COVID-19.

The 2015 version of the Code included an explicit requirement that an advertisement for therapeutic goods must not exploit a lack of knowledge of consumers, or contain language that could bring about fear or distress. The requirement also prohibited any advertising likely to lead someone to believe that they are suffering from a serious ailment.

Description

Section 10 requires advertising for therapeutic goods to support the safe and proper use of the goods by being consistent with the directions or instructions for use, and not exaggerating their efficacy or performance.

Advertising for therapeutic goods must not lead to people delaying necessary medical attention, or delaying the use of, or failing to use treatments prescribed by a medical practitioner. For example, advertisements should not encourage people to self-medicate rather than seek treatment from their medical practitioner. Advertising must also not encourage inappropriate or excessive use of the goods.

Advertisements must not claim, state, imply or represent that the goods advertised are infallible, unfailing, magical or miraculous; and they must not claim that a person may be harmed by not using the product.

Option

We are seeking feedback from stakeholders about the need for section 10 to be strengthened to prohibit advertisements from including content that may create fear or distress. *Creating fear and distress* would include a claim in an advertisement that would lead people to believe they are, or could in the future suffer from a serious ailment.

In particular, feedback is requested on whether introducing a clause similar to that in the 2015 version of the Code would be effective and justified: that is, introduce a requirement to the following effect:

> *Advertising for therapeutic goods must not exploit consumers' lack of knowledge or contain language that could bring about fear or distress.*

Questions

4. Do you support strengthening section 10 to expressly prohibit advertising that may cause fear and distress?
5. Is the form of words proposed above suitable for the purpose of prohibiting advertising that may cause fear and distress?

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

Issue

The Code does not apply to an advertisement that is directed exclusively to health professionals (see subsection 6(2)(a) of the Code). In effect, this means that advertisements directed to health professionals and healthcare facilities, to the exclusion of consumers, do not need to contain the mandatory statements and health warnings that are required in consumer advertisements. This is because health professionals have the training and knowledge to assess and select appropriate goods for their patients.

On occasion, advertisements for goods that can only be purchased by health professionals and health facilities are placed in the public domain. In these instances, the advertisements must comply with the Code and include the relevant consumer-directed mandatory statements and health warnings prescribed by sections 12 and 13 of the Code.

Some stakeholders have proposed that an alternative mandatory statement be available for use in advertisements for products that are not available for purchase by the public, but where those advertisements are accessible by the public and therefore must comply with the Code. The new statement would be required instead of the mandatory statements required by sections 12 and 13 for consumer advertisements.

Stakeholders argue that including the existing consumer mandatory statements in advertisements for goods that cannot be purchased by the general public is confusing and diminishes the importance of the statements.

Some goods that have been advertised broadly that are only available for purchase by health professionals and facilities include intraocular lenses, specialised wound dressings, hip implants, pacemakers, and some types of personalised medical devices such as dental realignment devices. Other products that are usually only purchased by healthcare facilities and for which the consumer mandatory statements are considered inappropriate include items such as surgical drapes and items of hospital furniture.

Additionally, some health services may promote therapeutic goods involved in their service delivery that cannot be purchased by consumers. In these situations, the consumer mandatory statements are also considered inappropriate. For example, an imaging centre might promote that they have a new Brand X MRI machine that provides higher resolution and faster scanning.

Advertising media where these types of goods have been advertised include social media and other internet platforms. Internet advertising of therapeutic goods intended exclusively for healthcare professionals should ideally be access-restricted; however, this is not universal in practice. During the COVID-19 pandemic, some stakeholders highlighted the benefits of being able to put advertising in the public domain to facilitate rapid identification of suppliers of key therapeutic goods.

Description

Presently, section 11 applies to advertisements for non-prescription medicines that can only be sold following a consultation with a pharmacist (pharmacist-only medicines): that is, a medicine that consists of, or contains a substance included in Schedule 3 and Appendix H to the Poisons Standard. An advertisement for such medicines must contain the following statement, prominently displayed or communicated:

Ask your pharmacist—they must decide if this product is right for you.

This mandatory statement recognises the professional responsibility of pharmacists when providing access to such medicines.

It is proposed to amend section 11 so that its application is broader and includes advertisements for products that are only available for purchase by health professionals and/or healthcare facilities. Advertisements of such goods would not be subject to the requirements of sections 12 or 13.

Option

It is proposed to include one or more new mandatory statements for use when:

1. goods that are only available for purchase by health professionals and facilities are advertised using media that cannot effectively be restricted to health professionals only; and

2. goods that are not available for consumer purchase but may be used as part of a service offering to consumers, are advertised to promote that service.

The TGA will expect however, that where restricted-access controls are feasible and appropriate, advertisements intended only for health professionals will continue to be hidden from the general public. Additionally, if goods are ordinarily prohibited under the Act from being advertised to consumers e.g. prescription medicines, then they will continue to be prohibited from being promoted in the public domain.

A new provision in section 11 of the Code would permit advertisers of relevant goods to use an alternative statement(s). Placing this provision in section 11 means that the requirements of sections 12 and 13 would not apply to these types of advertisements.

Included below is one approach, although precise wording changes to section 11 would be subject to legal drafting:

- section 11 may be renamed, for example, *Therapeutic goods that can be purchased only by or through a health professional or healthcare facility (required statements)*;

- one option could be to amend section 11 to include a new subsection, possibly along the following lines:

    (3) An advertisement for medical devices and other therapeutic goods[1] that are not available for purchase by the general public [or alternatively: that are only available for purchase by health professionals and healthcare facilities] must contain one of the following statements, as appropriate to the nature of the goods, prominently displayed or communicated:

[1] 'Other therapeutic goods' is defined in section 4 of the Code as therapeutic goods that are not medicines, biologicals or medical devices. A relevant example in this context is disinfectant for use in hospitals.

(a) THIS PRODUCT IS / THESE PRODUCTS ARE ONLY AVAILABLE FOR PURCHASE BY HEALTH PROFESSIONALS.

OR

(b) THIS PRODUCT IS / THESE PRODUCTS ARE ONLY AVAILABLE FOR PURCHASE BY HEALTH PROFESSIONALS. TALK TO YOUR HEALTH PROFESSIONAL ABOUT WHETHER THIS PRODUCT WOULD BE RIGHT FOR YOU.

While the preceding statements only refer to "health professionals", in practice, relevant products would include those available for purchase by both health professionals and healthcare facilities. To make this clear, it may be necessary to expand the required statement in the Code to:

THIS PRODUCT IS / THESE PRODUCTS ARE ONLY AVAILABLE FOR PURCHASE BY HEALTH PROFESSIONALS AND HEALTHCARE FACILITIES.

A consequential amendment to paragraph 13(1)(d) of section 13 may be needed to reflect that section 11 would apply to advertisements of relevant medical devices and other therapeutic goods, as well as pharmacist-only medicines.

An example of how this could be given effect is to change the current wording of paragraph 13(1)(d) from:

(d) an advertisement for a *medicine* to which section 11 applies;

to

(d) an advertisement for therapeutic goods to which section 11 applies.

Advertisements to which this new requirement applies would continue to need to comply with all other relevant Act and Code provisions.

Some suggestions for the new mandatory statement(s):

The statements included in the proposed new subsection above are suggestions only. There are other statements that could be considered, including the following:

This product / these products can only be purchased by health professionals.

This product / these products can only be purchased by health professionals and healthcare facilities.

This product / these products cannot be purchased by the general public.

This product / these products cannot be purchased by the general public. Talk to your health professional about whether this product would be right for you.

This product / these products can only be purchased by health professionals and healthcare facilities. *Talk to your health professional about whether this product would be right for you.*

Stakeholders are asked to indicate which of these suggested statements may be most appropriate.

These statements are only relevant to the advertising of medical devices and 'other therapeutic goods'. Advertisements for pharmacist-only, over-the-counter and complementary medicines will continue to be subject to relevant mandatory statements set out in sections 11, 12 and 13.

Questions

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

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

Issues

Complexity of the section and the number of mandatory statements

Some stakeholders have expressed the view that the requirements of section 12 can be unclear, with advertisers having difficulty in interpreting and applying this part of the Code. This includes establishing when to apply section 12 instead of section 13.

It is expected, however that advertisers will be able to correctly identify the relevant mandatory statements and health warnings for the products they are advertising. A comprehensive decision tree to guide advertisers through the selection of the correct mandatory information, statements and health warnings, was published on the TGA website in August 2019.

The inclusion of mandatory statements and health warnings in advertisements when space is limited

The amount of space that mandatory statements and health warnings take up in an advertisement has also been raised as a concern by advertisers, particularly advertisements on some digital platforms where the available space is limited.

Ambiguity about where the health warnings are to be found

Another issue that has caused confusion is the requirement for the advertiser to include information in the advertisement "… about where the health warnings can be found" when the advertised product has health warnings and these are not reproduced adjacent to the other mandatory statements.

Because the intent of section 12 is to ensure consumers know what the relevant health warnings are to inform a purchasing decision, the health warnings must be accessible by the consumer *prior* to purchase. It would not be acceptable, for example, for the advertisement to advise that the health warnings are available on the label of the goods, unless the label is reproduced in the advertisement or is otherwise easily accessible prior to purchasing the goods through the advertisement.

Description

Section 12 applies to advertisements that facilitate the sale of therapeutic goods that are not physically available for examination by the consumer immediately before or at the time of purchase. It ensures that important information that is available on the label of the good, or within the instructions for use of the good, is reproduced in the advertisement and available to the consumer to inform a purchasing decision. These types of advertisements might appear, for example, in a mail order catalogue or on a website. Section 12 does not apply to advertisements to which section 11 applies (currently for pharmacist-only medicines).

Advertisements for all products covered by section 12 must include relevant mandatory statements. These are either a combination of selected prescribed statements and health warnings - for products that have health warnings; or, for products that do not have health warnings, selected prescribed statements that relate to the label and directions for use for medicines, or instructions for use for medical devices and other therapeutic goods.

Importantly, for products with health warnings, the mandatory statements include information about situations in which the use of a particular product is contraindicated or may pose significant risks to the user. Including this information in the advertisement is intended to minimise the risk that a consumer will purchase and use a product that is not right for them.

The information required in the advertisement is set out in detail in subsection 12(3) of the Code for medicines; subsection 12(4) for medical devices; and subsection 12(5) for other therapeutic goods. The mandatory information required in advertisements of the different types of therapeutic goods are summarised below:

*Advertisements for **medicines** must prominently display or communicate:*

- the statement, '*Always read the label*', when the medicine does not have any health warnings;
- when the medicine does have health warnings, either:
  - the statement, '*This medicine may not be right for you. Read the warnings before purchase*', followed immediately by information about where the health warnings can be found; or
  - both the statement, '*Always read the label*', and the relevant health warnings listed in Schedule 1[2] to the Code.

[2] Schedule 1 to the Code includes a set of the most serious warning statements that must be included on the labels of medicines under a number of other requirements under the Act. For example, for listed (mostly complementary) medicines, the *Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2018*, and for registered over-the-counter medicines, the *Medicines Advisory Statement Specification 2017*. For both categories, the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* applies.

*Advertisements for a **medical device** must prominently display or communicate:*

- either of the statements, '*Always read the label*', or '*Always read the instructions for use*', as appropriate for the packaging of the device, when the medical device does not have any health warnings;
- when the medical device does have health warnings (as defined in section 4 of the Code), one of the following:
  - the statement, '*This product may not be right for you. Read the warnings before purchase*', followed immediately by information about where the health warnings can be found; or
  - either of the following, as appropriate for the packaging of the goods:
    - the statement, '*Always read the label*', and the applicable health warnings; or
    - the statement, '*Always read the instructions for use*', and the applicable health warnings.

*Advertisements for '**other therapeutic goods**'[3] must prominently display or communicate:*

- either of the statements, '*Always read the label*', or '*Always read the instructions for use*', as appropriate for the packaging of the goods, when the goods do not have any health warnings;
- when the goods have health warnings (as defined in section 4 of the Code), one of the following:
  - the statement, '*This product may not be right for you. Read the warnings before purchase*', followed immediately by information about where the health warnings can be found; or
  - either of the following, as appropriate for the packaging of the goods:
    - the statement, '*Always read the label*', and the applicable health warnings; or
    - the statement, '*Always read the instructions for use'*, and the applicable health warnings.

In addition, advertisements for each of the above categories of goods must include:

- the required statement from subsection 13(6) of the Code to follow the directions or instructions for use; and,
- where applicable, the required symptom statement or statements from subsection 13(7) of the Code.

Whereas the source of the applicable health warnings for medical devices and other therapeutic goods will vary e.g. included with the ARTG entry and/or on the label of the goods or in the instructions for use, the health warnings for medicines covered by section 12 are included in Schedule 1 to the Code.

[3] 'Other therapeutic goods' is defined in section 4 of the Code as therapeutic goods that are not medicines, biologicals or medical devices.

When included in advertisements, these health warnings alert potential purchasers of the presence of ingredients in medicines that are known to cause adverse events in susceptible individuals. For medical devices and other therapeutic goods, the health warnings bring attention to any risks associated with the use of the products in susceptible individuals. The inclusion of health warnings in the advertisement ensures that when the product is not available for physical examination before or at the time of purchase, consumers have the critical information they need to make an informed purchasing choice.

Options

An alternative way to access health warnings in online advertising

With regard to issues raised by advertisers about the amount of space required for mandatory statements and health warnings in online advertising, and the ambiguity of the requirement to include information in an advertisement about where health warnings can be found, we are seeking stakeholder feedback on the following approach for advertisements for therapeutic goods without prior examination:

1. where the health warnings are able to be prominently displayed in the advertisement they should be so included;

2. when the advertisement is genuinely limited by physical space or character count e.g. an advertisement on a mobile-friendly website that sells therapeutic goods, the mandatory statement THIS MEDICINE / PRODUCT MAY NOT BE RIGHT FOR YOU should be included in the advertisement, with the health warnings accessible by clicking on a prominently displayed and appropriately named link.

   The link could be named “Important health warnings”, and would take the consumer to a new page where either the product label or the relevant health warnings for the product are clearly displayed.

   An example of how this could be presented for a medicine with health warnings is:

   > THIS MEDICINE MAY NOT BE RIGHT FOR YOU. Click here for Important health warnings.

   For medical devices and other therapeutic goods, the word “PRODUCT” would replace “MEDICINE” in the above statement.

3. for this option, it would be necessary to prescribe when the use of a link for health warnings would be permitted.

Accessing health warnings through the image of a medicine label

Currently, the Code does not recognise that a reproduction of the contents of a medicine label in the advertisement can be used to alert consumers to health warnings. At present, an online retailer selling medicines would not comply with section 12 and Schedule 1 by reproducing the warnings and contraindications as they appear on the medicine labels, or showing an image of the part of the label that contains the warnings and contraindications.

However, the objectives of the use of health warnings could be achieved by providing an image of the label that was legible, and with consumers alerted to look at the image to see the important health information.

The mandatory statement ‘THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE’ would still be required in the advertisement, along with information about where the health warnings can be found.

Questions

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

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

Issue

Subsection 13(5) exemption

Some advertisers utilising short form advertising that does not qualify for the exemption provided by subsection 13(5) have reported difficulties complying with the requirements of section 13 because of content limitations. They have suggested that mandatory statements could be included via a link included in the advertisement, so as to still be available to inform consumers on a 'one click away' basis.

Other stakeholders have suggested that the subsection 13(5) exemption be extended to all digital social media platforms, with the relevant mandatory statements available via a link in the advertisement.

Description

Section 13 sets out the *general* information that all advertisements for medicines, medical devices and other therapeutic goods must contain, with the exception of advertisements for:

- pharmacist-only medicines, to which section 11 applies; or
- therapeutic goods where the goods are not available for physical examination at the point of purchase (i.e. advertisements to which section 12 applies).

Section 13 applies to advertisements used to promote goods, but do not facilitate the purchase of those goods. To obtain the advertised goods, the consumer will need to either:

- attend a physical retail outlet, such as a supermarket or pharmacy where the medicine, medical device or other therapeutic good is available to be examined before purchase, or
- locate an advertisement that does facilitate the purchase of the goods, such as an online store. Advertising in an online store would need to comply with section 12.

Section 13 specifies the minimum content requirement for these advertisements, including mandatory statements; health warnings for products for which there are health warnings; and other applicable mandatory statements for products for which there are no health warnings.

These requirements are to ensure that health information that is critical to a consumer's decision to purchase the good is brought to their attention before they purchase.

Some advertising i.e. radio advertisements that are 15 seconds or less in duration, or text only advertisements that consist of 300 characters or less, are exempted from some requirements of section 13 by subsection 13(5). Subsection 13(5) exempts relevant advertisements from including the mandatory statements and health warnings required by paragraphs 13(2)(c) for medicines, 13(3)(d) for medical devices, and 13(4)(d) for other therapeutic goods. However, some mandatory statements are still required e.g. by subsection 13(6).

Proposed approach

It is not proposed to extend the subsection 13(5) exemption to other types of short-form advertisements or digital social media platforms. This is because section 13 includes an option to include only the mandatory statement:

> THIS MEDICINE/PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL/INSTRUCTIONS FOR USE BEFORE PURCHASE.

Section 13 does not require any relevant health warnings to be reproduced in the advertisement, just the mandatory statement (above) that prompts consumers to read the product label or instructions for use prior to purchase. This is sufficient to alert consumers to any important health warnings relevant to the advertised product.

Sections 12 and 13: Wording of mandatory statements

Issues

Stakeholders have identified anomalies with some requirements for the inclusion of mandatory statements: for example, the requirement for "Always read the label" in an advertisement for a product not available for inspection at the time of purchase; and the requirement for the inclusion of both the statements "Always read the instructions for use", and "Follow the instructions for use", which are to some extent duplicative.

Stakeholders have suggested that advertisers should have the ability to consolidate or combine mandatory statements, where more than one mandatory statement is required, to save on advertising space, minimise any confusion that may arise from multiple statements, and minimise the risk that consumers will not read to the end of the warnings.

Another suggestion is the development of a 'grouped' mandatory statement for advertisements that include medicines, medical devices, and/or other therapeutic goods in the same advertisement i.e. one that effectively expands subsection 13(2A) to cover more than one 'product', rather than more than one 'medicine'.

Another suggestion is that the symptom statements mentioned in subsection 13(7) and required in advertisements by sections 12 and 13, should not be required in an advertisement because these statements are most relevant when the product is being used, rather than to inform a purchasing decision. A counter argument is that retaining the symptom statements in advertisements might prompt a consumer to seek medical advice for an ongoing or worsening condition, rather than trying the advertised product.

Options

As part of the process to consider how to improve the operation of sections 12 and 13, we are seeking views on the appropriateness of the mandatory statements required by these sections.

Alternative mandatory statements for use under sections 12 and 13

Feedback is sought on whether alternatives to the existing mandatory statements required by sections 12 and 13 might achieve the same objective.

For example, in some circumstances it may be appropriate to combine the existing required statements "Always read the label" and "Follow the directions for use" into "Always read the label and follow the directions". Similarly, "Always read the instructions for use" and "Follow the instructions for use" could be combined to "Always read and follow the instructions for use". These combined statements could be used in advertisements when the products do not have any health warnings.

Finding alternatives for the existing mandatory statements required in advertisements for products that have health warnings is more problematic because the existing statements are already concise. Stakeholders are asked to consider any practical alternatives that meet the stated objectives.

The following tables set out:

(i) the circumstances in which a mandatory statement is required under sections 12 and 13;
(ii) the existing statement(s) that apply in those circumstances;
(iii) the objective of the statement(s); and
(iv) an option for a replacement statement(s).

The tables do not include a new approach to advertisements of groups of products e.g. medicines with medical devices and/or other therapeutic goods, or the 'symptom' statements presently required by sections 12 and 13. There is a separate discussion about these issues following the tables.

NOTE: the obligation to 'prominently display or communicate' any replacement statement(s), as required by the Code (unless otherwise noted), remains.

Review of section 12 mandatory statements

Table 1: Medicines that *do not* have health warnings and are not available for inspection at the point of purchase

Existing statement	Objective	Replacement option
Always read the label. AND *Follow the directions for use*.	• Advise consumers to read the label and follow the directions for use.	*Always read the label and follow the directions.*

Table 2: Medicines that *have* health warnings and are not available for inspection at the point of purchase

Existing statement	Objective	Replacement option
EITHER *This medicine may not be right for you. Read the warnings before purchase*, followed immediately by information about where the health warnings can be found. OR *Always read the label,* followed by the applicable health warnings from Schedule 1. AND *Follow the directions for use*.	• Explain to the consumer that the medicine is not suitable for everyone. • Describe the situations for which the medicine is contraindicated or carries particular risks. • Advise consumers to read the label and follow the directions for use.	No alternative proposed – for feedback.

Table 3: Medical devices that *do not have* health warnings and are not available for inspection at the point of purchase

Existing statement	Objective	Replacement option
EITHER *Always read the label*. OR *Always read the instructions for use*, as appropriate for the packaging of the device. AND *Follow the directions/ instructions for use*.	• Advise consumers to read the label and follow directions / instructions for use.	*Always read the label and follow the instructions for use*. OR *Always read and follow the directions/instructions for use*, as appropriate for the packaging of the device.

Table 4: Medical devices that *have* health warnings and are not available for inspection at the point of purchase

Existing statement	Objective	Replacement option
EITHER *This product may not be right for you. Read the warnings before purchase*, followed immediately by information about where the health warnings can be found. OR *Always read the label*, and the applicable health warnings. OR *Always read the instructions for use*, and the applicable health warnings. AND *Follow the directions/ instructions for use*.	• Explain to the consumer that the product is not suitable for everyone. • Describe the situations for which the product is contraindicated or carries particular risks. • Advise consumers to read the label and follow directions / instructions for use.	No alternative proposed – for feedback.

Table 5: Other therapeutic goods that *do not have* health warnings and are not available for inspection at the point of purchase

Existing statement	Objective	Replacement option
EITHER *Always read the label.* OR *Always read the instructions for use*, as appropriate for the packaging of the goods. AND *Follow the directions/ instructions for use*.	• Advise consumers to read the label and follow directions / instructions for use.	*Always read the label and follow the directions.* OR *Always read and follow the directions/instructions for use,* as appropriate for the packaging of the goods.

Table 6: Other therapeutic goods that *have* health warnings and are not available for inspection at the point of purchase

Existing statement	Objective	Replacement option
EITHER *This product may not be right for you. Read the warnings before purchase*, followed immediately by information about where the health warnings can be found. OR *Always read the label*, and the applicable health warnings. OR *Always read the instructions for use*, and the applicable health warnings, appropriate for the packaging of the goods AND *Follow the directions/ instructions for use*.	• Explain to the consumer that the product is not suitable for everyone. • Describe the situations for which the product is contraindicated or carries particular risks. • Advise consumers to read the label and follow directions / instructions for use.	No alternative proposed – for feedback

Review of section 13 mandatory statements

Table 7: Medicines that *do not have* health warnings

Existing statement	Objective	Replacement option
Always read the label. AND *Follow the directions for use*.	• Advise consumers to read the label and follow directions for use.	*Always read the label and follow the directions.*

Table 8: Medicines that *have* health warnings

Existing statement	Objective	Replacement option
EITHER *This medicine may not be right for you. Read the label before purchase.* OR *Always read the label,* and the applicable health warnings from Schedule 1 (Parts 1 & 2). AND *Follow the directions for use*.	• Explain to the consumer that the product is not suitable for everyone. • Describe the situations for which the product is contraindicated or carries particular risks. • Advise consumers to read the label and follow directions for use.	*This medicine may not be right for you. Read the label before purchase.* OR *Always read the label and follow the directions,* and the applicable health warnings from Schedule 1.

Table 9: Medical devices that *do not have* health warnings

Existing statement	Purpose	Replacement option
EITHER *Always read the label*. OR *Always read the instructions for use* as appropriate for the packaging of the device. AND *Follow the directions/ instructions for use*.	• Advise consumers to read the label and follow directions / instructions for use.	*Always read the label and follow the directions.* OR *Always read and follow the instructions for use*, as appropriate for the packaging of the device.

Table 10: Medical devices that *do* have health warnings and the label of the device is visible on the primary pack

Existing statement	Objective	Replacement option
EITHER *This product may not be right for you. Read the label before purchase.* OR *Always read the label,* and the applicable health warnings. AND *Follow the instructions for use*.	• Explain to the consumer that the product is not suitable for everyone. • Describe the situations for which the product is contraindicated or carries particular risks. • Advise consumers to read the label and follow directions / instructions for use.	No alternative proposed – for feedback

Table 11: Medical devices that *do* have health warnings and the label of the device is not visible on the primary pack

Existing statement	Objective	Replacement option
EITHER *This product may not be right for you. Read the instructions for use before purchase.* OR *Always read the instructions for use*, and the applicable health warnings. AND *Follow the instructions for use*.	• Explain to the consumer that the product is not suitable for everyone. • Describe the situations for which the product is contraindicated or carries particular risks. • Advise consumers to read the label and follow directions / instructions for use.	No alternative proposed – for feedback

Table 12: Other therapeutic goods that *do not* have health warnings

Existing statement	Objective	Replacement option
EITHER *Always read the label*. OR *Always read the instructions for use*, as appropriate for the packaging of the goods. AND *Follow the directions/ instructions for use*.	• Advise consumers to read the label and follow directions / instructions for use.	*Always read the label and follow the directions.* OR *Always read and follow the directions / instructions for use*, as appropriate for the packaging of the device.

Table 13: Other therapeutic goods that *do* have health warnings and the label of the goods is visible on the primary pack

Existing statement	Objective	Replacement option
EITHER *This product may not be right for you. Read the label before purchase.* OR *Always read the label*, and the applicable health warnings. AND *Follow the directions/ instructions for use*.	• Explain to the consumer that the product is not suitable for everyone. • Describe the situations for which the product is contraindicated or carries particular risks. • Advise consumers to read the label and follow directions / instructions for use.	No alternative proposed – for feedback

Table 14: Other therapeutic goods that *do* have health warnings and the label of the goods is not visible on the primary pack

Existing statement	Objective	Replacement option
EITHER *This product may not be right for you. Read the instructions for use before purchase.* OR *Always read the instructions for use*, and the applicable health warnings. AND *Follow the directions/ instructions for use*.	• Explain to the consumer that the product is not suitable for everyone. • Describe the situations for which the product is contraindicated or carries particular risks. • Advise consumers to read the label and follow directions / instructions for use.	No alternative proposed – for feedback

Introducing a combined mandatory statement for advertisements of one or more medicines with medical device(s) and/or other therapeutic good(s)

Subsection 13(2A) presently provides for a mandatory statement when an advertisement relates to more than one medicine and at least one of those medicines requires a relevant health warning. The current statement is:

> THESE MEDICINES MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE.

The TGA proposes to amend subsection 13(2A) to provide for a single mandatory statement for use when an advertisement relates to one or more medicines, one or more medical devices, or one or more other therapeutic goods, in any combination, when the advertisement of at least one of those medical products requires a health warning as defined in section 4.

Potentially, subsection 13(2A) could be amended as follows (proposed changes are in *italics* and ~~strikethrough~~):

> (2A) If an advertisement relates to:
>
> (a) ~~more than one medicine:~~ *one or more medicines, one or more medical devices, or one or more other therapeutic goods, in any combination, and*
> (b) *at least one of those medical products requires a relevant health warning as defined in section 4*,
>
> ~~(c) the advertisement does not relate to one or more other therapeutic goods or medical devices; and~~
>
> ~~(d) at least one of the medicines advertised includes an ingredient in Part 1 or Part 2 of Schedule 1 for which there is a health warning; or~~
>
> then the following statement may be prominently displayed or communicated in the advertisement instead of the applicable statements mentioned in the table in paragraphs (2)(c), (3)(d) *and 4(d):*
>
> (c) THESE *MEDICAL PRODUCTS* MAY NOT BE RIGHT FOR YOU. READ THE LABEL/INSTRUCTIONS FOR USE BEFORE PURCHASE.

The reference to 'medical products' is proposed as a way to reinforce to consumers that the advertised products are not standard consumer goods and a decision to purchase and use them should be carefully considered.

Feedback on the requirement for 'symptom' statements in advertisements

Presently, subsection 13(7) requires the inclusion of 'symptom' statements when an advertisement contains a claim relating to a symptom of a disease, condition, ailment or defect.

The statements are either of:

> IF SYMPTOMS PERSIST, TALK TO YOUR HEALTH PROFESSIONAL.
>
> or
>
> IF SYMPTOMS WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTH PROFESSIONAL.

Subsection 13(7A) provides for the two symptom statements to be combined when they both apply, for example:

> IF SYMPTOMS PERSIST, WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTH PROFESSIONAL.

Under subsection 13(8) there is an exemption from the requirements of subsection 13(7) for radio advertisements (15 seconds or less in duration) and text only advertisements (of 300 characters or less).

The TGA is seeking the views of stakeholders on the symptom statements required in advertisements.

Questions

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?
15. What alternative formulation of these statements would be better to achieve the objective?
16. What alternative mandatory statements could be used in the circumstances set out in tables 2, 4, 6, 10, 11, 13 and 14?
17. Do you support the option for amendments to subsection 13(2A)?
18. Do you support the option of a new statement for advertisements that meet the requirement of the new subsection 13(2A)?
19. What are your views on the current 'symptom' mandatory statements?

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

Issues

Stakeholders have reported issues in relation to the use of Schedule 1 in practice. These include:

1. For some ingredients, the Code does not provide an exemption from the need to include a health warning when an ingredient is present only in trace or very small amounts, whereas an allowance of this nature is made in the *Therapeutic Goods Order No.92 – Standard for labels of non-prescription medicines*. This can lead to a situation where a warning is required in advertising but not on the label. One example is gluten, where 'gluten' must be included on the label only when in concentrations of 20ppm or more.
2. The need to apply different parts of Schedule 1 to products not available versus those available for inspection prior to purchasing is confusing. One suggestion is that it may be better to have different schedules for each of sections 12 and 13.
3. There are inconsistencies in the presentation of health warnings, both within and across the different parts of the table in Schedule 1 for the same ingredients.
4. Identifying the correct mandatory statements required by sections 12 and 13, and the correct health warning statements required by Schedule 1, is difficult.

In addition, we note that Schedule 1 needs to be updated to reflect current versions of the legislative instruments from which the health warnings included in the schedule are derived.

Description

Schedule 1 to the Code reflects the most serious health warning statements that sponsors of registered over-the-counter medicines and listed (mostly complementary) medicines are required to include on the labels of their products under a number of legislative instruments.

These include:

- *Therapeutic Goods (Permissible Ingredients) Determination (No.1) of 2021*;
- *Therapeutic Goods (Medicines Advisory Statements) Specification 2019*;
- *Therapeutic Goods Order No.92 – Standard for labels of non-prescription medicines* (TGO 92).

The health warnings in Schedule 1 are condensed, where possible, to make them more suitable for inclusion in advertisements, and contain information that consumers should be aware of when considering purchasing a medicine. The information assists decision making prior to the purchase of the goods, drawing attention to conditions where the use of the goods could be hazardous.

The health warnings are intended for consumers for whom the use of the goods would be particularly hazardous, including:

1. vulnerable populations, including children, pregnant women and the elderly; and
2. patients with medical conditions to which there is a contraindication to the use of the product e.g. kidney disease, heart problems, eye conditions, allergies.

Schedule 1 comprises a table with three columns, labelled: 'Ingredients', 'Circumstances' and 'Health Warning'. The statement in the Health Warning column meets the definition of a 'health warning' set out in section 4 of the Code. The definition provides that a 'health warning' for a medicine that contains an 'Ingredient' in column 1 of the table, in the 'Circumstances' set out in column 2 of that table, means the Health Warning statement in column 3 of the table.

The existing table in Schedule 1 is divided into four parts. Part 1 lists the health warnings to be included in advertisements of registered medicines that contain a specific ingredient. Part 2 lists the health warnings to be included in advertisements of listed medicines that contain a specific ingredient. Parts 3 and 4 include health warnings to be included in advertisements for registered or listed medicines that contain allergenic ingredients.

Sections 12 and 13 of the Code set out the circumstances in which the health warnings in Schedule 1 must be used in advertisements:

- Section 12 specifies rules in relation to advertisements for therapeutic goods that are not available for physical examination at the point of purchase. All Parts of Schedule 1 are potentially applicable in relation to these advertisements. In particular, the warnings in Parts 3 and 4 are important to prevent consumers purchasing medicines with ingredients to which they are allergic.
- Section 13 specifies the general rules in relation to advertisements for therapeutic goods. This section does not apply in relation to advertisements to which section 12 applies. Parts 1 and 2 of the table in Schedule 1 are applicable to advertisements to which section 13 applies. Parts 3 and 4 of the table are not required to be applied to these advertisements because the goods to which the advertisement applies may be examined by customers prior to purchase. Consequently, customers are able to read the label of these medicines and see if there are any relevant allergenic ingredient warnings.

The TGA needs to periodically review and update Schedule 1 entries to reflect any updates to the originating legislative instruments using the following guiding principles:

Guiding principles for health warning statements for Schedule 1

The following guiding principles are used to determine whether a warning or contraindication that is mandated for a medicine label should be adopted as a required health warning for advertising purposes.

Selection Principle 1 – Minimising poor outcomes

Health warnings in medicine advertising should alert consumers to situations in which there is a high likelihood of deleterious health consequences from the use of the medicine. Therefore, absolute contraindications (where there is no justifiable reason for using the medicine in the stated situation) that are required on medicine labels should be adopted as health warnings in Schedule 1 to the Code.

Similarly, warnings for ingredients known to commonly cause allergic reactions or to damage organs should be included as health warnings in the Code.

Selection Principle 2 – Protecting vulnerable consumers

Absolute and relative (i.e. a higher risk of an adverse event) contraindications and warnings against use in vulnerable consumers (such as infants, pregnant women, people with serious medical conditions and the elderly) should be included as health warnings in the Code.

Wording Principle 1 – Suitability for use in advertising

Some medicines are required to carry a lengthy list of warnings and contraindications on their labels. The same lengthy list may not be suitable for use in advertising and the resulting health warning should be as succinct and as short as possible.

Wording Principle 2 – Effect of the health warning

The wording of the health warning must not be likely to lead to people delaying necessary medical attention or delaying the use of, or failing to use, treatment prescribed by a medical practitioner. It must not encourage inappropriate or excessive use or generate unwarranted fear or distress.

Option

The TGA has reviewed the current versions of the instruments from which the relevant health warnings included in Schedule 1 are drawn and notes that Schedule 1 requires updating.

For example, Schedule 1 to the current Code drew relevant ingredient health warnings from the *Therapeutic Goods (Permissible Ingredients) Determination No.3 of 2018*. This determination has since been updated and is not yet reflected in the Code. The Therapeutic Goods (Medicines Advisory Statements) Specification 2019 also includes updates to advisory statements required on medicine labels (for principally over-the-counter and registered complementary medicines) to those on which the current Schedule 1 is based (the *Medicines Advisory Statements Specification 2017*).

Another consideration is health warnings required to be included on the labels of medicines through other mechanisms. These include:

a. any warning statement specified in any standard that applies to the medicine;

b. any warning statements required by the Secretary to be included on the label as a condition of registration or listing in relation to the medicine; and

c. any warning statements specified in the current Poisons Standard.

To minimise the risk that critical updates to health warnings on medicine labels are not included in advertisements, we are seeking stakeholder views on an option to replace Schedule 1 with a *new method for advertisers to identify the required health warnings* to be used in advertisements for relevant medicines.

The new method, as outlined below, would require advertisers to check the label of the medicine and determine the required health warning(s) using the approach below.

New method for identifying health warnings for use in advertisements

The required health warnings to be included in an advertisement would alert consumers to known contraindications for the use of the advertised medicine in susceptible individuals (through new Tables 1 and 2); and that the medicine contains a substance that may cause an allergic reaction in a susceptible person (new Table 3).

Additional warnings may be present on the label of the medicine that are not required to be included in an advertisement. These warnings alert consumers to the risks of using the medicine, for example, when recommended dosages are exceeded, or when used other than in accordance with the directions for use. These types of warnings are not considered essential in an advertisement as the risks arise from the improper use of the medicine, rather than as a consequence of a contraindication to its use.

The three tables from which health warnings would be derived in a replacement Schedule 1 include:

- Table 1: General health warnings
  - Table 1 would include health warnings for medicines contraindicated:
    - for use in consumers with pre-existing medical conditions;
    - for use during pregnancy and breast feeding;
    - for use in infants and children;
    - for use without health professional advice; and
    - without follow up with a health professional when using the medicine.
- Table 2: Specific health warnings
  - Table 2 would include health warnings for medicines that contain specific substances that may cause problems in susceptible individuals with no known pre-existing medical conditions or other contraindications; or where it is crucial that persons follow-up with a health professional without delay after a period of use. These include:
    - substances that may cause liver damage;
    - oral rehydration salts;
    - some antihistamines; and
    - some substances used in ophthalmic medicines.

- Table 3: Substance warnings
  - Table 3 would include health warnings for medicines that contain substances that may cause an allergic reaction in susceptible individuals, or substances derived from foods to which susceptible individuals may be allergic.

Accordingly, under this option, there are three steps to identifying the appropriate health warnings to be used in an advertisement:

Step 1:

First, check the label of the medicine to see if it includes a health warning(s) of a type similar to those listed in the new Table 1.

These general health warnings typically commence with a statement listed in COLUMN 1 of Table 1, which is then combined with the circumstance or condition listed in COLUMN 2 of Table 1.

If a relevant health warning is identified in Table 1, the advertiser must follow the requirements of section 12 or 13 (as appropriate for the type of advertisement) for what must then be included in the advertisement.

The medicine label may contain multiple general health warnings of a type listed in COLUMN 1. Where more than one entry in COLUMN 2 is relevant, these may be combined into a single sentence.

For example, if a medicine label contains the health warnings:

- Do not use if you have abdominal pain.
- Do not use if you have diarrhoea.
- Do not use if you have liver problems.

These may be combined in an advertisement to form a single health warning:

- Do not use if you have abdominal pain, diarrhoea or liver problems.

Example of new Table 1: General health warnings

Health warning (Column 1)	**Circumstance or condition (Column 2)**
1. Pre-existing medical conditions:	
Do not use if you have [*condition*] OR Do not use if you have [*condition*], except on the advice of a health professional.	• abdominal pain • allergy to aspirin/ benzydamine/ diclofenac/ flurbiprofen/ ibuprofen/ indomethacin/ ketoprofen/ mefenamic acid/ naproxen/ or other anti-inflammatory medicines • asthma • a condition where constipation should be avoided • diabetes • diarrhoea • epilepsy • glaucoma or another serious eye condition • heart failure/ heart problems • high blood pressure • impaired kidney function/ kidney problems • liver failure/ liver problems • nausea • problems with your immune system • signs of an infection • stomach pain • stomach ulcer • vomiting
2. Pregnancy and breast feeding:	
Do not use if you are [*circumstances*] OR Do not use if you are [*circumstance*] except on the advice of a health professional.	• pregnant • likely to become pregnant • considering becoming pregnant • breast feeding • lactating • in the first 6 months of pregnancy • in the last 3 months of pregnancy

Health warning (Column 1)	**Circumstance or condition (Column 2)**
3. Infants and children	
Do not use in/on/for/give to OR Not suitable for OR Not to be taken by OR Not recommended for use on/in OR Keep out of reach of children.	• infants under the age of 12 months • infants under the age of 12 months, except on the advice of a health professional • infants or children • children • children under 2 years of age • children under 2 years of age, except on the advice of a health professional • children under 3 years of age • children under 6 years of age • children 6 years of age or less • children under 9 years of age • children under 12 years of age • children under 'x' years of age' [where there are age-specific dosing instructions] • children between 'x' and 'y' years of age, except on the advice of a health professional • children and adolescents under 18 years of age • children with vomiting and/or diarrhoea, except on the advice of a health professional
4. **Seek medical advice**	
Talk to your health professional before	• use if you are taking other medicines • use if you are taking an oral contraceptive • use if you are taking a prescription analgesic medicine • use if you are taking a prescription anti-depressant or suffer from bipolar depression • use if you are taking an anticoagulant • use if you are taking warfarin • taking for thinning the blood or for your heart • use with other products containing aspirin or anti-inflammatory medicines • use if you are at risk of bleeding problems • use if you have kidney disease • use if using other eye products • use if you have high blood pressure/ heart problems • use if you are taking blood pressure medicines • use if you are diabetic

Health warning (Column 1)	Circumstance or condition (Column 2)
	• use if you are pregnant/ breast feeding/ considering becoming pregnant • use if you are aged 65 years or over
5. **If symptoms persist**	
Consult your health professional if	• symptoms persist • coughing persists • congestion persists • symptoms persist after two days of treatment • symptoms persist or recur within two weeks • no better after [*insert number of days as per approved Product Information*] days.

Step 2:

Advertisers should then check Table 2 to see if there are any specific health warnings applicable to the advertised product. These warnings do not fit into the general warnings listed in Table 1, e.g. the warnings may be peculiar to an ingredient of a medicine that is known to cause an adverse health effect in a susceptible individual without a known pre-existing condition or contraindication; or a cautionary warning about seeking medical advice in the event that symptoms persist.

These warnings must be included in the advertisement if the warnings are included on the medicine label, in addition to any relevant Table 1 warnings.

Example of new Table 2: Specific health warnings

Circumstance	Health warning
Contains a substance known to harm the liver in some people e.g. • Black cohosh • Chaparral • Greater celandine • Kava • *Piper methysticum*	This medicine may harm the liver in some people. OR This medicine may harm the liver in some people. Use only under the supervision of a health professional.
Oral rehydration salts e.g. • potassium chloride (when used for rehydration therapy)	If diarrhoea persists, seek medical advice. If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years – seek medical advice' (or words to that effect)

Circumstance	Health warning
Some antihistamines including • diphenhydramine • doxylamine • promethazine	This product should only be taken on medical or pharmacist advice.
Some substances used in ophthalmic medicines including • chloramphenicol • dibromopropamidine • propamidine	If your eye infection does not improve within 48 hours, seek immediate medical advice.

Step 3:

Advertisers should check the label of the medicine for required health warnings when a medicine contains a substance known to cause an allergic reaction, or is otherwise contraindicated for use in susceptible individuals. These substance warnings are required in advertisements to which section 12 of the Code applies, i.e. when the label of the advertised medicine is not available for review by the consumer at the time of purchase.

After confirmation that the label of the advertised medicine contains a warning about a substance or group of substances listed in COLUMN 1, in the circumstances set out in COLUMN 2 (if any), then the health warning from COLULMN 3 must be included in the advertisement.

It is important to note that advertisers will not need to determine if the "circumstances" mentioned in the table below have been met: the presence of the health warning on the product label will be the trigger for including the health warning in the advertisement.

Example of new Table 3: Substance warnings[4]

Substance (Column 1)	Circumstance (Column 2)	Health warning (Column 3)
aspartame		Contains aspartame. Phenylketonurics – this product contains aspartame (phenylalanine).
antibiotics	When the antibiotic is not an active ingredient and is present only as a residual impurity	Contains residual [*antibiotic name*]
benzoates, including: • benzoic acid • sodium benzoate		Contains benzoate(s)

[4] This table is based on the substances or groups of substances that are required to be declared on the label of medicines under Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.

Substance (Column 1)	Circumstance (Column 2)	Health warning (Column 3)
chlorhexidine	Topical applications	Chlorhexidine can cause severe allergic reactions
crustacea and crustacean products		Contains crustacea; or Contains crustacean products
egg and egg products		Contains egg; or Contains egg products
ethanol	Where present in a concentration of 3% v/v or more.	Contains alcohol
fish and fish products		Contains fish; or Contains fish products
galactose		Contains galactose
gluten or ingredient derived from gluten-containing grain	Where gluten is present in a concentration of 20 parts per million or more.	Contains gluten
hydroxybenzoic acid esters		Contains hydroxybenzoates
lactose		Contains lactose
milk and milk products		Contains milk; or Contains milk products
peanuts and peanut products, including: *Arachis hypogaea* arachis (peanut) oil		Contains peanuts; or Contains peanut products
phenylalanine		Contains phenylalanine
pollen		Contains pollen
potassium salts, including: • potassium bicarbonate • potassium chloride	Where the total potassium content of the maximum recommended daily dose is greater than 39 mg (1mmol) elemental potassium.	Contains potassium
propolis		Contains propolis
royal jelly		Contains royal jelly
saccharin, including: • saccharin calcium • saccharin sodium		Contains saccharin
sesame seeds and sesame seed products, including: • sesame seed • sesame oil • *Sesamum indicum*		Contains sesame seeds; or Contains sesame seed products
sodium salts, including: • sodium bicarbonate • sodium chloride	Where the total sodium content of the maximum recommended daily dose is greater than 120 mg of elemental sodium.	Contains sodium
soya beans and soya bean products		Contains soya beans; or

Substance (Column 1)	Circumstance (Column 2)	Health warning (Column 3)
		Contains soya bean products
sorbic acid and sorbic acid salts, including: potassium sorbate		Contains sorbates
sucralose		Contains sucralose
sugar alcohols, including: • erythritol • isomalt • lactitol • maltitol • mannitol • polydextrose • sorbitol • xylitol excluding: • glycerol	Where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose. **Requirement:** To declare on the label the quantity of sugar alcohols present per recommended maximum daily dose; and a statement 'Products containing (name of sugar alcohol) may have a laxative effect or cause diarrhoea'.	Contains sugar alcohols; or Contains [name of sugar alcohol] Where the 'circumstance' is met, include the warning: 'Products containing [name of sugar alcohol] may have a laxative effect or cause diarrhoea'
sugars – monosaccharides and disaccharides, including: • fructose • glucose • honey • invert sugar • lactose • maltose • sucrose	Where the presence of sugars may have a significant glycaemic effect and the total sugar content (including lactose, which requires a separate declaration) exceeds 100 mg per maximum recommended daily dose.	Contains sugars
sulfites, including: • potassium metabisulfite • sodium bisulfite • sodium metabisulfite • sodium sulfite • sulfur dioxide		Contains sulphites
tartrazine		Contains tartrazine
tree nuts and tree nut products, including: • almond oil • *Juglans nigra*		Contains tree nuts; or Contains tree nut products

Substance (Column 1)	Circumstance (Column 2)	Health warning (Column 3)
• macadamia nut oil • *Macadamia ternifolia* • *Prunus dulcis* • walnut		

Important note about Listed Medicines

Usually, the information included on the label of listed medicines will not have been reviewed by the TGA (unless the medicine had been subject to a TGA compliance review). The advertiser, in determining the warning statements to be included in an advertisement of that product, using the approach proposed above, may be relying on information included on a non-compliant label.

Listed medicine labels that do not include the required health warnings pose a risk to susceptible consumers, and those risks may be compounded by advertising that also fails to include the required health warnings.

We are seeking stakeholder views on whether this is an acceptable risk, taking into account the likelihood and frequency of non-compliant listed medicine labels, and the harm that could result from the advertising of a medicine that has a non-compliant label when there is a reliance on the label to identify the relevant health warnings to include in the advertisement.

Questions

20. Do you support the above approach for determining the relevant health warnings to be included in an advertisement of a relevant medicine?
21. How could the above procedure be improved, or made simpler or clearer to follow?
22. Do you have any suggestions or concerns in relation to any of the above tables?
23. This option relies heavily on the label of the medicine that is available to the advertiser. Is this appropriate?

Section 16 Endorsements and Section 17 Testimonials

Issues

Stakeholders have proposed changes to endorsements and testimonials:

1. For endorsements:

- to correct an inconsistency between the Act and the Code in terms of an exemption for government endorsement of a product, for example, during a public health campaign. (Note: this will be remedied in the drafting of the amended Code);
- a proposal for a new clause to prohibit endorsements by *former* health professionals, whose name and reputation may continue to carry significant weight;
- the need for a clear prohibition on endorsements by consumer organisations for uses and/or indications that are not included in the product's ARTG entry or instructions for use; and
- the need to distinguish in the Code between endorsements and testimonials to facilitate compliance. Stakeholders have noted that for some types of advertising it is difficult to navigate this section – e.g. influencer advertising. Is an influencer's post an endorsement or testimonial, and how does one tell the difference? Are sponsorships implied endorsements or testimonials? Stakeholders have recommended that the TGA's Code guidance be reviewed to help clarify these points.

2. For testimonials:

- some stakeholders have requested a revised Code permit testimonials from those involved in the direct sale or marketing of therapeutic goods to the public, with an additional safeguard that information pertaining to any actual or perceived conflict of interest also be disclosed to protect consumers. They have proposed that this could be achieved via prescribed mandatory statements. The current prohibition on sellers providing testimonials is considered by these stakeholders to be a major impediment for direct-sellers of therapeutic goods.

  Other stakeholders are opposed to relaxing this requirement, arguing that allowing direct sellers to provide testimonials for the products they are selling would give them an unfair market advantage. Others argue that direct sellers should not be permitted to provide testimonials, as they may embellish claims in order to facilitate sales, and the product may not have the same results, or effects, in different individuals;
- the current text should be reviewed to ensure testimonial disclosure requirements are clearly expressed, consistent and adequate to protect consumers and provide appropriate guidance and boundaries for advertisers; and
- the current text specifying the requirement for 'verification of the details' of a person providing a testimonial should be revised to ensure advertisers are clear on what is involved in the verification process.

Description

Section 16 describes the circumstances in which an advertisement for therapeutic goods can contain an endorsement. The section prohibits endorsements from health practitioners, health professionals, medical researchers, or a group of any of these persons to avoid the situation whereby a consumer is unduly influenced to purchase a therapeutic good by the weight they attach to statements made by healthcare-related professionals or bodies. This prohibition extends to endorsements from people that would be perceived to be health practitioners, health professionals or medical researchers as these would be implied health professional endorsements.

Organisations representing these persons may endorse a product in an advertisement when the advertisement includes the name of the organisation and discloses the nature of the endorsement, including whether valuable consideration (including payment) has been provided. These requirements ensure that consumers are aware of any interest, including a potential conflict of interest, the endorser has in providing the endorsement.

Section 17 prescribes the requirements for testimonials used in an advertisement for therapeutic goods. A testimonial is defined as a statement about therapeutic goods made by a person who claims to have used those goods. Since only natural persons can actually use therapeutic goods, corporations are not capable of providing testimonials.

Similar to endorsements, section 17 includes provisions that ensure consumers are aware of important facts about a testimonial to assist them weigh the importance of the testimonial in any decision to purchase the goods. Section 17 provides safeguards for consumers similar to section 16, including by prohibiting testimonials from persons who may have a conflict of interest in promoting the products, and prohibiting testimonials from persons who are health professionals, who may by virtue of their profession, have an undue influence on consumer purchasing decisions.

Another important requirement is that the claims made by a person providing a testimonial must be typical of the results that can be expected from the goods when used in accordance with the directions for use or the intended purpose of the goods.

Unsolicited posts or comments on the website, social media site, internet blog or other medium of an advertiser amount to a testimonial subject to the requirements of section 17 if they are applied or exploited for the benefit of the advertisement. Advertisers may be required to block or remove an unsolicited testimonial that does not meet the requirements of section 17.

Options

One possible approach is to combine sections 16 and 17 so that the requirements for testimonials and endorsements used in the advertising of therapeutic goods are specified in a single provision. Under a combined provision, we are seeking feedback on three options that respond to the changes suggested by stakeholders. For each option, the text of the provision would be to the effect of the following:

Option 1: Clarifications to testimonial and endorsement provisions

Key points

Option 1 maintains existing requirements, with the following changes:

- resolves the inconsistency between the Code and the Act concerning the exemption for government endorsement of products as part of a public health campaign;
- former health professionals, in addition to practising health professionals, would be prohibited from making endorsements in advertising, such that vulnerable consumers do not attach undue importance to these statements;
- the new provision would reiterate the prohibition on endorsements that spruik health benefits inconsistent with a product's indications or instructions;
- the new provision would clarify the requirement to 'verify the details' of a person giving a testimonial; and

- the new provision would make it clear that paid testimonials are considered 'marketing' and are not permitted. Only genuine testimonials made by someone who does not receive any form of valuable consideration would be permitted.

Outline of the new provision under Option 1

1. Testimonials and endorsements used in, or as, an advertisement for therapeutic goods must comply with all applicable Code provisions, in addition to the requirements of this section.
2. For the purposes of this section:
    a. a testimonial means a statement about a therapeutic good made by an individual that claims to have used those goods;

        Note: a testimonial should represent the honest opinions or current beliefs of the person making the statement(s).

    b. an endorsement is any advertising message, other than a testimonial, made by a person (including a corporation) that a consumer is likely to believe reflects the support or approval of the person making the endorsement.

        Note: an endorsement may be conveyed in a range of ways, including verbal statements, demonstrations, use of an individual's name, signature, likeness or other identifiable personal characteristic, or the use of the name, seal or logo of an organisation.
3. Claims made about therapeutic goods in a testimonial or endorsement used in an advertisement must be consistent with the label, the instructions for use, and the ARTG entry for the goods (where there is one).
4. Testimonials and endorsements must not be deceptive or misleading.
5. Where a testimonial or endorsement states or implies a health benefit from the use of the goods, that health benefit must be typical of the benefit expected from the goods when used in accordance with their indications, intended purposes and directions for use.

    Note: Claimed or implied health benefits must be consistent with the available body of evidence for the goods.
6. A testimonial used in, or as, an advertisement for a therapeutic good cannot be made by:
    a. a person who is involved in the production, sale, marketing or supply of the goods;
    b. an immediate family member of a person who is involved in the production, sale, marketing or supply of the goods, unless this relationship is disclosed in the advertisement;
    c. a person or organisation mentioned in paragraphs 8(a), 8(b) or 8(c).
7. A testimonial must only be used in an advertisement about therapeutic goods where the identity of the person providing the testimonial, and the content of the testimonial, has been verified by the person who advertises or causes the advertising of the relevant goods prior to the advertising occurring.
8. An endorsement used in, or as, an advertisement for a therapeutic good cannot be given by:
    a. a government authority, unless otherwise permitted by the Act or Regulations;
    b. a hospital, or a healthcare facility, or their employees or contractors;

c. a current or former health practitioner, health professional, medical researcher or a group of such persons, or someone presenting themselves as such a person;

Note: A health professional is a person listed in s.42AA of the Act.

d. an organisation that represents the interests of healthcare consumers, or represents the interests of the persons or groups of persons mentioned in paragraph 8(c), unless the advertisement containing the endorsement:

i. names the organisation; and

ii. discloses the nature of the endorsement as being:

A. based on an objective assessment of the body of available scientific evidence that supports the use of the good; and/or
B. given for valuable consideration, which is disclosed in the advertisement.

Note: An organisation means any group, association or body (whether incorporated or unincorporated).

9. For the purposes of paragraph 8(b), a healthcare facility does not include a community pharmacy.

Option 2: Broaden the range of people that can provide testimonials with greater disclosure requirements

Key points

Option 2 follows the approach proposed in Option 1, with three changes:

- persons involved solely in the marketing of therapeutic goods (including brand ambassadors) would be permitted to provide testimonials;
- family members of those involved in the manufacture or supply of the therapeutic goods would be permitted to provide testimonials; and
- all testimonials would require new mandatory statements, set out in paragraph (7) below.

Discussion

Option 2 proposes to remove the prohibition on those involved in the marketing of therapeutic goods to make testimonials for use in advertisements. This change corrects an inconsistency in the current Code, which prohibits those in marketing from making testimonials. The inconsistency arises when a person who is otherwise not involved in the marketing of a product provides a testimonial for some form of valuable consideration. In those circumstances, it can be argued that the person is consequently involved in the marketing of that product and their testimonial is not permitted.

The proposed replacement provision also addresses feedback from stakeholders who have expressed confusion over the application of the current provision to testimonials from social media influencers and brand ambassadors, as people involved in the 'marketing' (but not the manufacture or supply of therapeutic goods). Such individuals often do not have a stake in the sale of the advertised good.

Option 2 also proposes new mandatory statements in relation to all testimonials used in therapeutic goods advertising. Some stakeholders have expressed concerns about this initiative, including that mandatory statements would not ensure transparency for consumers and that advertisements would become overrun with mandatory statements.

Outline of the new provision under Option 2

1. Testimonials and endorsements used in, or as, an advertisement for therapeutic goods must comply with all applicable Code provisions, in addition to the requirements of this section.

2. For the purposes of this section:

   a. a testimonial means a statement about a therapeutic good made by an individual that claims to have used those goods;

      Note: a testimonial should represent the honest opinions or current beliefs of the person making the statement(s).

   b. an endorsement is any advertising message, other than a testimonial, made by a person (including a corporation) that a consumer is likely to believe reflects the support or approval of the person making the endorsement.

      Note: an endorsement may be conveyed in a range of ways, including verbal statements, demonstrations, use of an individual's name, signature, likeness or other identifiable personal characteristic, or the use of the name, seal or logo of an organisation.

3. Claims made about therapeutic goods in a testimonial or endorsement used in an advertisement must be consistent with the label, the instructions for use, and the ARTG entry for the goods (where there is one).

4. Testimonials and endorsements must not be deceptive or misleading.

5. Where a testimonial or endorsement states or implies a health benefit from the use of the goods, that health benefit must be typical of the benefit expected from the goods when used in accordance with their indications, intended purposes and directions for use.

   Note: Claimed or implied health benefits must be consistent with the available body of evidence for the goods.

6. A testimonial used in, or as, an advertisement for a therapeutic good cannot be made by:

   a. a person who is involved in the production, sale or supply of the goods;

   b. a person or organisation mentioned in paragraphs 9(a), 9(b) or 9(c).

7. An advertisement about therapeutic goods that contains a testimonial must include:

   a. the following statement that is prominently displayed or communicated:
      "Testimonials may not be reliable in determining whether a product is appropriate for others";

   b. in relation to a testimonial provided by a person who has received, or will receive, valuable consideration for providing the testimonial – the following statement that is prominently displayed or communicated:
      "This is a paid testimonial";

   c. in relation to a testimonial provided by a person who is an immediate family member of an employee, officer, or shareholder of a business that is responsible for the manufacture or supply of the therapeutic goods – the following statement that is prominently displayed or communicated:
      "This testimonial has been provided by a family member of someone involved in the manufacture or supply of this product".

8. A testimonial must only be used in an advertisement about therapeutic goods where the identity of the person providing the testimonial, and the content of the testimonial, has been verified by the person who advertises or causes the advertising of the relevant goods prior to the advertising occurring.

9. An endorsement used in, or as, an advertisement for a therapeutic good cannot be given by:

    a. a government authority, unless otherwise permitted by the Act or Regulations;

    b. a hospital, or a healthcare facility, or their employees or contractors;

    c. a current or former health practitioner, health professional, medical researcher or a group of such persons, or someone presenting themselves as such a person;

    Note: A health professional is a person listed in s.42AA of the Act, which includes professions such as naturopaths.

    d. an organisation that represents the interests of healthcare consumers, or represents the interests of the persons or groups of persons mentioned in paragraph 9(c), unless the advertisement containing the endorsement:

        i. names the organisation; and

        ii. discloses the nature of the endorsement as being:

            A. based on an objective assessment of the body of available scientific evidence that supports the use of the good; and/or
            B. given for valuable consideration, which is disclosed in the advertisement.

    Note: An organisation means any group, association or body (whether incorporated or unincorporated).

10. For the purposes of paragraph 9(b), a healthcare facility does not include a community pharmacy.

Option 3: Removal of prohibition on testimonials from direct sellers

Key points

Option 3 builds on the approach proposed in Option 2, with one further change:

- direct sellers would be permitted to use their own testimonials in or as advertisements for therapeutic goods on the proviso the testimonial would be accompanied by a statement to the effect that the person making the testimonial has a stake in the sale of the good (see additional mandatory statement at paragraph (7)(b), and proposed definition of 'direct seller' at paragraph (11).

Discussion

This change would permit direct sellers to provide testimonials, provided those persons include mandatory prescribed statements in their advertisements. The prescribed statement would overtly alert the consumer to the seller's conflict of interest.

Some stakeholders, including consumer representatives, have objected to this option, concerned that permitting direct sellers to provide testimonials is inappropriate in the context of therapeutic goods. Therapeutic goods are a specific class of good (not ordinary consumer goods), the purchase of which should be based on an individual's own circumstances and professional health advice. They also point to the risk that direct sellers may be less able to objectively assess their own testimonial's compliance with the Code requirements when attempting to foster a relationship that leads to a sale.

Some stakeholders have called for an outright ban on all testimonials in therapeutic goods advertising on the basis that testimonials may be inherently biased. The TGA recognises that testimonials can be very effective in influencing consumer choices. Consequently, the TGA is concerned to ensure the Code balances the protections sought by consumer and health professional groups without unnecessarily impinging on the way in which advertising is conducted.

Outline of the new provision under Option 3

1. Testimonials and endorsements used in, or as, an advertisement for therapeutic goods must comply with all applicable Code provisions, in addition to the requirements of this section.

2. For the purposes of this section:

    a. a testimonial means a statement about a therapeutic good made by an individual that claims to have used those goods;

        Note: a testimonial should represent the honest opinions or current beliefs of the person making the statement(s).

    b. an endorsement is any advertising message, other than a testimonial, made by a person (including a corporation) that a consumer is likely to believe reflects the support or approval of the person making the endorsement.

        Note: an endorsement may be conveyed in a range of ways, including verbal statements, demonstrations, use of an individual's name, signature, likeness or other identifiable personal characteristic, or the use of the name, seal or logo of an organisation.

3. Claims made about therapeutic goods in a testimonial or endorsement used in an advertisement must be consistent with the label, the instructions for use, and the ARTG entry for the goods (where there is one).

4. Testimonials and endorsements must not be deceptive or misleading.

5. Where a testimonial or endorsement states or implies a health benefit from the use of the goods, that health benefit must be typical of the benefit expected from the goods when used in accordance with their indications, intended purposes and directions for use.

   Note: Claimed or implied health benefits must be consistent with the available body of evidence for the goods.

6. A testimonial used in, or as, an advertisement for a therapeutic good cannot be made by:

   a. a person who is involved in the production, sale or supply of the goods, **other than a direct seller**;

   b. a person or organisation mentioned in paragraphs 9(a), 9(b) or 9(c).

7. An advertisement about therapeutic goods that contains a testimonial must include:

   a. the following statement that is prominently displayed or communicated:
   "Testimonials may not be reliable in determining whether a product is appropriate for others";

   b. in relation to an advertisement from a direct seller that contains their own testimonial– the following statement that is prominently displayed or communicated:
   "I benefit from the sale of these goods";

   c. in relation to a testimonial provided by a person, other than a direct seller, who has received, or will receive, valuable consideration for providing the testimonial – the following statement that is prominently displayed or communicated:
   "This is a paid testimonial";

   d. in relation to a testimonial provided by a person who is an immediate family member of an employee, officer, or shareholder of a business that is responsible for the manufacture or supply of the therapeutic goods – the following statement that is prominently displayed or communicated:
   "This testimonial has been provided by a family member of someone involved in the manufacture or supply of this product".

8. A testimonial must only be used in an advertisement about therapeutic goods where the identity of the person providing the testimonial, and the content of the testimonial, has been verified by the person who advertises or causes the advertising of the relevant goods prior to the advertising occurring.

9. An endorsement used in, or as, an advertisement for a therapeutic good cannot be given by:

   a. a government authority, unless otherwise permitted by the Act or Regulations;

   b. a hospital, or a healthcare facility, or their employees or contractors;

   c. a current or former health practitioner, health professional, medical researcher or a group of such persons, or someone presenting themselves as such a person;

      Note: A health professional is a person listed in s.42AA of the Act, which includes professions such as naturopaths.

   d. an organisation that represents the interests of healthcare consumers, or represents the interests of the persons or groups of persons mentioned in paragraph 9(c), unless the advertisement containing the endorsement:

i. names the organisation; and

ii. discloses the nature of the endorsement as being:
   A. based on an objective assessment of the body of available scientific evidence that supports the use of the good; and/or
   B. given for valuable consideration, which is disclosed in the advertisement.

Note: An organisation means any group, association or body (whether incorporated or unincorporated).

10. For the purposes of paragraph 9(b), a healthcare facility does not include a community pharmacy.

11. In this section, ***direct seller*** means a person who is an independent contractor, dealer, distributor or representative (however described), without fixed retail location, and who is responsible for the advertisement and supply of therapeutic goods directly to consumers.

Questions

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

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?

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

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

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.

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

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

Issues

Change to the wording of subsection 20(1)

Some stakeholders have identified that the wording in section 20 needs to be more precise, consistent with the original purpose of that section, so that the prohibition in relation to free samples applies both to the *provision* of a sample, and the *offer* of a sample. The provision of a sample can be considered an advertisement of that product in and of itself.

For section 20 to comprehensively prohibit the use of samples in advertising (other than for goods included in Schedule 3), all offers of samples and the actual giving of a sample of a therapeutic good in promotional contexts must be prohibited. This does not extend to samples provided by a health professional in the course of a consultation with a patient.

Expanding Schedule 3

Some stakeholders have proposed that advertisers and sponsors should be able to apply for the inclusion of additional goods to Schedule 3 and the TGA has received requests along these lines. Those who support increasing the number and types of goods included in Schedule 3 argue that risks of inappropriate use of these goods would be mitigated if there are carefully considered criteria to guide the selection process for additional goods. For example, the goods provide a clear public or individual health benefit, and the goods can be used safely without guidance from a doctor, pharmacist or other health professional.

Description

Consistent with the Quality Use of Medicines Framework, section 20 prohibits advertisements for therapeutic goods from containing an offer of a sample. The exception to this is a limited number of therapeutic goods listed in Schedule 3 to the Code. These are condoms; therapeutic goods that are or contain sunscreen; stoma management devices for self-management; and continence catheter devices for self-management.

The objective of this provision is to ensure that consumers are not influenced to purchase therapeutic goods on the basis of samples alone; that therapeutic goods are selected according to need.

Further, this provision recognises the importance of samples in progressing public health efforts and the need, in some cases, for samples to facilitate a 'trial and error' approach to finding a suitable product for self-managing certain conditions.

For example, samples can assist:

- in broadening the use of sunscreens and condoms, contributing to important, protective public health benefits; and
- consumers that are self-managing stomas or continence catheter devices to identify the most suitable products for them, noting that their needs are likely to change over time and the potentially serious consequences of the unavailability of suitable products.

Options

Amend section 20 to specify that both the offer, and provision, of a sample are prohibited

The TGA supports amending the wording of subsection 20(1) of the Code to provide advertisers and consumers with clarity on this issue. An amendment would make it clear that both the offer of a sample of therapeutic goods in an advertisement, and the provision of a sample, other than for the products included in Schedule 3, are prohibited.

Subsection 20(1) could be amended along the following lines:

- An advertisement for therapeutic goods must not contain, *or consist of*, a sample or an offer of a sample *of therapeutic goods*.

Permit applications for therapeutic goods to be considered for inclusion in Schedule 3

We are seeking feedback from stakeholders on the merits of implementing a process for receiving and considering applications to include additional therapeutic goods in Schedule 3.

If supported, an application and assessment process would need to be designed. As an initial step, the TGA is interested in the views of stakeholders on whether such a process should be permitted and whether the guiding principles listed below would be appropriate to guide such a process.

The process could refer to the following guiding principles:

Guiding Principle 1 – Clear health benefit

To include a new item in Schedule 3, there must be an overriding public or individual health benefit associated with the advertising of the offer of samples – and that benefit must outweigh the risk of inappropriate use of the goods. To be able to establish a health benefit, the nature and intended purpose of the goods concerned need to be considered.

A stakeholder requesting the inclusion of a class of goods in Schedule 3 would need to demonstrate how the advertising of the availability, or offer, of a sample would provide a significant public or individual health benefit when compared to advertising that does not involve samples.

The proposal should discuss the potential for misuse or diversion of the samples into illicit use. Control measures should be included in the proposal to ensure samples are not supplied to children unless expressly permitted, e.g. where advertising is permitted through Schedule 2. The proposal should consider and recommend, where appropriate, whether conditions on the Schedule 3 entry may assist with resolving any issues raised in the above.

Guiding Principle 2 – Schedule 3 entries cannot be limited to just one brand/range of brands

Where a clear health benefit to including goods in Schedule 3 can be established, the goods need to be listed as a class of goods, rather than a particular brand. For example, 'condoms' rather than 'Brand X condoms'.

Guiding Principle 3 – Only lawful goods can be offered or used for samples

Therapeutic goods supplied in Australia need to be included in the ARTG, or be exempt from the requirement to do so. The supply of goods via advertising (including the offer and provision of a sample) that are not in the ARTG, or are not the subject of an exemption, is unlawful. Goods will not be included in Schedule 3 if they are not capable of being lawfully advertised in Australia at the time of consideration.

Questions

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)?

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?

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

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?

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

Issues

Some stakeholders have indicated that the purpose of sections 28 and 29 is not clear from the reading of the Code and that compliance with these sections may be improved if their intent or purpose was better explained e.g. within the Notes of the provisions.

Stakeholders have also requested that the relevant Notes within section 28 clarify that where a legislative instrument requires a warning statement that refers to a restricted representation to be used in an advertisement, the use of that restricted representation will not breach the Act.

For example, the permissible ingredients determination requires the label of listed medicines containing black cohosh to carry a warning that black cohosh has been associated with liver failure in rare cases. As this warning is required to be used on the label by a legislative instrument, it can be included in the label advertisement without breaching the Act. Similarly, where the Code requires medicines containing black cohosh to include an equivalent warning in broader advertising, it can also be included in an advertisement without breaching the Act.

Description

Section 28 of the Code, along with section 42DD of the Act, defines "restricted representations" for the purposes of advertising therapeutic goods. In general terms, restricted representations are diseases or conditions that require diagnosis, treatment or supervision by a suitably qualified healthcare professional, or the testing for which (including a self-administered test) requires medical interpretation or follow up.

Unless approved or permitted by a delegate of the Secretary of the Department of Health, restricted representations must not be used in advertisements for therapeutic goods to the

public. This is to ensure that vulnerable people are not taken advantage of and do not delay seeking medical advice for their conditions because of a self-diagnosis or self-treatment using a product they have seen advertised for that condition.

Section 29, along with paragraph 42DF(4)(c) of the Act, sets out the criteria that the Secretary must take into account in determining whether to approve the use of a restricted representation.

Option

This option is to replace the existing Notes to sections 28 and 29 with Notes along the lines of:

Section 28:

Note 1: This section identifies a "serious form of a disease, condition, ailment or defect" for the purpose of section 42DD of the Act.

Note 2: Sections 42DF and 42DK of the Act provide for the Secretary to approve or permit the use of a restricted representation in certain circumstances.

Note 3: See sections 42DL and 42DLB of the Act for offences and a civil penalty provision in relation to advertising therapeutic goods, where the advertisement contains an unauthorised restricted representation.

Note 4: Restricted representations appearing in an advertisement in the form of a warning or contraindication that is required by a legislative instrument to be included in that type of advertisement can be used in advertising without the Secretary's approval or permission.

Section 29:

Note 1: This section sets out the public interest criteria the Secretary of the Department of Health must consider when deciding under section 42DF of the Act whether to approve or refuse to approve the use of a restricted representation in advertising.

Section 30 Prohibited representations: clarifications

Issue

Noting that 'mental illness' is a prohibited representation, stakeholders have sought clearer guidance on the use of terms such as 'mild anxiety' and 'stress' in advertising. As these could be symptoms of milder forms of mental illness, stakeholders are unsure about what can be said in advertisements.

Other stakeholders have asserted that it is not possible to differentiate 'mild' from other forms of anxiety or stress. They note the difficulties establishing clear thresholds, including that many mental health conditions are on a spectrum with no clearly defined boundaries; symptoms are subjective and experienced differently between individuals; and diagnosis is often difficult and delayed, often initially reliant on a self-assessment by an individual prior to them seeking professional help.

The TGA and the TGACC have considered the issues raised and propose that no changes to the operation of section 30 are required.

While section 30 clearly prohibits mental health representations in advertising, the effect of including the relief of stress and relief of mild anxiety as permissible indications for some medicines in the *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021* (permissible indications determination) is unclear.

The permissible indications determination allows 'stress' and 'mild anxiety' as permissible indications for medicines when these terms are used consistent with certain requirements.

For example, the indications 'Helps reduce occurrence of symptoms of mild anxiety', 'Decrease/reduce/relieve symptoms of stress', and 'Decrease/reduce/relieve symptoms of mild anxiety', are permitted indications provided there is a label statement 'If symptoms persist, talk to your health professional', and the product presentation does not imply or refer to mental illnesses, disorders or conditions.

A separate issue is that there are other prohibited representations prescribed in Schedule 2 to the Regulations, and a Note to section 30 to this effect would increase the awareness of advertisers to these representations.

Description

The representations described in section 30, along with those specified in paragraph 6B(1)(b) of the Regulations, are prohibited in the advertising of therapeutic goods.

The representations that are prohibited in advertising are recognised as being particularly emotive for consumers. They include:

- any representation regarding abortifacient action i.e. an action that may induce a miscarriage or abortion;
- any representation about the treatment, cure, prevention or diagnosis (including screening), monitoring or susceptibility to the following diseases:
  - cancer;
  - sexually transmissible diseases;
  - human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS);
  - hepatitis C virus (HCV); and
  - mental illness.

The use of specified prohibited representations in broader advertising may be permitted on public health grounds by a delegate of the Secretary of the Department of Health under section 42DK of the Act.

Option

This option is to add Notes to section 30 to:

- draw attention to the other prohibited representations set out in Schedule 2 to the Regulations; and
- clarify that, where a legislative instrument requires a warning statement that refers to a prohibited representation to be used in an advertisement, the use of the prohibited representation will not breach the Act. For example, the permissible indications determination requires the label of listed medicines containing ademetionine to carry the warning "Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)". As this warning is required to be used on the label pursuant to a legislative instrument, it can be included in the label advertisement without breaching the Act.

The proposed Notes could be along the following lines:

> **Note 1**: Subsection 42DJ(1) of the Act provides that representations of a kind specified in Regulations made for the purposes of that subsection are prohibited representations about therapeutic goods of a kind specified in those regulations.

Note 2: Subregulation 6B(1) of the Regulations provides that the representations mentioned in this instrument are prohibited representations. It also provides that the representations specified in Part 1 of Schedule 2 to the Regulations are prohibited representations.

Note 3: Section 42DK of the Act provides for the Secretary to permit the use of a prohibited representation in certain circumstances.

Note 4: See sections 42DL and 42DLB of the Act for offences and a civil penalty provision for advertising therapeutic goods, where the advertisement contains an unauthorised prohibited representation.

Note 5: Prohibited representations appearing in an advertisement in the form of a warning or contraindication that is required by a legislative instrument to be included in that type of advertisement can be used in advertising without the Secretary's permission under section 42DK of the Act.

Other issues considered

Stakeholders have identified other examples where advertising has not complied with certain aspects of the Code, for example, in relation to the requirements of sections 9 and 15. However, it is not proposed that changes to these sections of the Code are necessary at this time. A short description of the issues raised is included below for completeness.

Section 9: Accuracy

Description

Section 9 sets out the requirements for accuracy, truthfulness and appropriate comparisons in the advertising of therapeutic goods, and for any claims made in an advertisement to be consistent with the inclusion of the goods in the ARTG.

All claims made in therapeutic goods advertising must be both valid and accurate, and all information presented in an advertisement must have been substantiated prior to the advertising. Substantiating evidence can include clinical study reports, literature reviews, or an objective critical review of data presented by a clinical expert. Claims that are not therapeutic claims, for example, 'fast acting' and 'Australia's leading brand', must also have been appropriately substantiated.

Therapeutic goods advertising must be truthful, balanced and not misleading or likely to mislead persons to whom the advertisement is directed. The requirement for balanced advertising is intended to prevent advertisers of therapeutic goods from making exaggerated claims as to their effectiveness.

If the advertising compares therapeutic goods, or classes of therapeutic goods, it must not disparage the compared goods or class of goods by claiming, either directly or indirectly, that the goods against which the advertised product is being compared could cause harm, or are unlikely to be effective.

Advertising of therapeutic goods included in the ARTG must be consistent with the information included in the entry. For example, an advertisement for a good included in the ARTG with an indication of reducing muscle soreness must be consistent with this indication.

Issue

Some stakeholders have raised concerns about advertisements that make claims that:

- exaggerate the health benefits of complementary health products;
- suggest that a nutritional supplement will provide a health benefit in the absence of a nutritional deficiency; or
- are inconsistent with new evidence that challenges the pre-existing body of evidence of the benefits provided by those products.

Proposed approach

The TGA considers the issues raised are compliance issues, rather than arising because of an inconsistency or other fault with the Code.

Section 15: Scientific or clinical representations

Description

Section 15 sets out the requirements for an advertisement that makes a scientific or clinical representation, or when the advertisement contains an explicit or implied citation to scientific or clinical literature. The section specifies that all scientific and clinical language and terms must be appropriate, clearly communicated, and must be readily understood by the advertisement's target audience. Scientific or clinical representations must be consistent with the body of scientific or clinical evidence applicable to the therapeutic goods that are the subject of the advertisement. Taken together these provisions generally prevent the use of scientific or clinical 'jargon' or highly specialised scientific or medical terminology in advertising of therapeutic goods.

If research results are explicitly or implicitly cited in the advertisement, the advertisement must identify the researcher and the financial sponsor of the research, where the advertiser knows, or ought reasonably to know that information. The research must be cited in a way that allows consumers to access the study. This provision does not require an advertiser to provide consumers with a copy of the cited research. The provision does, however, prevent citation of research that is not available to the consumer for reasons of confidentiality.

Issue

Some stakeholders have expressed the view that where clinical trial results are being cited in advertising, e.g. to justify the advertised claims about a specific ingredient, especially herbals, advertisers must confirm that the ingredient used in their product is the same as in the clinical trial cited. In addition, the clinical trial data must be similarly relatable to other product characteristics, for example, the formulation, the dose, the population, the duration of treatment (whether it matches the product) etc. Section 15 does not specifically set out this requirement.

Proposed approach

The TGA considers that any advertising that misrepresents research or clinical trial data in an advertisement is in breach of the requirements of section 9 of the Code.

Section 9 sets out the requirements for accuracy, truthfulness and appropriate comparisons in the advertising of therapeutic goods and for all claims to be both valid and accurate.

In relation to clinical study reports, literature reviews, critical reviews of data and other sources of scientific evidence, section 9 places the obligation on advertisers to ensure that the information presented is directly relevant to the advertised product.

Because section 9 imposes these obligations, the TGA does not suggest any amendments to section 15.

In addition, the Assessed listed medicines evidence guidelines (2018) (evidence guidelines) sets out an approach for products where terms such as 'clinically' and 'scientifically' in combination with 'proven', 'tested', 'trialled' etc. are used (pages 55 and 56 of the evidence guidelines refer). These types of statements are not appropriate unless supported by unequivocal data from robust clinical trials on the *actual product*.

Webinars on this paper and providing other Code feedback

During the consultation period the TGA will run webinars to outline the options presented in this paper and provide an opportunity for attendees to ask questions to assist in the preparation of their submission.

While the issues canvassed above are the main issues raised by the TGACC and identified through the TGA's experience in administering the Code, this consultation may be used to raise other issues in relation to the scope, operation and interpretation of the Code.

Implementation

After the closure of this consultation, all feedback received will be considered in informing amendments to the Code.

Once amendments to the Code have been finalised, the TGA will update guidance to advertisers to reflect the changes.

Further information regarding the implementation of a revised Code will be communicated in the second half of 2021.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Compliance Branch	May 2021

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