Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Improvements to the Therapeutic Goods Advertising Code

Consultation paper

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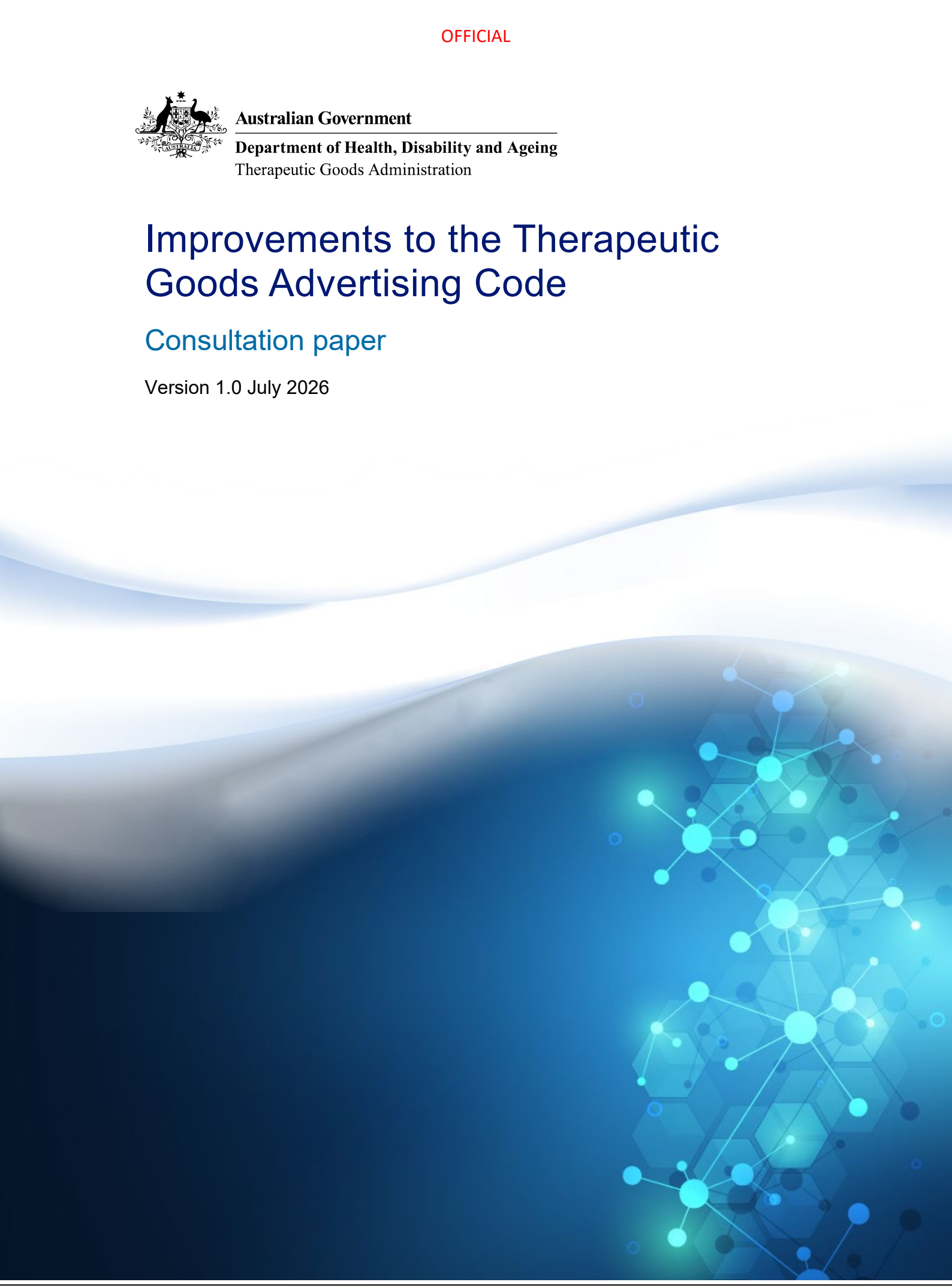

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All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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Overview

The Therapeutic Goods Administration (TGA) within the Department of Health, Disability and Ageing is seeking feedback on options and proposed changes to improve the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Code).

We are reviewing parts of the Code to make sure it:

- is clear and easy to apply
- reflects current advertising practices
- supports safe and appropriate use of therapeutic goods.

This consultation focuses on issues where improvements may be needed. It is not a full review of the Code.

About this consultation

This consultation paper is presented in 4 parts:

- Part 1: We outline key issues raised by stakeholders and present options for change. In some cases, we identify a preferred option.
- Part 2: We propose targeted changes to improve clarity, consistency and usability of the Code.
- Part 3: We outline minor or technical changes to improve how the Code operates.
- Part 4: We identify issues that do not require changes to the Code but would benefit from clearer guidance for advertisers.

Your feedback will help us decide whether to:

- update the Code, or provide clearer guidance to advertisers
- understand the impact of proposed changes on stakeholders.

How to respond

We have posed questions within this consultation paper to help guide feedback. We also welcome any additional comments, via a separate response document if you wish.

You do not have to answer all the questions, and none are mandatory.

You can submit your views by clicking the link and answering the questions from the consultation paper.

You can also upload your own response document on the final page of the link above.

If you have any questions about this consultation, please contact advertising.consultation@tga.gov.au.

Background

The TGA regulates the advertising of therapeutic goods in Australia through a combination of measures set out under the *Therapeutic Goods Act 1989* (the Act), the Therapeutic Goods Regulations 1990 (the Regulations), and the Code.

Advertising to the public is allowed for the majority of medical devices, as well as most medicines available for over-the-counter sale, with the Code setting out the required standards for this to occur. The advertising of prescription-only and certain pharmacist-only medicines, and biologicals to the public is generally prohibited.

Therapeutic goods are intended to influence people's health. Consumers may be more vulnerable to advertising claims when making decisions about their health and may not always be able to critically assess whether a particular therapeutic good is suitable for them. For this reason, advertising for therapeutic goods is subject to stricter requirements than advertising for everyday consumer goods.

The Code sets the standards for advertising therapeutic goods to the public. It helps make sure advertisements:

- promote the safe and proper use of therapeutic goods
- are ethical
- do not mislead or deceive consumers
- are not inconsistent with public health campaigns
- support informed health care choices.

For more information see Applying the Advertising Code.

Clear and lawful advertising supports safe use of therapeutic goods. It helps consumers make informed decisions and encourages them to seek advice from a health professional when needed.

Part 1 – Potential options for improvement

Issue 1A: Mandatory statements for advertisements about therapeutic goods that are not available for purchase by the public

Some therapeutic goods that can be lawfully advertised to the public are only available for supply through a health professional and are not sold directly to consumers. Examples include orthodontic appliances and prosthetic devices such as artificial joints. Advertising for these goods can support informed health care choices by helping patients discuss diagnosis and treatment options with their health practitioner.

Section 16 of the Code (extract below) currently requires advertisements for these goods to include a mandatory statement to inform consumers that the advertised good is not available for direct purchase by the public.

> **16 Advertisements—therapeutic goods not available for purchase by general public**
>
> Where:
> (a) an advertisement about therapeutic goods is published or disseminated to the general public; and
> (b) the goods are only available for supply through a health professional;
> then the advertisement must contain the following statement, prominently displayed or communicated:
>
> THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC

There are also some therapeutic goods that are never supplied to consumers. Examples include in vitro diagnostic (IVD) devices used in laboratories, and hospital equipment such as magnetic resonance imaging (MRI) machines and x-ray machines. Although it may be lawful to advertise these

goods to the public, advertising is generally not directed to consumers but must still comply with the Code.

Problem

Industry stakeholders have indicated that the mandatory statement set out in section 16 of the Code may give consumers the impression the advertised good is not available for supply to consumers at all, rather than being available through a health professional. Stakeholders have suggested that, consistent with other mandatory statements in the Code, advertisements for these goods should instead direct consumers to a relevant source of further information, such as a health professional who can supply the goods.

Stakeholders have also noted that the Code does not clearly distinguish between:

- goods that are supplied to consumers through a health professional; and
- goods that are not supplied to consumers under any circumstances.

Options for change

To clarify the application of section 16 of the Code for these types of therapeutic goods, the following options are proposed:

1. Amend the Code to introduce a new mandatory statement for advertisements about therapeutic goods which are only available for supply through a health professional, such as *'This product [or treatment with this product] is only available through a [Health Professional].'* This mandatory statement, or similar, would allow advertisers to specify whether the product, or treatment with the product, is accessible to consumers, and it will allow advertisers to specify the kind of health professional consumers must consult to access the product.

   This option would retain the existing mandatory statement in section 16 of the Code, *'This product is not available for purchase by the general public'* solely for advertisements about goods that are not supplied to consumers under any circumstances.

2. Amend the Code to introduce a new mandatory statement for advertisements about therapeutic goods that are only available for supply through a health professional (as set out in **option 1** above). In addition, under this option the Code or advertising guidance would be clarified to indicate that a Code-mandated statement is not required for advertisements about therapeutic goods that are not supplied to consumers at all.

3. Retain the 'status quo' by continuing to require the existing mandatory statement for advertisements about therapeutic goods that are only available for supply through a health professional. Stakeholder concerns would instead be addressed through updated guidance clarifying that advertisers may include additional explanatory information at their discretion. For example, guidance could specify that the mandatory statement *'This product is not available for purchase by the general public'* may be accompanied by explanatory wording indicating that the advertised good can be purchased through a specific kind of health professional.

   Under this option, the Code would not expressly clarify whether a mandatory statement is required for advertisements about therapeutic goods that are not supplied to consumers under any circumstances. This issue could instead be addressed through guidance explaining that the Code does not specify a mandatory statement for advertisements about such goods.

With all three options, the TGA also proposes to update existing advertising guidance to explain that advertisers may provide accompanying information alongside mandatory statements, to explain how the advertised good can be accessed by consumers.

While some therapeutic goods do not have specific supply restrictions under the legislation, product sponsors may still implement supply controls for commercial reasons or to promote the appropriate use of the goods. For example, certain listed medicines (such as 'practitioner dispensing only' products) are intended to be supplied only to consumers who have consulted a health professional. Depending on the mandatory statement used in an advertisement, it may be necessary to include additional information to clarify the pathway for access to the good, including whether consultation with a specified health professional is required.

Preferred option

Option 1 is the preferred option because it clearly distinguishes between goods that are supplied to consumers through a health professional and goods that are not supplied to consumers at all. This approach provides consumers with clear and actionable information about how a product can be accessed, supports informed healthcare choices, and reduces the risk of consumer confusion. This option is expected to have minimal compliance costs for industry, as only minor adjustments to advertising would be required.

Option 2 is not the preferred option because, while it introduces a new mandatory statement for goods supplied through a health professional, it does not require advertisements about therapeutic goods, which cannot be supplied to consumers under any circumstances, to clearly indicate that the product is not available for purchase. This option does not improve transparency and could contribute to consumer confusion about the availability of advertised goods.

Option 3 is not the preferred option because it does not require advertisements to include a mandatory statement directing consumers to a relevant health professional, nor does it introduce a mandatory statement for advertisements about therapeutic goods that are not available for purchase by consumers. While advertisers could voluntarily include explanatory information under this option, reliance on guidance alone would limit consistency and reduce the effectiveness of the regulatory framework.

Question 1

Do you agree with the implementation of a mandatory statement to the effect of '[This product] or [Treatment with this product] is only available through a [Health Professional*]' for advertisements in the public domain about therapeutic goods that are only available for supply through a health professional?

* With this statement, advertisers can specify the type of health professional consumers must consult to access the good or treatment with the good.

(Yes / No / Unsure). If no, please provide your preferred option.

Question 2

Do you agree with the implementation of a mandatory statement to the effect of 'This product is not available for purchase by the general public' for advertisements in the public domain about therapeutic goods that are not available for supply to consumers?

(Yes / No / Unsure). If no, please provide your preferred option.

Issue 1B: Advertising requirements for software-based medical devices

The TGA regulates software and artificial intelligence (AI) models and systems when they meet the definition of a medical device under section 41BD of the Act.

Software-based medical devices (including AI models and systems) have been regulated by the TGA for many years. Over the past decade, software has become increasingly important in medical devices and digital adoption more broadly, with rapid innovation in technology driving significant changes.

Advances in computing technology and software production have led to a large increase in the number of software-based medical devices available on the Australian market, particularly stand-alone software that meets the definition of a medical device. These kinds of products are known as software as a medical device (SaMD) and the Code applies the same advertising requirements to SaMD products as it does to all other medical devices.

In 2024, the TGA conducted a review to:

- determine whether our existing legislation, regulations and guidance are appropriate to meet the challenges associated with increasing use of medical software and AI across the healthcare sector, and
- identify measures to clarify and strengthen existing regulation to mitigate risks and leverage opportunities associated with medical software and AI use in the therapeutic goods sector.

Although the findings from this review indicated the TGA's existing legislative framework is largely appropriate for the increasing use of AI in the therapeutic goods sector, it also identified a desire from stakeholders for the current advertising rules to be tailored to:

- address the unique characteristics associated with the promotion, purchase and supply of SaMD products, including those incorporating AI, and
- improve access to important information that will help consumers:
    - choose the most appropriate SaMD for them,
    - mitigate risks associated with the use of SaMD, and
    - easily identify SaMD products that meets Australian regulatory requirements for medical devices administered by the TGA.

Problems

The following key areas where reform may be necessary to address the issues raised by stakeholders have been identified:

1. To be lawfully supplied and advertised in Australia, medical devices must be included in the Australian Register of Therapeutic Goods (ARTG), unless specifically exempt or excluded. The availability of SaMD products through digital environments and online global marketplaces such as 'app stores' means Australian consumers and health professionals cannot always easily determine which SaMD products have met Australian regulatory requirements for medical devices or those included in the ARTG.
2. Subsection 20(1) of the Code sets out mandatory statements for advertisements about medical devices which remind consumers to *'Always read the label'* and *'Follow the directions for use'*. The terms used in these mandatory statements may not be appropriate for advertisements about SaMD, such as mobile apps, which may not have a 'label' or 'directions for use'. Therefore, to effectively mitigate risks associated with the use of SaMD products it may be appropriate for the Code to mandate cautionary statements that are specific to the use and supply of SaMD products.

3. Under subsection 20(2) of the Code, if an advertisement facilitates directly the purchase or supply of a medical device, and the device cannot be physically inspected before purchase, the advertisement must include health warnings or a direct link to the warnings.[1] As many SaMD products are typically advertised in digital or virtual environments where they can be purchased and supplied to consumers almost instantaneously, it may be appropriate to introduce requirements for these types of advertisements to always include health warnings. It may not be desirable for these types of advertisements to just include a link to relevant health warnings as consumers may only review the content in the initial advertisement before purchasing and using the SaMD.

4. The TGA's review into the use of AI in SaMD products found that stakeholders want advertisements to clearly indicate when a SaMD is, or operates using, an AI model or system. Currently, the Code does not set out specific requirements for advertising AI-enabled SaMD, however, it may be necessary to mandate specific requirements for advertisements about AI-enabled SaMD to mitigate risks associated with the use of these devices.

Options for change

The options presented below aim to explore ways the Code could better reflect the unique challenges associated with the advertising and supply of SaMD products, including those that are based on AI models and systems. These options seek to:

- help consumers and health professionals identify SaMD products that are included in the ARTG
- support informed consumer decision making by ensuring essential information is available, easy to understand and suited to digital environments
- ensure advertising remains accurate, balanced, and ethical, consistent with the Code's objective to prevent misleading or deceptive representations
- enhance regulatory certainty for advertisers while reducing ambiguity about how existing provisions apply to SaMD products, and
- ensure regulatory requirements for the advertising of SaMD, particularly those incorporating AI, align with Australia's National AI Plan.

Importantly, these options are exploratory only. They do not indicate a preferred approach or commitment to legislative change. Instead, they are presented to facilitate discussion and test whether updates to the Code are needed to ensure advertising for SaMD products continues to meet the needs of consumers, industry and the evolving digital health environment.

Option 1 – Improve transparency about ARTG inclusion

Sponsors of medical devices can voluntarily include the ARTG number for their device in advertising material.

Under this option, the TGA would amend the Code to require the ARTG number for SaMD products to be displayed in advertisements, and on any platform that facilitates direct purchase or supply, similar to measures for medical device software that have already been introduced in Europe[2]. This option is

[1] Essential Principle 13 requires a medical device's IFU to include any warnings, contra-indications, precautions or restrictions. If a warning, contra-indication, precaution or restriction is necessary for the consumer to make an informed decision about purchasing the good, it is a health warning, which must be included in these types of advertisements.

[2] Guidance on the safe making available of medical device software (MDSW) apps on online platforms – Medical Device Coordination Group Document (EU) MDCG 2025-4 - June 2025

intended to improve transparency and help Australian consumers and health professionals identify SaMD products that meet Australian regulatory requirements.

The TGA is also seeking feedback on additional measures that could improve transparency about whether SaMD products are included in the ARTG and comply with Australian regulatory requirements. Specifically, the TGA would like feedback on the potential inclusion of the following information in advertisements for SaMD products:

- the implementation of a 'tick' or other recognisable symbol to indicate the SaMD is included in the ARTG
- the inclusion of a link to the instructions for use (IFU) for the SaMD when an advertisement facilitates directly the supply of the good
- the inclusion of the name, address and contact details of the sponsor and
- the inclusion of the Unique Device Identification (UDI) number, where applicable.

Requiring this information in advertisements may improve transparency and assist consumers and health professionals to make informed decisions when choosing SaMD products.

Question 3

Do you support mandatory inclusion of the ARTG number in advertising about SaMD products?

(Yes / No / Unsure)

Please provide a brief explanation about your response.

Question 4

Do you support the introduction of any of the following measures in advertisements for SaMD products to improve transparency about the ARTG inclusion and compliance with Australian regulatory requirements ?

- The implementation of a 'tick' or other recognisable symbol to indicate the SaMD is included in the ARTG.

  (Yes/ No/ Unsure)

  Please provide a brief explanation about your response.

- The inclusion of a link to the instructions for use (IFU) for the SaMD when an advertisement facilitates directly the supply of the good.

  (Yes/ No/ Unsure)

  Please provide a brief explanation about your response.

- The inclusion of the name, address and contact details of the sponsor.

  (Yes/ No/ Unsure)

  Please provide a brief explanation about your response.

- The inclusion of the Unique Device Identification (UDI) number.

  (Yes/ No/ Unsure)

  Please provide a brief explanation about your response.

Option 2 – Introduce software specific mandatory statements

Under this option, the Code would be amended to introduce a new mandatory statement, or a selection of new mandatory statements, for advertisements about SaMD products that are practical to the digital and virtual environments where these products are commonly advertised, purchased and supplied.

As previously mentioned, the mandatory statements required by subsection 20(1) of the Code may not have a practical application to the digital and virtual environments where SaMD products are advertised, particularly as SaMD products do not have a physical 'label' which sets out the important product information.

Examples of mandatory statements that may be suitable for advertisements about SaMD products are *'Review the intended use and the health warnings before using this product'* or *'Always read the instructions for use'*.

Note: The purpose of a mandatory statement is to direct consumers to critical information about a therapeutic good that must be considered before using the product.

Question 5

Do you agree with the introduction of a specific mandatory statement or selection of statements for advertising about SaMD?

(Yes / No / Unsure).

If yes, please provide your preferred option.

Option 3 – Require all relevant health warnings to be included in advertisements for SaMD that facilitate directly the purchase or supply

Under this option, the Code would be amended to introduce a requirement for health warnings to be included in advertisements that facilitate directly the purchase or supply of a SaMD. As mentioned above, a link to relevant health warnings would no longer be sufficient for these types of advertisements as consumers may only review the content in the initial advertisement before accessing the SaMD. Embedding health warnings in advertising that facilitates the direct purchase or supply of SaMD products will help to ensure relevant health warnings are always presented to consumers before the SaMD is supplied to them for use.

Question 6

Do you agree with the proposal to require all relevant health warnings to always be included in advertising for SaMD products that facilitate directly the purchase or supply?

(Yes / No / Unsure)

If no, please explain where the health warnings should appear in advertising about SaMD products that facilitate directly the purchase or supply.

Option 4 – Introduce disclosure requirements for SaMD incorporating artificial intelligence (AI)

With this option, the Code would be amended to require advertisements for SaMD to clearly disclose when the product is, or operates using, an AI model or system to supports its intended use. For example, advertisements for AI-enabled SaMD products could be required to include a mandatory statement such as *'This product uses artificial intelligence (AI) technology to support its intended purpose'*.

For SaMD products that incorporate generative AI, a mandatory statement such as *'There can be limitations with information generated using artificial intelligence (AI)'* may also be appropriate.

The introduction of these disclosure requirements is intended to support responsible AI adoption, promote transparency around the use of AI and mitigate risks associated with AI-enabled SaMD products.

Question 7

Do you support the inclusion of a mandatory statement to inform users when a SaMD product is, or operates using, an AI model or system?

(Yes / No / Unsure)

If yes, please explain which mandatory statement(s) you think should be considered, in terms of disclosing whether a SaMD product uses AI.

Question 8

Should advertisements about SaMD products that are, or operates using, a *generative* AI model or system include additional warnings?

(Yes / No / Unsure)

If yes, please explain which warning statement(s) you think should be included in advertising about SaMD that are, or operates using, a generative AI model or system.

Question 9

Is there further information you would like to be included in online advertising about AI-enabled SaMD products?

(Yes / No / Unsure)

If yes, please explain what other information should be included in advertising about AI-enabled SaMD products to support informed decision making by consumers and health professionals.

Note: While these options relate specifically to the regulation of advertisements about SaMD, it is important to understand that these advertisements will be required to comply with all other relevant Code and Act provisions.

Issue 1C: Whether to allow the use of paid testimonials in advertising about therapeutic sunscreens

Section 24 of the Code sets out the requirements for using testimonials and endorsements in advertisements for therapeutic goods. A testimonial is a statement about a therapeutic good made by a person who claims to have used that good personally or to have used it while caring for someone else. Testimonials are often provided through online advertising such as social media, including through product reviews and user comments.

Endorsements are a form of support or approval for a product. In relation to advertising about therapeutic goods, endorsements may refer to features of the advertised goods but do not testify about the personal use of the goods.

Consumers should be able to trust that testimonials used in advertisements for therapeutic goods are genuine unbiased accounts of an ordinary consumer's use of the product. As such, paragraph 24(4)(a) of the Code prohibits the use of testimonials in advertisements about therapeutic goods if the testimonial is given by persons involved in the production, marketing or supply of the advertised goods. Relevantly, a person who is engaged in the marketing or supply of therapeutic goods includes influencers, direct sellers and other persons who have received, or will receive, valuable consideration for making the testimonial.

Valuable consideration in exchange for a testimonial may include cash payments, gifts, services, or a range of other incentives such as free flights, accommodation, discounted products or samples of free products. For more information, see: Testimonials and endorsements in advertising.

Problem

The TGA has received requests from stakeholders to amend the Code to allow persons, including social media influencers, to receive valuable consideration in exchange for testimonials that are about therapeutic sunscreen products (i.e., sunscreen products that are therapeutic goods).

These stakeholders argue that Australians are confused about sun protection and that more concerted efforts are required to encourage individuals, particularly adolescents, to engage in sun protection behaviours. They contend that the Code's restrictions on paid testimonials reduces positive messaging about sunscreens, in the face of increasingly unchecked anti-sunscreen messaging on social media.

Stakeholders claim social media influencers can play an important role in promoting sun protection behaviours by providing paid testimonials to share their personal experiences about the physical (non-therapeutic) attributes of therapeutic sunscreens. These may include features such as the product's texture (for example, whether it is light, greasy or fast-absorbing), its appearance on the skin (such as whether it leaves a visible residue or white cast), its feel during application, and characteristics like scent or fragrance. These features can be a significant influencing factor when deciding whether to use that product.

Stakeholders also assert that this type of advertising about therapeutic sunscreens could boost public health efforts to encourage young people in Australia to adopt sun protection behaviours, arguing that testimonials from influencers are more likely to change behaviour than testimonials from ordinary consumers.

Notably, while subsection 24(6) of the Code prohibits certain persons from endorsing therapeutic goods (including, for example, current and former health professionals), the Code does not expressly prohibit other persons from endorsing a therapeutic good in exchange for valuable consideration.

In some cases, this *may* allow social media influencers to provide paid endorsements for therapeutic sunscreens that focus on physical attributes of the product without referring to their personal experience using the good.

However, stakeholders assert that endorsements cannot adequately address the main barriers to proper sunscreen use, particularly concerns about the look and feel of the sunscreens. They argue that these barriers can be more effectively addressed through testimonials, including those delivered by social media influencers.

Options for change

To address stakeholder requests and concerns about the current restrictions on using paid testimonials in advertising for therapeutic sunscreens, the following options are being considered.

The options under consideration include the following:

1. Amend the Code to allow advertising about therapeutic sunscreens to include paid testimonials about any aspect of a therapeutic sunscreen product including its perceived effectiveness.

2. Amend the Code to allow advertising about therapeutic sunscreens to include paid testimonials only about their physical attributes, such as the look and feel of the product.

3. Retain the 'status quo' and continue to prohibit the use of paid testimonials in advertising about therapeutic sunscreens.

Preferred Option

Option 3 is the preferred option. The TGA believes the prohibitions on paid, or incentivised testimonials are necessary due to the inherent conflict between the testimonial-giver's interest in remuneration and their duty to provide a genuine and unbiased view about a product.

The TGA has previously reviewed this issue, including earlier proposals from industry, businesses and advertisers to change the testimonial rules in the Code. Consumer groups have repeatedly opposed these proposals. They have expressed concerns about the reliability of paid testimonials highlighting that:

- the testimonial-giver's financial incentive may conflict with their obligation to provide an honest and impartial account

- the purchase of therapeutic goods should be based on an individual's own circumstances and professional health advice, and

- receiving health advice from people who are not health professionals nor familiar with the personal circumstance of the consumer may not be beneficial to consumers.

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 advertising is conducted.

The TGA believes that advertisements for sunscreens should be consistent with public health advice and part of a broader message about different sun protection behaviours such as wearing protective clothing, sunglasses and hats, and seeking shade. While Option 1 and 2 may have the potential to increase influencer advertising about sunscreens on social media, it is not clear that this would translate into stronger public health messaging about all the necessary sun protection behaviours.

Question 10

Do you agree with the TGA's preferred option (Option 3) to continue to prohibit the use of paid testimonials in advertisements for therapeutic sunscreens?

(Yes / No / Unsure).

If no, please provide your preferred option (i.e. option 1 or option 2) and explain your answer.

Question 11

Do you think allowing paid testimonials in advertisements for therapeutic sunscreens will affect consumer trust in sunscreen advertising?

Strongly Disagree (i.e. Definitely won't affect consumer trust)

Disagree

Neither Agree nor Disagree

Agree

Strongly Agree (i.e. Definitely will affect consumer trust)

Question 12

Do you think paid testimonials in social media advertising could influence how consumers understand or engage in sun protection behaviours?

(Yes / No / Unsure).

If yes, please explain your answer.

Part 2 – Proposed clarifications and amendments

Issue 2A: Clarity regarding the definition of 'prominently displayed or communicated'

Part 4 and 5 of the Code requires critical information, such as mandatory statements and health warnings, to be 'prominently displayed or communicated' in specified advertisements about therapeutic goods. This requirement ensures consumers can easily notice and understand essential safety information when making purchasing decisions and is intended to support safe and informed use of therapeutic goods.

Type of statement	When they are required	Example
Mandatory statement	The mandatory statement(s) that must be included in an advertisement depends on the type of therapeutic goods being advertised, how the goods are purchased or supplied, and sometimes the type of advertisement, as outlined in the Code.	Section 19(1) of the Code requires advertisements for medicines to include the statement prominently displayed or communicated: *"Always read the label and follow the directions for use"*.

Health warning	Health warnings may refer to contraindications, precautions or restrictions on using a therapeutic good based on the type of good or the ingredients it contains. They are only required in advertisements that facilitate the direct purchase or supply of a therapeutic good where the good cannot be physically inspected by the consumer before purchase.	Paragraph 19(2)(f) of the Code requires advertisements that facilitate the direct purchase or supply of a medicine to prominently display or communicate a list of relevant health warnings or provide a link to relevant health warnings. An example of a health warning for certain medicines is *'This medication may cause drowsiness'*.

Problem

In earlier versions of the Code, the definition of 'prominently displayed or communicated' explicitly stated that visual statements must stand out so they can be easily read from a reasonable viewing distance. The current definition in section 4 of the Code, does not expressly require visual statements in an advertisement to 'stand out'.

Stakeholders have indicated that the absence of this wording in the current definition creates ambiguity and compliance uncertainty. Specifically, stakeholders have questioned whether the Code requires visual statements, which must be 'prominently displayed or communicated', to have 'prominence' within an advertisement.

4 Definitions

prominently displayed or communicated, in relation to a statement in an advertisement, means:

(a) either:

(i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or

(ii) for a spoken statement—able to be clearly heard and understood; and

(b) repeated as often as is necessary to be noticed by a viewer or listener.

Although the Code's current definition of 'prominently displayed or communicated' omits an explicit reference to the requirement for information to 'stand out' its intended meaning remains unchanged, as the word 'prominent' inherently involves the element of standing out. As such, the TGA expects such information to clearly stand out from the surrounding text and imagery so it can be easily noticed and/or understood to support informed decision making by consumers.

Proposed change

To support the compliance of advertisers, and to avoid ambiguity, the TGA is proposing to amend the definition of 'prominently displayed or communicated' in the Code to include a reference to 'standing out' as part of the requirements for visual statements.

Reason

Amending the definition of 'prominently displayed or communicated' in the Code, to include the element of 'standing out' aligns with the Code's objective to promote the safe and proper use of the therapeutic goods by minimising misuse, overuse or underuse. The TGA also notes that improved clarity of the definition of 'prominently displayed or communicated' for advertisers may help to reduce reliance on supplementary guidance.

The proposed change is expected to have minimal compliance costs for industry, as it reflects existing TGA expectations and current guidance. Retaining the status quo would perpetuate ambiguity and increase the risk of non-compliance, whereas revising the Code provides certainty and supports better advertising outcomes.

Question 13

Do you agree with the proposed change to the definition of 'prominently displayed or communicated'?

(Yes / Partially agree / No / Unsure).

Please explain your answer and tell us:

- how these changes may affect you and
- your suggestions or comments for updated Code guidance.

Issue 2B: Whether permitted advertisements about vaccines should be exempt from certain requirements in the Code

To support the Australian Government's vaccination programs, the TGA has made instruments under section 42DK of the Act that conditionally permit the use of specified restricted representations in specified advertisements about certain vaccines. These instruments are commonly referred to as restricted representation permissions.

The Therapeutic Goods (Restricted Representations - Influenza Vaccines) Permission 2022 is an example of a restricted representation permission that allows health practitioners and specified businesses to use self-developed materials to promote the use and supply of influenza vaccines. In the absence of such permissions, representations about vaccine-preventable diseases such as influenza are prohibited under subsections 42DL(7) and 42DLB(4) of the Act.

Permitted advertisements about vaccines are distinct from advertisements that form part of, or otherwise comprise, a government public health campaign, which are already exempt from the Code under paragraph 6(1)(b).

Problem

Subsection 19(1) of the Code sets out general requirements for advertisements about medicines including the requirement to state the trade name of the medicine, one or more accepted indications for the medicine, and include the mandatory statement *'Always read the label and follow the directions for use'*.

While these requirements are essential for advertisements about medicines consumers access and administer themselves, not all are applicable to advertisements about vaccines made in accordance with a restricted representation permission. For example, where a permission does not allow the specified advertisements to refer to the vaccine's trade name or indications. Additionally, the requirement to include the statement 'Always read the label and follow the directions for use' is not applicable because these medicines are not self-administered.

Proposed change

The TGA proposes to include an exception in the Code for advertisements about vaccines made in accordance with a restricted representation permission under section 42DK of the Act, to ensure these

advertisements can comply with the Code without being subject to requirements that are not applicable.

Reason

As mentioned above, the general requirements for advertisements about medicines in subsection 19(1) of the Code are incompatible with the requirements imposed by restricted representation permissions.

Advertisements about vaccines, made according to a restricted representation permission, promote the availability of vaccines at vaccination services or workplaces, rather than to provide detailed product information or encourage self-selection. Consumers consult a health professional at the point of service to determine the suitability of a vaccine, distinguishing these advertisements from those for consumer medicines.

Introducing an exception would ensure that vaccine advertisements (made in accordance with a 42DK permission) are consistent with the therapeutic goods legislation. While the general requirements for advertisements about medicines would not apply to these advertisements about vaccines, relevant requirements of the Code would continue to apply to ensure that vaccine promotion is consistent with public health campaigns, is not misleading and supports the safe and proper use of vaccines.

Question 14

Do you agree that advertisements about vaccines made in accordance with an instrument under section 42DK of the Act should be exempt from section 19(1) of the Code, where those requirements are incompatible with the conditions of the instrument?

(Yes / Partially agree / No / Unsure).

Please explain your answer and tell us:

- how these changes may affect you and
- your suggestions or comments for updated Code guidance.

Issue 2C: Clarify that references to vaccine-preventable diseases are restricted representations

A restricted representation is a representation (such as a statement or claim) in an advertisement about therapeutic goods that refers to a form of a disease, condition, ailment or defect identified in the Code as a ‘serious form’ of a disease, condition, ailment or defect.

The definition of a ‘serious form’, of a disease, condition, ailment or defect, is provided in section 28 of the Code (extracted below).

28 Restricted representations — serious form of disease, condition, ailment or defect

For the purposes of section 42DD of the Act, a form of a disease, condition, ailment or defect is a **serious form** if:

(a) it is medically accepted that the form requires diagnosis or treatment or supervision by a health practitioner who is suitably qualified, except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management;

or

(b) there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), which requires medical interpretation or follow-up;
but does not include;
(c) pregnancy, other than pregnancy with a medical, obstetric or surgical complication.

'Restricted representations' must only be used with the TGA's prior approval or permission. Unauthorised use of restricted representations is prohibited under the Act. This requirement helps protect consumers, particularly those affected by serious conditions, from misleading or exploitative advertising. It also reduces the risk that consumers will try to self-manage serious medical conditions without appropriate professional advice.

Problem

Due to the potential for all vaccine-preventable diseases to cause serious disease, the TGA currently considers representations about vaccine-preventable diseases, such as influenza, COVID-19 and respiratory syncytial virus (RSV), to be restricted representations.

Stakeholders have questioned whether this approach is appropriate in all circumstances, particularly where the severity of the disease can range from mild and self-manageable to life-threatening. For example, the Australian Immunisation Handbook states influenza "can be a mild disease" but may also cause "very serious illness in otherwise healthy people".[3] Similarly, COVID-19 is described as capable of causing "mild to moderate disease", while posing a higher risk of severe illness in older adults and people with certain medical conditions.[4] On this basis, stakeholders argue that vaccine-preventable diseases may not always meet the criteria for a serious form of disease, condition, ailment or defect as defined in paragraph 28(a) of the Code.

The increasing availability of rapid antigen self-tests (RATs) for vaccine-preventable diseases has added further uncertainty. Under paragraph 28(b) of the Code, a disease is serious if there is a diagnostic test available, including a self-test test, that requires medical interpretation or follow-up. However, current health advice indicates that follow-up with a doctor is not *always* required after using RATs for some vaccine-preventable diseases. This also raises questions whether all vaccine-preventable diseases meet the definition of 'serious forms' under paragraph 28(b) of the Code.

Proposed change

Due to the potential for all vaccine-preventable diseases to cause serious illness, the TGA proposes to amend the definition of 'serious form' in section 28 of the Code to explicitly include **all** vaccine-preventable diseases. This amendment would ensure that any reference to a vaccine-preventable disease in advertising is treated as a restricted representation. This would apply regardless of whether the disease presents in a mild or self-manageable form that does not require medical diagnosis, treatment, or supervision, or the disease requires medical follow-up in relation to the results from a self-administered test.

This proposal is clarificatory in nature as it reflects the TGA's long-standing position that all representations relating to vaccine-preventable diseases, including influenza, RSV and COVID-19, are restricted representations.

This proposal aligns with restrictions in other legislative instruments, including the Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025 which specifically prohibits the product

[3] Australian Immunisation Handbook - https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/influenza-flu
[4] Australian Immunisation Handbook - https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/covid-19

presentation[5] of listed medicines from referring to serious forms of respiratory diseases such as influenza. Accordingly, this proposal is not expected to affect current advertising requirements (including product labels) for these products.

Reason

Amending the definition of 'serious form' to classify all references to vaccine-preventable diseases as restricted representations aligns with the Code's objective to ensure that advertisements for therapeutic goods are not inconsistent with current public health campaigns. This approach supports the Australian Government's public health strategy for managing vaccine-preventable diseases as it ensures that only clinically relevant therapeutic goods can be advertised to diagnose, treat or prevent these diseases.

Amending the Code to clarify that **all** references to vaccine-preventable diseases are restricted representations will provide clarity for advertisers and reduce the need for case-by-case assessment. Maintaining the status quo would perpetuate ambiguity and increase the risk of non-compliance.

The proposed amendment is expected to have minimal compliance costs for industry, as it is clarificatory in nature and reflects the TGA's long-standing position that all representations about vaccine-preventable diseases are restricted representations.

As mentioned above, the TGA has previously granted permissions, made under section 42DK of the Act, for advertisers to use restricted representations referring to vaccine-preventable diseases to support public health campaigns. The TGA will expand on these where the use of the restricted representation is necessary for the appropriate use of the advertised good or necessary in the interests of public health.

Question 15

Do you support the proposed amendment to include all vaccine-preventable diseases in the definition of 'serious form' in section 28 of the Code?

(Yes / No / Unsure).

Please explain why you do or do not support this proposal.

Question 16

What impacts (positive or negative) do you foresee for your organisation or stakeholders if this change is implemented?

Question 17

Are there alternative approaches you believe would better address the ambiguity while supporting public health objectives?

Question 18

Do you have any evidence or examples that should be considered in finalising this proposal?

[5] The definition of 'presentation' in the Act *"in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods".*

Issue 2D: Addition of therapeutic goods to the list of permitted samples in Annexure 2 of the Code

Section 25 and Annexure 2 of the Code provide rules about which therapeutic goods can be offered as free samples in, or as, an advertisement. Advertisers are not permitted to promote or distribute samples of any therapeutic goods that are not listed in Annexure 2 of the Code. The objective of these provisions is to ensure that therapeutic goods are used according to need, to support the safe and proper use of therapeutic goods.

The existing entries in Annexure 2 include limited categories of medicines, medical devices and other therapeutic goods that have well established efficacy/performance, public health benefits and safety profiles and, in the case of medicines, are consistent with the government policy on Quality Use of Medicines.

These provisions recognise 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 chronic conditions.

The TGA has published guidance on how advertisers can seek to add to the list of permitted samples in Annexure 2 of the Code.

Sample products should generally meet the following criteria in order to be included in the list of permitted samples:

- the product must have clear health benefits or social welfare benefits when offered as a sample
- an application must not be brand specific
- the therapeutic good must be entered in the ARTG
- the good must not require health professional advice to be used appropriately or safely
- the advertisement which is, or contains, the sample must be capable of complying with the Code.

Applications for new samples

Stakeholders have requested the following categories of therapeutic goods be added to the list of permitted samples in Annexure 2 of the Code:

- topical pain relief products regulated as listed medicines
- disposable insulin pen needles
- topical scar treatments regulated as medical devices
- skin barrier emollient and moisturising preparations (including topical nappy rash products).

Proposed additions to Annexure 2

Based on the criteria outlined in the TGA's Code guidance, the TGA proposes to add disposable insulin pen needles and topical nappy rash products to the list of permitted samples in Annexure 2 of the Code.

Topical pain relief products, topical scar treatments and the broader category of skin barrier emollient and moisturising preparations are not proposed for inclusion.

Reasons

Disposable insulin pen needles

Disposable insulin pen needles are proposed for inclusion because they have clear health benefits for individuals, namely people with diabetes, who use insulin and require disposable insulin pen needles for the administration of this medicine. Samples of disposable insulin pen needles have the benefit of helping people with diabetes find the appropriate needle length for their individual circumstances. There are multiple brands of disposable insulin pen needles in the ARTG, therefore, this would not be a brand specific category.

To comply with the Code and ensure these goods are advertised only in a manner consistent with their intended purpose, samples of disposable insulin pen needles must only be advertised and supplied to consumers with diabetes who already use insulin pen devices and have been trained by a health professional in their safe use. Accordingly, the TGA proposes to impose a condition restricting the advertising and supply of these goods as samples to this consumer group.

Unmedicated topical nappy rash products

The TGA also proposes to include topical nappy rash products. Nappy rash is a common condition, and trying a small amount of a product can help parents or carers determine whether it suits their baby's skin. These products are low-risk, widely used, and do not require health professional advice. Unlike broader moisturising or skin-barrier products, this is a clearly defined category of therapeutic goods with clear health benefits for a specific group (infants with nappy rash).

Skin barrier emollient and moisturising preparations (broad category)

A proposal to include the broad category of 'skin barrier emollient and moisturising preparations' was not supported. It covers many products with different therapeutic uses, and there was no evidence that sampling would provide a clear health benefit across the entire category. Only the unmedicated topical nappy rash sub-category met the criteria.

Topical pain relief products

There are many brands of topical pain relief products in the ARTG, which are generally regulated as low-risk therapeutic goods. These products are used by a wide range of people for distinct types of pain, from pain associated with arthritis to chronic pain conditions or sport injuries. As the target group and expected benefit vary so widely, a clear health benefit for a specific population could not be identified in the context of sampling.

Topical scar treatment products

There are many brands of topical scar treatment products in the ARTG, and they are generally regulated as low-risk therapeutic goods that can be self-selected and administered by consumers. These products usually require regular application over several weeks before any improvement is seen. A sample-sized amount would not allow users to see meaningful results, so it does not provide a clear benefit in the context of sampling.

Question 19

Do you have any objections with the TGA's proposal to include 'insulin pen needles' and 'unmedicated topical nappy rash products' in the list of permitted samples in Annexure 2 of the Code?

(Yes / No / Unsure).

If yes, please explain what your objections are to the proposed inclusion of these products in the list of permitted samples in Annexure 2.

Question 20

Are there other products you would like to propose for inclusion in the permitted list of samples in Annexure 2?

Please note, if you propose for a category of therapeutic goods to be included in the permitted list of samples in Annexure 2, you are required to address the criteria set out in the TGA guidance How can I seek to add to the list of permitted samples in the Code?

Part 3 - Administrative amendments

Issue 3A – The exception in the Code for the Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022

Paragraph 6(1)(c) of the Code provides that the Code does not apply to an advertisement made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission* 2022. The effect of this provision is that such advertisements may include representations about the safety of COVID-19 vaccines, which would otherwise be prohibited under paragraph 9(1)(a) of the Code.

This exception was introduced to support public health messaging during the COVID-19 pandemic.

Problem

On 20 October 2023, the Australian Government determined that the COVID-19 pandemic is no longer a Communicable Disease Incident of National Significance. However, paragraph 6(1)(c) of the Code continues to exempt advertisements made in accordance with the 2022 permission from the operation of the Code, including the prohibition on representing products as safe. Comparable exemptions do not apply to advertisements about vaccines for other common communicable diseases, such as influenza.

Proposed change

The TGA proposes to remove paragraph 6(1)(c) of the Code. The TGA considers that advertisements about COVID-19 vaccines should now be subject to the same regulatory requirements as advertisements for other vaccines. This would mean, among other things, that non-government advertisements about COVID-19 vaccines would not be able to make representations concerning the

safety of the vaccines. The TGA considers that product safety claims are only appropriate in the context of government-produced materials developed for public health campaigns.

Reason

Apart from the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022,* the only exceptions from the Code in relation to the promotion of vaccines apply only to government health campaign permissions which allow the Commonwealth, state or territory governments to use restricted or prohibited representations when promoting vaccines. These campaign materials are developed without commercial interests, do not promote specific brands, and are intended to support public health objectives through disease awareness and education.

Under the *Therapeutic Goods (Prohibited and Restricted Representations—Government Health Campaigns) Permission 2026*, government-produced promotional materials about vaccines (including for COVID-19 vaccines) may continue to be used by businesses, such as general practices, and are exempt from the Code under paragraph 6(1)(b). These materials may include safety statements.

Issue 3B – General requirements for advertisements

Part 4 of the Code includes requirements such as mandatory statements, health warnings, and other key information that must appear in advertisements for therapeutic goods. These rules ensure that essential safety information is clear and consistent, so consumers can make informed decisions about the goods they use.

Within Part 4, there are:

- Requirements for the inclusion of mandatory statements in certain kinds of advertisements, which are set out in Division 2. The requirements in Division 2 are specifically for advertisements about therapeutic goods that consist of, or contain, a substance included in Schedule 3 of the Poisons Standard (pharmacist only medicines), therapeutic goods not available for purchase by the public, and short-form advertisements.
- Requirements for the inclusion of mandatory statements and other information in advertisements about medicines, medical devices and other therapeutic goods which are set out in Division 3.

Apart from specified mandatory statements, the rules in Division 3 in Part 4 of the Code require advertisements about therapeutic goods to include:

- the name of the medicine or the trade name for a medical device or ‘other therapeutic good’
- an accurate description of the good – if it is a medical device or other therapeutic good
- one or more accepted indications – if the good is a medicine or an ‘other therapeutic good’
- one or more accepted intended purposes – if the good is a medical device.

In addition to these requirements, if the advertisement facilitates the direct purchase or supply of the good without the consumer being able to physically inspect the good before purchase, the advertisement must include additional information such as:

- the names of the active ingredients if the product is a medicine,
- names of the ingredients included in the Poisons Standard – if the product is a medical device or ‘other therapeutic good’ and
- health warnings (or a direct link to health warnings).

Problem

Section 18 of the Code provides that Division 3 in Part 4 of the Code does not apply to an advertisement mentioned in Division 2. A 'note' at the beginning of Division 2 in further states that advertisements mentioned in this Division do not need to comply with Division 3.

This wording may create uncertainty because it suggests that advertisements covered by Division 2 are exempt from all requirements in Division 3. However, this is not the intended effect.

Requirements relating to basic product information such as the product name, a description of the good, and its accepted indication or intended purpose are set out in Division 3 and apply to the types of advertisements mentioned in Division 2. This information is essential to enable consumers to understand the purpose of the advertised good and who may benefit from using it.

Proposed change

Consistent with Division 3 of Part 4 of the Code, it is proposed for the three types of advertisements set out in Division 2 (in Part 4 of the Code) to include the following general requirements:

- the name of the medicine (as per paragraph 19(1)(a)) or the trade name – if it is a medical device or 'other therapeutic good' (as per paragraphs 20(1)(a) and 21(1)(a) respectively)
- an accurate description of the good if it is a medical device or other therapeutic good (as per paragraphs 20(1)(b) and 21(1)(b) respectively)
- one or more accepted indications if the good is a medicine or an 'other therapeutic good' (as per paragraphs 19(1)(b) and 21(1)(c) respectively) and
- one or more accepted intended purposes if the good is a medical device (as per paragraph 20(1)(c)).

Reason

These amendments will ensure consistent application of the Code and certainty about what information must appear in the types of advertisements mentioned in Division 2 in Part 4 of the Code. The amendments will also ensure all advertisements are required to provide clear, basic product information to support safe and informed decision-making.

Issue 3C - Mandatory statements for medical devices

According to paragraph 20(1)(d) of the Code, advertisements about medical devices are required to prominently display or communicate either of the following mandatory statements:

- Always follow the directions for use
- Always read the label and follow the directions for use.

Problem

Some stakeholders have requested to use the term 'instructions for use' instead of 'directions for use' in the mandatory statement for advertisements about medical devices. This is because the term 'instructions for use' is commonly used by manufacturers of medical devices, and using this term in advertising will align with the title of the information sheet (commonly known as the 'instructions for use') that is provided with the medical device.

The term 'directions for use' is still used in relation to the information sheet that is provided with certain medical devices.

Proposed change

The TGA is proposing to amend section 20 of the Code to allow advertisements about medical devices to use one of the following mandatory statements:

- Always follow the instructions for use or
- Always follow the directions for use or
- Always read the label and follow the instructions for use or
- Always read the label and follow the directions for use.

Reasons

Providing additional options for the mandatory statements will allow advertisers to use the most relevant terminology for their device and will help to ensure the mandatory statement effectively conveys to consumers the need to follow the relevant information that is provided with the device. This change is expected to reduce confusion for advertisers and consumers.

Part 4 - Issues that will be addressed in advertising guidance

Issue 4A – Clarification of what constitutes 'generic information'

There are restrictions on the dissemination of 'generic information' about ingredients or components of therapeutic goods that, although they are not products supplied to consumers, come within the meaning of therapeutic goods because they are represented to be:

- for therapeutic use; or
- for use as an ingredient or component in the manufacture of other therapeutic goods.

In Part 5-1 of the Act, 'generic information', includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic goods, excluding advertisements about the goods, generic information included in an advertisement about the goods, or bona fide news (section 42B of the Act refers).

Section 42DO of the Act provides that generic information to which Part 5-1 applies must comply with the provisions of the Code that are prescribed by the regulations for the purposes of section 42DO, as if those provisions applied to generic information in the same way as they apply to advertisements.

The provisions of the Code with which generic information must comply are prescribed by regulation 8 of the Regulations (extracted below).

> **8 Compliance with the Code**
>
> For section 42DO of the Act, sections 8, 9, 10, 11, 12, 24 (to the extent that it relates to endorsements) and 26 of the Therapeutic Goods Advertising Code are prescribed.

Problem

Stakeholders have raised concerns that although regulation 8 of the Regulations requires 'generic information' to comply with specific sections of the Code, the Code itself does not explain what generic information is or how the rules apply. Stakeholders have proposed that section 4 of the Code include a definition about 'generic information' and section 5 of the Code to specify which parts of the Code apply to 'generic information'.

Stakeholders have highlighted that the lack of clarity about 'generic information' may also affect compliance, as disseminating non-compliant generic information is an offence under the Act.

Proposed solution

While 'generic information' must comply with prescribed sections of the Code, the Act states that 'generic information' does not include advertising about a therapeutic good nor does it include 'generic information' that is within an advertisement about a therapeutic good. The Regulations impose these requirements. However, given stakeholder interest, and potential compliance implications, the TGA proposes to provide additional clarity on the requirements for generic information by publishing guidance on the TGA website.

Providing guidance about this topic will address stakeholder concerns, improve understanding and support compliance without unnecessary legislative change.

Question 21

Which parts of the Code, when applied to generic information, are most difficult to interpret in practice (e.g., sections 8, 9, 10, 11, 12, 24 and 26)?

Question 22

What additional guidance, in relation to generic information, is needed?

Issue 4B – The requirement for citations to scientific and clinical research in advertising

Section 11 of the Code sets out requirements for advertisements about therapeutic goods that include scientific or clinical representations, or that refer to scientific or clinical research (whether expressly or by implication).

Relevantly, advertisements that refer to scientific or clinical research must comply with the requirements in subsection 11(3) of the Code (extracted below).

11 Scientific or clinical representations

(3) An advertisement about therapeutic goods that refers to scientific or clinical research, expressly or by implication, must:

(a) identify the researcher; and

(b) identify the financial sponsor of the research where the advertiser knows, or ought reasonably to have known, that information; and

(c) sufficiently identify the research by proper citation to enable consumers to access that research.

Representations that state or imply that scientific or clinical literature is available to support a claim are likely to give consumers the impression that the advertised product has been proven through rigorous clinical or scientific studies. Therefore, advertisers must support these representations through a transparent and accessible citation.

The purpose of this rule relates to the objects of the Code to ensure advertisements about therapeutic goods *'are ethical and do not mislead or deceive the consumer or create unrealistic expectations about the performance of the therapeutic goods.'*

The concept of an implied reference is necessary to ensure that advertisers do not circumvent the requirements of section 11 by using suggestive terms or imagery while avoiding direct mention of research.

Problem

Industry stakeholders have advised that the citation requirements set out in subsection 11(3) of the Code are difficult to understand, particularly when an advertisement implies (rather than explicitly states) that scientific or clinical research underpins a claim. They have noted that existing TGA guidance may have contributed to confusion by not clearly explaining what an 'implied reference' to research is, making it unclear when a citation is required.

Proposed solution

The TGA proposes to update and clarify the existing advertising guidance on the TGA website to better explain how section 11(3) applies, including the circumstances in which a representation may constitute an implied reference to scientific or clinical research.

Due to the complexity and the potential for variation within different contexts, a guidance-based approach with examples and context-specific explanations is preferred.

An example of how this information could be described in guidance is provided in Attachment 1. The examples and considerations are not exhaustive and are intended to help advertisers understand when the citation requirements in subsection 11(3) of the Code are triggered. The onus is on advertisers to ensure that any express or implied reference to scientific or clinical research is accompanied by clear, accessible and accurate citations.

Question 23

Would illustrative examples in guidance showing express vs implied references to research (and the resulting citation obligations) address current pain points?

Question 24

What additional guidance, in relation to Section 11 of the Code, is needed?

Attachment 1: Requirement for citations to scientific and clinical research in advertising

All claims made in advertisements for therapeutic goods must be supported by appropriate evidence. For most products, other than those relying on traditional use, this evidence will include scientific or clinical studies, whether conducted by the sponsor or published in the broader scientific literature.

When an advertisement refers or draws attention to research, in a way that gives the impression that scientific findings support the claim, the relevant study must be cited so consumers can verify the information if they choose.

Whether a scientific or clinical representation requires a citation depends on the overall context of the advertisement, including the wording, imagery and setting, and how a reasonable consumer is likely to interpret the claim.

Express references to scientific or clinical research

An express reference occurs when an advertisement clearly and directly refers to a piece of scientific or clinical research. This includes naming the research, describing it, or presenting data from it. In these situations, the advertiser must provide a citation in accordance with subsection 11(3) of the Code.

A representation is an express reference to scientific or clinical research when it includes any of the following:

- Naming, citing or describing a scientific or clinical study, researcher, research institution or publication, including:
  - The title, author, or publication of a study.
  - The name of the researcher, laboratory, clinic or institution.
- Statements explicitly noting numerical findings, outcomes or results from research, such as:
  - “Clinically proven X% improvement…”
  - “Studies show X% more effective…”
  - “Based on clinical trials there were twice as much…”
- Presenting a graph, table, or visual that is clearly derived from research data.

Examples of express references to scientific or clinical research may include the following statements:

- “A clinical study conducted by the University of Sydney found…”
- “Scientifically tested formula reduces symptoms by X%.”
- ‘Our study on 230 adults in NSW demonstrated that…’
- “Published in the Journal of Dermatological Science…”
- A chart showing pre- and post-treatment results from a study.

Please note that each of these statements may only form part of a representation that is considered an express reference to scientific or clinical research. Depending on the context in which these statements appear, the statements are likely to require more detail about the research to be considered as express references to scientific and clinical research.

Implied references to scientific or clinical research

An implied reference occurs when the overall presentation of a representation suggests or conveys the impression that scientific or clinical research supports a claim – even if no study, researcher or data is explicitly named. In these cases, section 11(3) of the Code still applies and supporting research must be cited.

No single element may imply research on its own, but a combination of representations within the advertisement (including text, visuals and product claims) may give the impression that scientific evidence is being referenced.

For example, a representation may be an implied reference to scientific or clinical research if:

- It is a claim about a novel mechanism of action or results that would not ordinarily be expected by that type of therapeutic good, for example:
  - "Can detect pregnancy within 12 hours after conception"
  - "50% reduction in hospital admissions for asthma"
- The representation uses technical or scientific language, imagery or symbols that imply research involvement or a structured assessment has been conducted on the product or its ingredients:
  - The patented extraction process yields high concentrations of 'ingredient x500'
- The claim describes or compares product performance in a way suggesting measured evidence:
  - "Proven to work 2 times faster than other products that contain X ingredient."
- The advertisement uses visual elements that resemble research findings:
  - graphs, charts and trend lines
  - "before/after" results, including images, that appear to be data driven.

Examples of implied references to scientific or clinical research may include the following statements:

- "Clinically tested ingredients"
- "Clinically trialled formula."
- "Backed by cutting-edge dermatological science."
- "Independent testing confirms superior absorption."
- Including a bar graph demonstrating improvement, without naming the study.

Please note that each of these statements may only form part of a representation that is considered an implied reference to scientific and clinical research. Depending on the context in which these statements appear, the statements are likely to require more detail about the research to be considered as implied references to scientific or clinical research.

Version history

Version	Description of change	Author	Effective date
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