



Australian Government

Department of Health

Therapeutic Goods Administration

# Guidance on applying the 2021 Advertising Code rules

Part 4 - Mandatory statements and other required information

Part 5 - Additional requirements for advertisements about particular therapeutic goods

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**TGA** Health Safety  
Regulation

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# Contents

<b>Explanatory information in relation to mandatory requirements</b>	<b>4</b>
Prominently displayed or communicated	4
Target audience consideration	4
<b>Part 4 - Mandatory statements and other information required in advertising</b>	<b>6</b>
Application of Part 4 of the Code	6
What are mandatory statements?	7
Mandatory statements for particular advertisements	8
Therapeutic goods only available from a pharmacist	8
Therapeutic goods not available for purchase by the general public	9
Short form advertisements	10
Mandatory statements and requirements for other advertisements	12
Medicines	12
Medical devices	13
Other therapeutic goods	14
Additional requirements for therapeutic goods not available for inspection before purchase	16
Health warnings	18
When health warnings apply	18
When using an image also provide warnings in text form	21
Health warnings which are legally required and contain restricted representations	21
<b>Part 5 – Additional requirements for advertisements about particular therapeutic goods</b>	<b>22</b>
Analgesics	22
Complementary medicines	22
Vitamins and minerals	23
Sunscreens	25
Weight management	25

# Explanatory information in relation to mandatory requirements

## Prominently displayed or communicated

Provisions in Part 4 and Part 5 of the [Code](#) require that certain information is prominently displayed or communicated in advertisements. This is because that information is critical to the consumer when self-selecting a product.

This requirement **must** be met where the Code specifies it, including for:

- mandatory statements
- health warnings or links to health warnings
- other statements required by a legislative instrument.

The phrase prominently displayed or communicated is defined in section 4, definitions, of the [Code](#):

***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.

The font style and size when included in a visual advertisement is not specified.

Font embellishments including serifs, italics, cursive, shadows, calligraphy, poster and other fancy or irregular fonts may affect the extent to which statements can be easily read or understood in the context of the advertisement.

- ✗ Use of dark patterns or other techniques that obscure, minimise or divert attention from the information that is required to be prominently displayed may be taken as evidence of failure to prominently display or communicate the required information.



Statements that **stand out** from the surrounding content are more likely to meet the benchmark for prominently displayed or communicated.

## Target audience consideration

It goes without saying that advertisers will consider the target audience of the advertisement when preparing it.

To meet the requirement to be prominently displayed or communicated, an advertisement directed to people with eyesight or hearing difficulties may require special consideration to ensure the message is received in its entirety.

- ✓ For written advertisements, mandatory statements and required information must be on the same page that the advertisement for the therapeutic good is displayed
  - appropriate attention must be given to font style, size, contrast and placement in relation to the rest of the advertisement.
- ✓ If the written advertisement is on social media, the mandatory statements and required information 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, the mandatory statement and required information must be prominently communicated to be as part of the advertisement for the therapeutic good
  - competing background audio may detract from the prominence of spoken statements.

## Part 4 - Mandatory statements and other information required in advertising

Therapeutic goods may be advertised through many different channels, such as:

- radio or TV
- internet, including websites, marketplace and other apps
- social media
- supermarkets
- pharmacies
- catalogues and magazines
- billboards or sandwich boards
- direct marketing such as mail-order.

Regardless of the platform where the advertising occurs, it must include mandatory statements and other information specified in the Code so that the ad provides consumers with important:

- information about the product
- warnings about the product's use
- advice to seek assistance, when required.

### Application of Part 4 of the Code

While Part 4 of the [Code](#) applies broadly to advertising for therapeutic goods, it does not cover:

- labels of therapeutic goods
- consumer medicine information
- instructions for use
- patient information leaflets
- advertisements that do not refer, expressly or by implication, to a claim relating to therapeutic use, and that only consist of one or more of the:
  - name of the good
  - picture of the good
  - price of the good
  - point of sale
- advertisers should note that these advertisements must only contain one or more of the above to be excluded from the operation of Part 4 of the Code. For example, they must not also include a buy-now button.

## What are mandatory statements?

Part 4, Division 2 of the [Code](#) sets out mandatory statements that must be included in the advertising of therapeutic goods, determined by the category of the good, and in some circumstances the type of advertising.

As therapeutic goods are not considered to be ordinary consumer goods, mandatory statements and information, including warnings, are important to ensure that consumers purchase and use these goods appropriately and safely.

They provide information about:

- the therapeutic good and its suitability
- the warnings, contra-indications, precautions or restrictions in relation to use of the product.

The table below provides a **condensed version** of the mandatory statements by category of product.

For the expanded versions click on the provided link.

Category	Mandatory statement
<a href="#">Therapeutic goods only available from a pharmacist</a> (medicines and devices in Schedule 3 and Appendix H of the Poisons Standard)	<b>ASK YOUR PHARMACIST ABOUT THIS PRODUCT</b>
<a href="#">Therapeutic goods not available for direct purchase by the general public</a>	<b>THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC</b>
<a href="#">Short form advertisements</a>	<b>ALWAYS FOLLOW THE DIRECTIONS FOR USE</b>
<a href="#">Medicines</a>	<b>ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE</b>
<a href="#">Medical devices</a>	<b>ALWAYS FOLLOW THE DIRECTIONS FOR USE</b> or <b>ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE</b>
<a href="#">Other therapeutic goods</a>	<b>ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE</b> or <b>ALWAYS FOLLOW THE DIRECTIONS FOR USE</b>

## Mandatory statements for particular advertisements

### Therapeutic goods only available from a pharmacist

Read this section together with Section 15 of the [Code](#).

Pharmacist-only medicines or devices that contain ingredients listed in both Schedule 3 and Appendix H of the [Poisons Standard](#) may be advertised to consumers.

All advertisements in this category must contain the following statement prominently displayed or communicated to ensure that a pharmacist authorises the sale of the good to the consumer:

#### **ASK YOUR PHARMACIST ABOUT THIS PRODUCT**

The pharmacist will consider the needs of the consumer and determine if the product is right for them.

The mandatory statement for other medicines or devices, for example **ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE** required for [other medicines](#), is not required for pharmacist-only products as the pharmacist will ensure the consumer is aware of this requirement.



Pharmacist-only medicines or devices that have ingredients that are **not** included in Appendix H of the [Poisons Standard](#) **cannot** be advertised to consumers.

#### **Example**

Jill needs to purchase a medicine that contains an ingredient included in Schedule 3 and Appendix H of the [Poisons Standard](#). Jill can only purchase this medicine at a pharmacy after consulting with a pharmacist.

- ✓ When advertising for such medicines, the advertiser must include the statement:

#### **ASK YOUR PHARMACIST ABOUT THIS PRODUCT**

- ✓ Jill can see and understand that the product can only be purchased from a pharmacy and then only purchase it after asking the pharmacist about the product.
- ✓ Jill has a conversation with the pharmacist to determine if the product is right for her and, if appropriate, purchase it from the pharmacy.



## Therapeutic goods not available for purchase by the general public

Read this section together with Section 16 of the [Code](#). This section does not apply to therapeutic goods that are included in Schedule 3 of the [Poisons Standard](#).

There are certain therapeutic goods that cannot be purchased directly by consumers. For example, goods that can only be purchased through health professionals or that are not intended to be used by consumers.

Advertisements for products that are only available for supply through [a health professional](#) or that are not available for supply to consumers must contain the following statement, prominently displayed or communicated:

### **THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC**

- ✓ For written advertisements, this statement must be prominently displayed on the same page that the advertisement for the therapeutic good is displayed
  - this means that if the therapeutic good is displayed on a landing webpage as well as its own product webpage, the mandatory statement must be included on both pages and any other pages that the product is displayed on.
- ✓ For audio advertisements, this statement must be clearly communicated as a part of the advertisement for the therapeutic good.

#### **Example**

While scrolling social media, Jack sees an advertisement for a dental implant. It includes a link to the supplier's website.

The social media advertisement does not include a purchase price or a link for purchase.

The dental implant is only available for purchase in Australia by a dentist.

- ✓ As Jack can view this advertisement, the advertiser prominently displays the statement:

### **THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC**

- ✓ Jack can see and understand that the product is not available for him to purchase. Jack may obtain the product by discussing it with his dentist.
- ✓ The other requirements of the Code must also be met.

If the advertisement is only accessible by health professionals, then the mandatory statement is not required.

#### **Example**

Jacob is interested in HIV tests and searches online. He sees an advertisement for a laboratory test which can only be purchased by a suitably accredited pathology provider.

The advertisement includes a statement

### **THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC**

- ✓ Jacob understands that he cannot purchase these tests.

## Short form advertisements

Read this section together with Section 17 of the [Code](#).

Short form advertisements are where limited time or space restricts the messages that can be included in the advertisement. These kinds of advertisements are rare. They include:

- Radio advertisements that are 15 seconds or less in duration
- Text only advertisements
  - that consist of 300 characters or less that are published in hard copy print media, and
  - there is no reasonable capacity to include a picture, logo or other imagery as part of the advertisement.

Where advertisements have scope to contain pictures, videos or any other types of representations they do not qualify as short form advertisements, even where the text of the advertisement is 300 characters or less.

Advertisements in [social media are not considered short form](#) advertisements as there is an ability to include pictures.

Short form advertisements must contain the following statement, prominently displayed or communicated:

### **ALWAYS FOLLOW THE DIRECTIONS FOR USE**

The mandatory statement is included when calculating the number of characters to meet the definition of a short form advertisement.

Any additional requirements in [Part 5 of the Code](#), for example for analgesics, traditional use of complementary medicines, sunscreens and weight management must still be met in all advertising including short form advertisements.

Any reference to a website advertisement in a short form advertisement must lead to content that meets all requirements of the Code.

#### **Example**

A radio script for the advertising of Beans Beat-Your-Headache tablets:

*Don't let headaches ruin your day. Beans Beat-Your-Headache tablets can temporarily relieve pain associated with headache. Buy some today for your cupboard. Incorrect use can be harmful. Always follow the directions for use.*

- ✓ contains the mandatory statement for short form advertising
- ✓ contains the statement required for analgesics
- ✓ 15 seconds or less radio advertisement meets the criteria for using the short form mandatory statement.

**Example**

This is the radio script for the advertising of Beans BooBoo plastic strips:

*Keep a few Beans BooBoo plastic strips in every bag you carry – just in case. They are used to cover abrasions, big and small, not just for kids. They come in several fun funky colours. Purchase them at all leading pharmacies and supermarkets.*

- ✗ does not contain the mandatory statement
- ✓ 15 seconds or less radio advertisement meets the criteria for use of the short form mandatory statement.

**Example**

A classified advertisement published in a print newspaper advertises Beans Happy-Prostate:

*Do you find it hard to wee? Do you need some prostate support? Do you have medically diagnosed benign prostatic hypertrophy? Beans Happy-Prostate contains stinging nettle which is traditionally used in Western Herbal Medicine to support prostate health. (254 characters)*

- ✓ contains [traditional use qualifier](#)
- ✗ does not contain the mandatory statement
- ✗ contains an unapproved use of a restricted representation
- ✓ 300 characters or less meets the criteria for use of the short form mandatory statement. Note that when adding the mandatory statement, the ad must remain within the total number of characters for a short form advertisement.

**Example**

This is the advertising material for Beans Arnica Soothe Cream that is intended to be published on a billboard:



Image:

Text overlaying the image on the billboard:

**Beans Soothe Cream**

*It makes your skin happy, healthy and hydrated.*

*Use it every day on eczema to leave your skin feeling supple and smooth.*

- ✗ does not contain mandatory statements
- ✗ does not contain traditional use qualifier such as 'arnica is traditionally used in homoeopathic medicine'
- ✗ does not contain health warnings
- ✗ does not meet short-form advertisement criteria because an image can be used.

## Are social media advertisements considered short form?

Advertisements in social media are not considered short form advertisements. There is capacity in social media advertising to include pictures and the mandatory statements.

Social media advertisements:

- have capacity to include the applicable mandatory statements
- can include links to the required health warnings.

## Mandatory statements and requirements for other advertisements

### Medicines

Read this section together with Section 19 of the [Code](#).

An advertisement about a medicine must contain the following statement, prominently displayed or communicated:

**ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE**



This mandatory statement is not required on [pharmacist-only medicines](#) or devices that contain ingredients that are captured in Schedule 3 [and](#) Appendix H of the current [Poison Standard](#). Please see the [mandatory statement for pharmacist-only products](#).

These advertisements must meet the requirements set out in section 19(2) of the [Code](#). All advertisements must have the name and certain information about the therapeutic good including the correct:

- name of the medicine
- at least one accepted indication
- the mandatory statement.

If your advertisement is for a therapeutic good that can be purchased without seeing the product first, there are additional requirements. See [Therapeutic goods not available for inspection before purchase](#) for details.

**Example**

Beans Pty Ltd (Beans) is the sponsor of a folic acid supplement Befol which is a listed medicine on the ARTG and does not contain any scheduled substances included in the [Poisons Standard](#).

Beans advertises Befol in a television commercial which also includes the website address where consumers can purchase the good.

Both the TV commercial and the website are required to be compliant advertisements.

Befol is indicated for reducing the risk of having a child with spina bifida/neural tube defects.

- ✓ Along with other required information for a medicines advertisement, Beans prominently displays and communicates in the commercial:

**ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE**

- ✓ The website, which includes a point of sale, contains further information required for advertisements that facilitate purchase, and where the goods can't be inspected before purchase, such as:
  - dosage form (as defined by the standard TGO 92)
  - quantity (as defined by the standard TGO 92)
  - active ingredients
    - strength: 400 micrograms folic acid
  - statements as required by a legislative instrument (in this case [the 42DK permission](#) and the [permissible indications determination](#)) which include:
    - To reduce the risk of having a child with spina bifida or neural tube defects you should start taking this medicine at least four weeks before conception and during the first trimester of pregnancy.
    - Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- ✓ while representations that refer to spina bifida and neural tube defects are restricted representations, their use are permitted by [the 42DK permission](#). Separate approval to use them in advertising is not required.
  - see [Health warnings which are restricted representations](#) for more information.

**Medical devices**

Read this section together with Section 20 of the [Code](#).

An advertisement about medical devices must contain one of the following statements prominently displayed or communicated:

**ALWAYS FOLLOW THE DIRECTIONS FOR USE**

*or*

**ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE**

The shorter form must only be used for suitable medical devices, for example those that do not have a label for consumers to read and where adding '**ALWAYS READ THE LABEL**' would be inappropriate.

The Code has been written to facilitate the advertising of medicines and medical devices together, such as on the same page of a catalogue, by aligning the mandatory statement requirements. The longer mandatory statement should be used where both medicines and devices are advertised together:

### **ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE**

This statement will apply to both the advertised medicine and medical device. Please note that this statement cannot be used for [pharmacist only medicines](#).

Along with a mandatory statement above, the advertisements for medical devices must also contain:

- ✓ the trade name of the device
- ✓ an accurate description of the device
- ✓ one or more accepted intended purposes for the device.

If your advertisement is for a therapeutic good that can be purchased via the advertisement without seeing the product first, i.e. the advertisement is a point of sale, there are additional requirements. See [Therapeutic goods not available for inspection before purchase](#) for details.

#### **Example**

A company advertises a blood pressure monitor to consumers during a television program.

Amy sees this advertisement and thinks it might be useful for monitoring her high blood pressure between GP visits.

- ✓ During the advertisement Amy can see and hear ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE, along with the other required information for a medical device.
- ✓ Amy goes to the pharmacy to buy the blood pressure monitor. She reads the product information on the label and the directions for use. She is able to assess whether the product is suitable for her before purchasing.
- ✓ The advertisement is consistent with the [Non invasive blood pressure monitors](#) permission.

## **Other therapeutic goods**

Read this section together with Section 21 of the [Code](#).

An [other therapeutic good](#) is a type of therapeutic good that is not regulated as a medicine, biological or medical device such as a:

- sterilant
- disinfectant
- tampon
- menstrual cup.

- ✗ Sanitary pads and period underwear are not regulated as therapeutic goods.
- ✗ Disinfectant products do not include hand sanitisers.
  - Many hand sanitisers are consumer goods which are not subject to therapeutic goods regulation however some are regulated by the TGA as medicines.
    - The relevant mandatory statement for medicines must be used when advertising those hand sanitisers that are regulated as medicines.

An advertisement about other therapeutic goods must contain the following statement prominently displayed or communicated:

**ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE**

Where there is no label on or attached to the therapeutic good, the following statement must be prominently displayed or communicated:

**ALWAYS FOLLOW THE DIRECTIONS FOR USE**

Along with a mandatory statement above, the advertisements for other therapeutic goods must also contain:

- ✓ the trade name of the device
- ✓ an accurate description of the device
- ✓ one or more accepted indications for the good.

If the advertisement is for a therapeutic good that can be directly purchased without seeing the product first, i.e. the advertisement is a point of sale, there are additional requirements. See [Therapeutic goods not available for inspection before purchase](#) for details.

**Example**

Helena sees a twitter post for Beans tampons. The post includes the statement:

**ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE**

The twitter post ad also includes other required information for the Beans tampons':

- trade name
- an accurate description
- an indication.
- ✓ The advertisement is considered compliant with the mandatory statements part of the Code.

## Additional requirements for therapeutic goods not available for inspection before purchase

Advertisements that facilitate purchase of the goods and where those goods cannot be physically inspected before they are purchased, for example online sales, have additional requirements.

Advertisements that include a point of sale and where the goods are not available for inspection before purchase must also include:

- ✓ the required health warnings or a link to the health warnings, prominently displayed or communicated
- ✓ extra information about the good including:
  - dosage form for medicines (as defined by the standard TGO 92)
  - quantity of the medicine (as defined by the standard TGO 92)
  - each active ingredient
- ✓ for a medical device that contains an ingredient listed in a Schedule to the Poison Standard, the advertisement must list those ingredients
- ✓ any warnings or statements that are required by law to be on the label
  - these [must be reproduced in the text](#) of the advertisement
    - this may include using the statements in closed captions, alt-text, and or spoken.
- ✗ An image of the product label is not sufficient to meet the requirement of being prominently displayed or communicated. Issues with images may include resolution of text, failure to load, the presentation and use of different fonts on labels.
  - Images may still be included in the advertisement however they should not be relied upon to communicate the mandatory statements and warnings.

### Example

Simona is a registered pharmacist at Beans Pharmacy Pty Ltd. Simona creates a new website to advertise and sell therapeutic goods from their pharmacy.

Each of the advertisements includes an image of the therapeutic good but also contains the:

- ✓ name of the therapeutic good
- ✓ size of the container/package
- ✓ accepted indications
- ✓ ingredients
- ✓ mandatory statements
- ✓ health warnings
- ✓ related goods with a link to them.

The website is compliant because the health warnings and mandatory statements have been reproduced on the website in a way that stands out and can be easily read, and the advertisement includes the other required information about the therapeutic good.



Simona then opens a business Facebook page to reach more customers.

She posts an advertisement and provides a phone number to call to purchase the goods. The advertisement contains the image of the therapeutic good and the following:

- ✓ name of the therapeutic good
- ✓ size of the container/package
- ✓ link to the pharmacy website product page
- ✓ accepted indications
- ✓ mandatory statements
- ✓ health warnings
- ✓ the hash tags are collapsed below a 'see more' expandable.

This post is considered compliant with the [Code](#).

Because a purchase can be made from the advertisement it was necessary to include the additional information required in advertisements that facilitate sale and where the product, and its label or packaging, cannot be inspected before purchase.

### Example

Paul receives a mail order catalogue for therapeutic goods. Paul calls the supplier selling the goods. The call centre operator tells Paul that in the catalogue they have an energy boosting vitamin product which includes 50 capsules for \$30.

Paul asks if the product is right for him and the call centre operator tells him it will help cure his fatigue. The operator does not tell Paul the mandatory statements, health warnings, or the indications for the medicine.

Paul completes his purchase over the phone (although there is also a mail option) and is excited to try his new vitamin product to boost his energy levels.

When the product arrives, Paul reads the health warnings on the label and notices that it is an iron supplement which is not suitable for use with his haemochromatosis condition (high iron level). Paul reviews the product in the catalogue and it also did not contain this information.

- ✗ The catalogue must contain the health warnings and other information required for goods that cannot be inspected before purchase.
- ✗ The call centre operator should have discussed with Paul the required information such as the health warnings before he completed the purchase.

A [complaint](#) was referred to the TGA for investigation.

## Health warnings

Some medicines, medical devices and other therapeutic goods have associated health warnings.

The health warnings may refer to contraindications, precautions or restrictions on using a therapeutic good based on the type of good it is or the ingredients it contains.

This is essential information for consumers to decide if a product is appropriate and to make an informed decision about:

- whether the product is suitable for them and their individual circumstances
- whether to purchase the product.

The health warnings may be required on the label or instructions for use.

Where a therapeutic good has an associated health warning, Part 4, Division 3 of the [Code](#) requires advertisements for that good to include the warning.

As long as an advertisement contains the required health warnings for the good the advertiser is also able to elaborate or provide further warnings.

The Code sets a minimum requirement, as set out below.

## When health warnings apply

### Medicines

Many medicines have vital health warnings on the label because they are required by legislative instruments such as:

- [Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines](#)
- [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)
- [Therapeutic Goods \(Permissible Ingredients\) Determination \(No. 3\) 2021](#)

If one or more health warnings apply, they must be prominently displayed or communicated in an advertisement where the consumer can purchase the product without physically inspecting it first. They can do this by prominently displaying or communicating:

- a list of the health warnings, or
- a prominent link to the health warnings
  - the link provided to the consumer must give **direct** access to the warnings or a document which contain those warnings, such as the instructions for use. A link to a website where the consumer needs to locate the warnings themselves is not sufficient.

See [Therapeutic goods not available for inspection before purchase](#) for more details.

Where a health warning is required by a legislative instrument to be on the label, and that health warning is necessary for the consumer to make an informed choice about purchasing the good, then that warning is required to be replicated in text within the advertisement for the therapeutic good.

**Example**

Beans Pharmacy Pty Ltd (Beans) advertises Beaniprofen on their pharmacy website. Beaniprofen contains a non-steroidal-anti-inflammatory drug (NSAID) ibuprofen. Consumers can directly purchase Beaniprofen via an 'add to cart' function and have it delivered to them.

Beans understand when purchasing online consumers cannot inspect the pack so the advertisement must contain the health warnings, along with the other required information, in text form.

- ✓ Beans prominently displays the health warnings on the Beaniprofen label and on the pharmacy website:

**DO NOT USE IF YOU HAVE HEART FAILURE**

**DO NOT USE IF YOU HAVE A STOMACH ULCER**

- ✓ The restricted representations HEART FAILURE and STOMACH ULCER are a part of a required statement by a legislative instrument.
  - Beans do not need separate TGA approval to use the restricted representation in advertising.
  - see [Health warnings which are restricted representations](#) for more information.
- ✗ The ibuprofen ingredient lists several more health warnings than are listed. Advertisements that facilitate the direct purchase of the product must contain ALL of the required health warnings.

**Example**

Jill's 6-year-old daughter has been diagnosed with Irritable Bowel Syndrome. Jill has read that the condition may be improved by using a probiotic.

An advertisement for Beans Probiotic says it can assist with medically diagnosed Irritable Bowel Syndrome and that she can buy it online. The probiotic contains *Bacillus coagulans* as an ingredient.

- ✓ The health warning NOT SUITABLE FOR CHILDREN appears on the label and is prominently displayed in the advertisement.

Jill has been made aware that the product is not suitable for children so she chooses not to purchase the product.

- ✓ The advertising does not encourage the inappropriate use of therapeutic goods.
- ✓ The advertising supports the consumer in making an informed decision about their therapeutic good needs.

**Medical devices**

Sponsors of medical devices that are regulated by the TGA are required to hold evidence to demonstrate that their device meets certain safety, quality and performance requirements. These are known as Essential Principles and are specified in Schedule 1 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).

Essential Principle 13 relates to information that must be supplied with the medical device on the label or in the instructions for use. Where it specifies certain information is to be communicated to the user, the advertiser must ensure it is included on:

- the label
- the packaging
- instructions for use or patient leaflets.
- ✓ Where the information is a health warning it must appear in the advertisement.
- ✓ Third party advertisers can contact the sponsor of the product to obtain the required health warnings to include in advertisements they intend to publish.

If the advertisement is for a therapeutic good that can be directly purchased without seeing the product first, there are additional requirements. See [Therapeutic goods not available for inspection before purchase](#) for details.

### Example

Jack suffers from joint pain, heart failure and has a pacemaker.

A door-to-door salesman arrives selling a medical device, Beanz Electro Therapist. The salesman tells Jack that it will help relieve the pain in his ankle.

Jack purchases Beanz Electro Therapist and it is delivered the next day. Jack sees that the instructions for use includes a warning on the packaging **DO NOT USE IF YOU HAVE A PACEMAKER.**

- ✗ This warning is a health warning that along with the mandatory statement must have been clearly communicated to Jack before the salesman completed the order for purchase.

## Other therapeutic goods

Therapeutic goods which are not classified as medicines, medical devices or biologicals are called other therapeutic goods. Where a health warning applies to another therapeutic good, it is required to be present in advertising that facilitates the purchase of the good i.e. point of sale advertising.

Ensure that the advertising includes:

- ✓ the [general requirements for advertising other therapeutic goods](#)
- ✓ if the advertisement is for a therapeutic good that can be directly purchased without seeing the product first, further requirements apply. See [Therapeutic goods not available for inspection before purchase](#) for details.

**Example**

A pharmacy advertises a range of therapeutic goods on its website. The website has a 'buy now' functionality.

The advertisement includes the promotion of a new disinfectant which includes Chlorhexidine as an active ingredient. Consumers can have the disinfectant sent directly to them.

- ✓ The website advertisement includes the heading 'Warnings' under which it says:

**NOT TO BE USED ON SKIN**

- ✓ This is required to appear on the label as set out in the [Therapeutic Goods \(Standard for Disinfectants and Sanitary Products\) \(TGO 104\) Order 2019](#) and therefore is required at point of sale advertising where the good cannot be inspected before purchase.

The pharmacy is compliant with the [Code](#) in this regard.

## When using an image also provide warnings in text form

Using an image of the product label in online advertising can assist consumers to assess and choose a therapeutic good when they cannot physically inspect it.

While the label may contain the required health warnings, the Code requires them to be reproduced in text form in the advertisement where there is a click-to-buy option or equivalent functionality.

Using an image of the product by itself may not be sufficient to meet the requirement of being [prominently displayed or communicated](#). Issues with images may include resolution of text, failure to load, the presentation and use of different fonts on labels.

- Any warnings that are required by law to be on the label must be reproduced in the text of the advertisement.
  - They may be included by using the statements in closed captions, alt-text, and or spoken in a script.

This ensures that consumers can always access essential product information even if they cannot load an image or are using screen readers due to visual impairment.

In instances where advertising leads to a purchase made by telephone, advertisers must be able to demonstrate to the TGA how they have provided consumers with the health warnings before any purchase is made. This may include through the advertising itself, sales procedures, sales scripts or directly on order forms if appropriate.

## Health warnings which are legally required and contain restricted representations

There are certain required health warnings that contain [restricted representations](#). It is therefore reasonable to ask whether you need to apply to the TGA to use a restricted representation where it is required by law to be in the advertisement.

Approval to use a restricted representation is **not needed** where a health warning is required by a legislative instrument to be:

- on the label of the good, or
- in an advertisement that facilitates the purchase of the good.

If you are unsure what a restricted representation is, please review the webpage on this topic at [restricted representations](#).

## Part 5 – Additional requirements for advertisements about particular therapeutic goods

Part 5 of the [Code](#) sets out the requirements for advertisements about analgesics, complementary medicines, sunscreens, and weight management therapeutic goods.

These are additional requirements to those presented in [Part 4 – mandatory statements](#).

### Analgesics

Read this section together with Section 23(1) of the [Code](#).

An advertisement about an analgesic must contain the following warning statement prominently displayed or communicated:

#### INCORRECT USE COULD BE HARMFUL

There are representations about analgesics which are prohibited in all circumstances, including that taking analgesics:

- ✗ is safe
- ✗ will relax
- ✗ relieve tension
- ✗ sedate
- ✗ stimulate.

For full details about these restrictions see Part 1 of Schedule 2 of the Therapeutic Goods [Regulations](#).

### Complementary medicines

Advertisements about complementary medicines that contain one or more claims based on evidence of traditional use, must include a statement about the reliance on the traditional use; prominently displayed or communicated.

Refer to the TGA [evidence guidelines](#) for detailed information on tradition of use.



It is not sufficient for the advertisement to only state 'based on traditional use'.

An example is:

**<ingredient> IS TRADITIONALLY USED IN <insert *therapeutic tradition*> MEDICINE**

Refer to the complementary therapeutic tradition such as:

- Homoeopathy

- Anthroposophy
  - Western Herbal Medicine
  - Ayurveda
  - Rongoa
  - Traditional Chinese Medicine.
- ✓ Where more than one tradition of use is relied upon a single statement can be developed to cover both, or more, ingredients/claims.
- The traditional use statement can refer to single or multiple ingredients OR the product, as appropriate.
- ✓ Where it is misleading to use the traditional use statement for the total product, single ingredients should be called out.
- It must remain clear which ingredient is associated with which tradition.
- ✓ Multi-tradition medicines must not claim a single tradition for the entire medicine.
- It must be it clear which ingredients are used in which traditions for specific indications as relevant.
- ✗ Do not attempt to translate an indication that is specific to Traditional Chinese Medicine (TCM), Ayurvedic medicine and indigenous traditions of use such as Rongoa into a western indication.
- For example, the TCM indication 'remove excess heat from the body' must not be replaced by 'reduces fever'.

## Vitamins and minerals

These restrictions are provided for in Part 1 of Schedule 2 of the Therapeutic Goods [Regulations](#). This is briefly covered here as the Code and Regulations interact closely in this matter.

Certain representations or claims about particular complementary medicines are prohibited, including for vitamins or minerals advertisements.

- ✗ Do not use representations about the:
- name of a vitamin or mineral that is not an approved name for the vitamin or mineral
  - ingredient that it is a vitamin or mineral when it is not approved as a vitamin or mineral
  - amount of a vitamin or mineral present in a product, expressed as a percentage or proportion of the recommended daily or dietary intake or allowance
  - recommended daily or dietary intake or allowance of a vitamin or mineral unless the amount shown is that recommended by the National Health and Medical Research Council.
- ✗ Do not use representations that vitamin products are:
- a substitute for good nutrition or a balanced diet
  - superior to or more beneficial in any way than dietary nutrients.

**Example**

Beans Chest Reliever is advertised to relieve chest congestion. The product contains Echinacea and Zinc.

One ingredient has traditional evidence and the other has scientific evidence to support the claims.

- ✓ Beans uses the following statements in the advertisement for the product:

**ECHINACEA IS TRADITIONALLY USED IN WESTERN HERBAL MEDICINE**

**Zinc has been scientifically shown to support a healthy immune system.**

- ✓ Clearly identifies the separate ingredients which have different types of evidence to support the claims.

As the advertisement includes the claim 'scientifically shown', the advertising must cite or provide links to the scientific evidence to support that claim. Consumers should be able to access the studies based on the information provided in the advertisement.

**Example**

Advertising for Beans Chinese Ginseng claims to relieve stress of daily life.

The product contains ginseng, lavender, lemongrass, chamomile and dandelion.

No further information is provided.

- ✗ The required information (Part 4 of the Code) has not been included in the advertising.
- ✗ The advertisement does not disclose that the evidence being relied upon is traditional use in Traditional Chinese Medicine and Western Herbal Medicine.
- ✗ Separate statements for the claim that the medicine relieves stress are required for each ingredient if they rely on different traditions of use such as:
  - Ginseng is traditionally used in Traditional Chinese Medicine.
  - Lavender and chamomile are traditionally used in Western Herbal Medicine.

**Example**

Rachel comes across a commercial for Beanz Chesty while watching television.

The advertiser claims that the active ingredient horseradish in Beanz Chesty relieves the symptoms of chest congestion.

The advertisement for Beanz Chesty includes the following statement prominently displayed and also verbally communicated:

**Horseradish is traditionally used in Western Herbal Medicine to relieve chest congestion.**

- ✓ All other requirements are also contained in the advertisement and so it is considered compliant with the Code.



## Sunscreens

An advertisement about a therapeutic good that is, or contains, a sunscreen and that claims or implies the sunscreen will prevent sunburn or skin cancer must:

- ✓ depict the sunscreen as being *only one* component of sun protection
- ✓ include statements or visual representations, prominently displayed or communicated, to the effect that:
  - prolonged high-risk sun exposure should be avoided
  - frequent use and reapplication in accordance with the directions of use is required for effective sun protection.

### Example

Darryl is a marketing manager for BeanScreen Pty Ltd. He posts on Beans' social media about their new BeanScreen product. The post is:

@BeanScreen  
**Have you seen our new Sunscreen?**  
*It is all you need for a full day in the sun.*  
 One application will last all day.  
*Click here to purchase*

- ✗ this post is not compliant with section 23(3) of the Code because it:
  - does not depict sunscreen as being only one component of sun protection
  - does not support the need for frequent use or application
  - does not include the message to avoid high risk sun exposure.

## Weight management

An advertisement about therapeutic goods that makes claims relating to weight management must:

- prominently display or communicate the need for a healthy energy-controlled diet and physical activity
- not indicate that the goods could correct or reverse the effects of overeating or over-consumption of food or drink
- not include visual representations, statistics or testimonials of individuals that are inconsistent with the results that would be expected to be achieved on average by consumers of the goods.

Weight management includes the following:

- weight loss
- weight control
- weight maintenance
- measurement reduction

- clothing size reduction
- hunger suppression.

**Please note:**

- Any claims made in the advertising of medicines must be in accordance with the accepted indications for the product on the Australian Register of Therapeutic Goods.
- Before and after photos may indicate a claim in the eyes of the consumer.
- Trade or product names could be written in such a way as to be considered a claim and would therefore be subject to the Code when included in advertising.

## Version history

Version	Description of change	Author	Effective date
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## Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605

<https://www.tga.gov.au>



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