



# 2021 Therapeutic Goods Advertising Code



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# Welcome

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- Slides will be made available on the TGA website
- Questions to the **panel** – please use only the **Q&A** tool
  - Questions will be answered at the end of the presentation
- Relevant links will be sent to you via the chat function box
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# Topics to be covered

- Transition period
  - Repeal of the 2018 Code
- Changes to the Code
- How to comply with the 2021 Code
  - Mandatory statements
  - Health warnings
  - Testimonials and endorsements

# Transition period

- The 2021 Code commenced on 1 January 2022
- A 6-month transition period will apply until 30 June 2022
- All advertisements must comply with the 2021 Code from 1 July 2022
- The 2018 Code will be repealed on 1 July 2022



**Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021**

I, John Skerritt, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 29 November 2021

Adjunct Professor John Skerritt  
Deputy Secretary  
Health Products Regulation Group  
Department of Health

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# Changes to the Advertising Code

## Provisions removed

Approved advertisements

- Removed as pre-approvals of certain ads ceased 1 July 2020

Table of health warnings at  
Schedule 1

- Removed as health warnings are no longer required for all types of ads, only direct sales to consumers where product cannot be inspected before purchase

‘Symptoms’ mandatory statement

- Requirement abolished. Advertisers are still able to use the symptom statements if desired.

Provisions relating to analgesics and vitamins  
(s42(2) and s25)

- These are prohibited representations which are incorporated into the Therapeutic Goods Regulations (Part 1 of Schedule 2, Items 4 and 8).

Prohibited representations

- Removed section on prohibited representations (s30, 2018 Code) and incorporated unchanged in the TG Regulations (Part 1 of Schedule 2, Item 10).

Some definitions

- Some definitions were removed. Dictionary definition applies.

# Changes to the Advertising Code

## Provisions added

### Samples and incentives (Part 7)

- New section created for samples, with a new definition of sample
- Expanded list of permitted samples

### Price information (Part 9)

- Part 9 brings price information into the substantive provisions of the Code

### Requirements for particular therapeutic goods

- New Part 5 for additional requirements when advertising particular therapeutic goods

# Changes to the Advertising Code

## Provisions clarified

### Application of the Code (s5 & s6)

- Code does not apply to advertisements directed exclusively to **any person** listed in s42AA of the Act, not just health professionals.
- The Code, other than Part 9, does not apply to the dissemination of price information.

### Price information (Part 9)

- Clarifies that therapeutic goods that are unregistered but contain a substance in Schedule 3, 4 or 8 of the Poisons Standard, cannot have price information published.

### Traditional use

- Term paradigm removed as it was not defined.
- The Regulations define the term, and labelling requirements provide that the specifier or traditional context qualifier is used.

### Comparisons (Part 3)

- Clarified to include comparisons with therapeutic services as well as goods.

# Changes to the Advertising Code

## Provisions clarified

### Scientific / clinical representations (Part 3)

- Clarified that in addition to labels, consumer medicine information and patient information leaflets, this section does not apply to 'instructions for use'

### Mandatory statements (Part 4)

- Part 4 divided into 3 divisions: preliminary, mandatory statements for particular advertisements and mandatory statements for other advertisements

### Endorsements and Testimonials (Part 6)

- Those who cannot make a testimonial or endorsement:
  - Current or former health professionals, health practitioners and those representing themselves as being such a person
  - Anyone receiving valuable consideration
- Advertisements must disclose when testimonials are provided by the immediate family member of a person engaged in the marketing or supply of the goods



# Changes to the Advertising Code

## Provisions clarified

### Samples (Part 7)

- Provision applies to the sample itself and the offer of a sample in an advertisement
- Goods including a substance in Schedule 2, 3, 4 or 8 of the current Poisons standard cannot be offered as a sample
- For goods on the ARTG, the sample must be a pack accepted in relation to the inclusion (not smaller or bigger)

### Advertising to children (Part 12)

- Goods that include a substance included in Schedule 2, 3, 4 or 8 of the current Poisons Standard cannot be advertised to children

### Public health campaigns (Part 3)

- It is a general requirement for all advertising not to be inconsistent with public health campaigns

# How to comply with the 2021 Code

- Mandatory statements
- Health warnings
- Testimonials and endorsements
- Samples
- Scientific or clinical representations
- Restricted representations



# ORIMA research – mandatory statements



## Findings:

- Requires further education of and behaviour change amongst consumers, especially younger consumers
- Multiple and lengthy mandatory statements did not resonate with consumers – prefer something authoritative and to the point
- Precautionary behaviours were not consistently adopted due to limited awareness and understanding of these goods
- Young consumers were less likely to be confident using these products yet exhibit less caution in using them and purchased them more frequently
- It would be very challenging to provide further education and behaviour change through the mandatory statements alone. Slogan campaign suggested

# Mandatory Statements

Advertisements  
about medicines

ALWAYS READ THE LABEL AND FOLLOW THE  
DIRECTIONS FOR USE

Advertisements  
about medical  
devices

ALWAYS FOLLOW  
THE DIRECTIONS FOR  
USE

*or*

ALWAYS READ THE  
LABEL AND FOLLOW  
THE DIRECTIONS FOR  
USE

Advertisements  
about other  
therapeutic  
goods

ALWAYS READ THE  
LABEL AND FOLLOW  
THE DIRECTIONS FOR  
USE

*or*

ALWAYS FOLLOW  
THE DIRECTIONS FOR  
USE

# Mandatory Statements

Pharmacist-only  
medicines

ASK YOUR PHARMACIST ABOUT  
THIS PRODUCT

Not available for  
purchase by the  
general public

THIS PRODUCT IS NOT  
AVAILABLE FOR PURCHASE BY  
THE GENERAL PUBLIC

Short form  
advertisement

ALWAYS FOLLOW THE  
DIRECTIONS FOR USE

# Health Warnings

- **When using an image also provide warnings in text form**
- **Medicines**
  - Health warnings on labels required by other legislative instruments must also be in the advertisement
  - Prominently displayed or communicated where the consumer can purchase the medicine without physically inspecting it first
- **Medical Devices**
  - Follow Essential Principles specified in Schedule 1 of the Medical Devices Regulations
  - If there is a requirement for information to be on the label or pack, it must be provided with the device
  - Where required by a legislative instrument, the health warning must also be in the advertisement
  - Prominently displayed or communicated when not available for inspection prior to purchase (e.g. online)
  - The consumer must be able to easily access and identify the product's instructions for use from a website advertisement

# Health Warnings

- **Other therapeutic goods**
  - Prominently displayed or communicated where cannot be inspected before purchase
  - Where health warnings are associated they must be present in the advertising
  - Provide a direct access link to the warnings or a document such as instructions for use
- **Health warnings which are restricted representations**
  - Do not need to apply for approval for the restricted representation health warning as it is a requirement of a legislative instrument

# Prominently displayed or communicated

- Health warnings and mandatory statements are to be prominently displayed and communicated
- An image of the product label is unlikely to be to meet this requirement but that depends on how the image is presented
- The health warnings and statements that are on the label can be reproduced in the text of the advertisement
- Requirement is specific to goods where the messages are critical to the consumer when selecting a product for treatment
- The target audience of the advertisement should be considered
  - For example, an advertisement directed to people with eyesight difficulties may require special consideration to ensure the message is received in its entirety



# Testimonials and Endorsements

- Testimonials are not the same as endorsements
- There are some common requirements for both testimonials and endorsements
- Both must not be inconsistent with:
  - the label of the goods,
  - the goods' ARTG entry (and for exempt goods must not be inconsistent with indication on the label)
  - the directions for use of the goods
  - If either a testimonial or an endorsement refers to a health benefit – that health benefit must be typical of the benefits expected from the good when used as directed

# Endorsements

- Endorsements - section 24(6) of the Code
- The endorsement must not reference the individual's personal experience using the good – this would be a testimonial
- Endorsements of therapeutic goods can be very influential on consumers – the Code specifies which organisations and individuals must not endorse therapeutic goods
- Some organisations may endorse good, as long as certain requirements are met.

# Endorsements

## Restrictions

- Endorsements are not permitted to be given by:
  - a government or government authority, hospital or healthcare facility
  - employees of above
  - current or former health practitioners, professionals or medical researchers
  - persons who represent themselves as being qualified or trained to diagnose
- Are permitted to be given by brand ambassadors so long as their personal experience with the product is not included.
- May be permitted by **organisations that represent** healthcare consumers, current or former health practitioners, professionals or researchers. Only if the advertisement discloses the name of the organisation and if they receive/d valuable consideration for the endorsement.

# Endorsement examples

- ✓ Christopher is a celebrity
- ✓ Christopher is approached by a company to endorse their new vitamin product
- ✓ Christopher is photographed with the product and is therefore taken to be endorsing the product,
- ✓ Christopher might say he supports the company behind the product but he can not talk about his experience with using the product
- x Dr George Famous used to be a celebrity and is now a medical doctor working in a hospital
- x Dr Famous is asked by the company who makes a ventilation device he uses in the ICU if he will endorse the product
- x Dr Famous is videoed using the equipment in the course of his work and he provides his endorsement in the ad
- x This is prohibited because he is a health practitioner and a government and healthcare employee

# Endorsement examples

- ✓ Famous Pty Ltd is a manufacturer of pharmaceutical products. LillyPilly is a floristry organisation.
- ✓ LillyPilly endorse the vitamins manufactured by Famous Pty Ltd and are paid for the endorsement.
- ✓ This is permitted as LillyPilly does not represent healthcare consumers or government.
- ✗ The National Neuropathic Pain (NNP) foundation endorses a new vitamin.
- ✗ The endorsement appears in an advertisement for the therapeutic good.
- ✗ The NNP foundation was paid by the sponsor of the vitamin. The advertisement does not disclose that the foundation receives financial support from the producer of the therapeutic good.
- ✗ This is prohibited because NNP represents the interests of healthcare consumers and the valuable consideration they receive is not disclosed in the advertisement.
- ✓ If the advertisement discloses that NNP has received valuable consideration from the company with words to the effect "[Company] provides financial support to NNP", this is permitted.

# Testimonials

- An advertisement about therapeutic goods must not contain a testimonial unless:
  - the advertiser has verified the content of , and the identity of the person making the testimonial
- Restrictions apply to ensure the testimonial is genuine and not motivated by monetary or valuable benefit or incentive
- Paid testimonials are not permitted

# Testimonials

## Restrictions

- Testimonial from people who have received something of value (valuable consideration – could be money or free product or the promise of discounts) must not be used in advertisements.
- Testimonials cannot be made by:
  - A person who is engaged in the production, marketing or supply of therapeutic goods including anyone who is paid (or who are provided other valuable consideration)
  - An immediate family member of such a person unless the advertisement discloses that the person who made the testimonial is an immediate family member of the relevant person
  - A person or organisation involved in government, health care or representing interests of healthcare consumers
  - Health professionals or those who are represented as having health expertise

# Testimonial examples

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- ✓ Sally is a beauty writer who purchases four different SPF30+ sunscreen products and writes an article about her experience using each product
- ✓ Sally was not prompted to do this and does not receive valuable consideration for these testimonials from the company or the sponsor of the products
- ✓ Sally writes a testimonial for each of the products and publishes it on her blog. She states that she has not been paid for the testimonials. These testimonials are used by the companies in their advertising
- ✓ *Sally must ensure that if her content is an advertisement that the requirements of the Code are applied*
- x LaSuns Pty Ltd asks Sally to provide a testimonial detailing her experience with using their SPF30+ sunscreen product
- x Le Suns Pty Ltd publish Sally's testimonial on their website advertisement or their SPF30+ sunscreen product
- x In exchange for the article, Sally and her editor receive a year's supply of product
- x LeSuns Pty Lty would not be compliant with the Code as they are using a testimonial from a person involved in the marketing of the advertised goods



# Other Code changes

- **Traditional use qualifiers**
- **Scientific or clinical representations**
- **Advertising to children**
  - Additional items have been added to the list of products that can be advertised to children:
    - Face masks and gloves
    - Hand sanitisers
    - Oral hygiene products
    - Menstrual cups
    - Wound care dressings for first aid
- **Samples**
  - Additional samples that can be offered are:
    - Personal lubricants
    - COVID-19 RATs for self-testing
    - Disinfectants, hand sanitisers
    - Face masks and gloves
    - Lancets and blood glucose strips
    - Nicotine replacement therapies
    - Oral hygiene products and rehydration products
    - Wound care dressings for first aid
  - The guiding principles state that any samples included in the Code must have clear health or social welfare benefits, cannot be brand-specific, must be entered on the ARTG (as required) and must not require health professional advice for safe and appropriate use
  - Applications can be made to the TGA for samples to be added to the Code, addressing the guiding principles

# Code Guidance

- 2021 Code guidance material published to the TGA website in December 2021
- The 2018 guidance will remain on the TGA website until 30 June 2022, after which time the 2018 Code will be repealed and the accompanying guidance will no longer apply
- Further guidance is being finalised and will be published over the transition period
- The ARGATG will undergo a full update in mid-2022
- Feedback accepted via advertising enquiries online form or email

## Guidance on applying the Advertising Code rules

24 December 2021

**24 December 2021:** The 2021 Advertising Code takes effect on 1 January 2022 and will be subject to a 6-month transition period until 30 June 2022 where both the 2018 and 2021 Advertising Codes will apply. The Advertising Code guidance has been updated to reflect changes to the Code. Further changes will be made to advertising education and guidance material over the coming months.

**On this page:** [Mandatory statements](#) | [Health warnings](#) | [Prominently displayed or communicated](#) | [Testimonials and endorsements](#) | [Included in the ARTG, not TGA approved](#) | [Consistent with the ARTG entry](#) | [Accurate, truthful, not misleading](#) | [Substantiation of claims](#) | [Safe and proper use](#) | [Product and service comparisons](#) | [Scientific or clinical representations](#) | [Advertising lawfully to children](#) | [Samples](#) | [Public health campaigns](#) | [Price information](#)

### Mandatory statements

Part 4 of the [Therapeutic Goods \(Therapeutic Goods Advertising Code\) Instrument 2021](#) (the Code) sets out statements that must accompany the advertising of specific therapeutic goods. Mandatory statements have been simplified in the 2021 Code following consumer testing.

Therapeutic goods are available through a range of avenues other than at a pharmacy including:

- Internet
- Social media
- Radio
- Direct marketing such as mail-order
- Supermarkets.

Regardless of the platform where the advertising of medicines, devices and other therapeutic goods is conducted, they must include mandatory statements because they provide information about the product, warnings about the product's use and guidance for consumers to seek assistance if required.

Part 4 of the Code requires certain information to be 'prominently displayed or communicated' in advertisements as defined in Section 4 of The Code. Examples of how to present information in this manner are provided in the related section of this guidance.

For written advertisements, statements must be prominently displayed on the same page that the advertisement for the therapeutic good is displayed.

If the written advertisement is on social media, the statement must be available at all times and not collapsed into a view that is only visible if the consumer selects 'see more' or similar.

For audio advertisements, this statement must be prominently communicated to be as part of the advertisement for the therapeutic good.

This principle can be applied to other variations of possible advertisements.

### Pharmacist-only medicines

# Links and further information

Guidance on applying the advertising Code	<a href="https://www.tga.gov.au/guidance-applying-advertising-code-rules">https://www.tga.gov.au/guidance-applying-advertising-code-rules</a>
Therapeutic Goods Advertising Code: Comparing 2018 and 2021 code	<a href="https://www.tga.gov.au/therapeutic-goods-advertising-code-comparing-2018-and-2021-codes">https://www.tga.gov.au/therapeutic-goods-advertising-code-comparing-2018-and-2021-codes</a>
The Therapeutic Goods Advertising Code	<a href="https://www.tga.gov.au/therapeutic-goods-advertising-code">https://www.tga.gov.au/therapeutic-goods-advertising-code</a>
Restricted and prohibited representations	<a href="https://www.tga.gov.au/restricted-and-prohibited-representations">https://www.tga.gov.au/restricted-and-prohibited-representations</a>
Make a <b>report</b> about non-compliant advertising	<a href="https://compliance.health.gov.au/ac-report/">https://compliance.health.gov.au/ac-report/</a>
Make an <b>enquiry</b> about advertising:	<a href="https://compliance.health.gov.au/ac-enquiry">https://compliance.health.gov.au/ac-enquiry</a>
Apply to use a restricted representation in advertising:	<a href="https://compliance.health.gov.au/ac-rr/">https://compliance.health.gov.au/ac-rr/</a>
Outcomes from past investigations:	<a href="https://compliance.health.gov.au/ac-cii">https://compliance.health.gov.au/ac-cii</a>

Rowena and Kate are currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

**LIVE POLL**

# More information – Social media

	Website	<a href="https://www.tga.gov.au">https://www.tga.gov.au</a>
	Facebook	<a href="https://www.facebook.com/TGAgovau/">https://www.facebook.com/TGAgovau/</a>
	Twitter	<a href="https://twitter.com/TGAgovau">https://twitter.com/TGAgovau</a>
	YouTube	<a href="https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw">https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw</a>
	Topic blogs	<a href="https://www.tga.gov.au/blogs/tga-topics">https://www.tga.gov.au/blogs/tga-topics</a>
	LinkedIn	<a href="https://www.linkedin.com/company/therapeutic-goods-administration/">https://www.linkedin.com/company/therapeutic-goods-administration/</a>
	Instagram	<a href="https://www.instagram.com/tgagovau/?hl=en">https://www.instagram.com/tgagovau/?hl=en</a>

# Questions?



# Contact us

Advertising Compliance  
Education & Policy  
Section

Enquiries Portal Form at:

<https://compliance.health.gov.au/ac-enquiry/>



**Australian Government**

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**Department of Health**  
Therapeutic Goods Administration