Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Guidance on applying the 2021 Advertising Code rules

Part 8 – Restricted representations

Version 1.1, February 2023

Contents

Part 8 - Restricted representations

Read this section together with Section 27 of the Code.

What are restricted representations?

A restricted representation is a representation (a statement or claim) in an advertisement for a therapeutic good which refers to (expressly or by implication) to a serious form of a disease, condition, ailment or defect.

A **serious** form means:

- that the disease, condition, ailment and/or defect is medically accepted to require diagnosis or treatment or supervision by a suitably qualified health professional
  - except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management
- 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.

A representation does not have to be a therapeutic claim to be considered a restricted representation. For example, these representations are all considered to be restricted representations:

- 'Do not use this product if you have **diabetes**'
- 'We proudly support **Osteoporosis** Australia'
- 'May help relieve pain associated with **arthritis**'.

The table below provides further examples of restricted representations.

Statement	Guidance
Source of iron for the treatment and prevention of medically diagnosed iron deficiency and iron deficiency anaemias	Iron deficiency and iron deficiency anaemias are conditions that require diagnosis by a health professional and ongoing medical supervision.
Suitable for asthma patients	Asthma is not suitable for self-treatment or management. It must be medically diagnosed and requires monitoring.
Please SEEK ADVICE before using this product if you are diabetic as your foot condition may require treatment by a healthcare professional	Diabetes is a serious condition that must be medically diagnosed and requires monitoring and treatment by a qualified health professional. Secondary conditions associated with diabetes can be prevented through careful management of the condition supervised by health professionals.

Statement	Guidance
This medicine can be used for the temporary relief of pain associated with arthritis, osteoarthritis and fibrositis pain	Arthritis, osteoarthritis and fibrositis are conditions that require diagnosis, monitoring and treatment by a health professional.
To provide effective relief of ear pain associated with Otitis Media	Otitis Media (middle ear infection) is a condition that requires to be diagnosed, treated and monitored by a health professional.
May help reduce the risk of transmission of sexually transmissible disease (STD)	STD's require monitoring and treatment by a qualified health professional. STD's are also classified as a prohibited representation which must not be referred to in advertising without approval.
Assists with temporary relief of pain associated with mild arthritis	The use of the qualifier 'mild' may be interpreted as being a less serious form of arthritis and therefore not a restricted representation.

What is not considered a restricted representation?

The following are not restricted representations:

- pregnancy, other than pregnancy with a medical, obstetric, or surgical complication
- any of the diseases mentioned in Schedule 2 of the Regulations as these are prohibited representations.

Can I use a restricted representation in advertising?

Restricted representations can only be used in advertisements for therapeutic goods that are available to consumers if TGA has permitted or approved the use of that representation.

Approval to use a restricted representation under section 42DF of the Act can be granted following a successful application from the advertiser.

Prior to commencing an application, advertisers should familiarise themselves with the related guidance and checklist.

A permission or approval to use a restricted representation is not required for warnings or contra-indications that are required by a legislative instrument to be included in an advertisement. These include a statement required by the following:

- the Required Advisory Statements for Medicine Labels (the Therapeutic Goods (Medicines Advisory Statements) Specification)
- the Permissible Ingredients specification (the Therapeutic Goods (Permissible Ingredients) Determination)
- the Permissible Indications specification (the Therapeutic Goods (Permissible Indications) Determination)
- the Poisons Standard
- a standard that applies to the medicine (for example, Therapeutic Goods Order 92).

How do I apply to use a restricted representation?

Applications to use a restricted representation in advertising are submitted using an online application form.

The application form is comprised of two (2) parts. Advertisers should ensure they have the necessary information and supporting documents prior to commencing their application. The application form cannot be saved and accessed at a later time.

Each application is assigned a unique identification number. Include the application number for any queries regarding your application. Send these by email to advertising.exemptions@tga.gov.au(link sends e-mail).

What are the public interest criteria associated with a restricted representation application?

When deciding whether to approve or refuse the use of a restricted representation in advertising the Secretary takes into consideration the public interest criteria set out in the Code.

The public interest criteria asks whether the reference to a serious form of a disease in an advertisement would be likely to:

- take advantage of the vulnerability of consumers or particular groups of consumers, when faced with the disease, condition, ailment or defect
- result in consumers not seeking medical advice
- have a negative impact on public health.

The public interest criteria provides a framework against which the Secretary can assess the suitability of the restricted representation for use in advertising to consumers.

The Secretary can also consider other aspects of the public interest that may be appropriate.

Prior to commencing an application, advertisers should familiarise themselves with the related guidance and checklist.

Will a restricted representation approval or permission be limited to a particular product?

An applicant applies for permission to use a restricted representation in advertising for a specific therapeutic good. The application is made under section 42DE of the Act.

The application specifies the product (with ARTG number if applicable) and the type of restricted representation they want to make in advertising. The application includes justification for the use of the representation. Detailed guidance on how to apply for approval is available at Guidance for submitting an application for approval to use a restricted representation.

The approval given to the applicant is given under section 42DF of the Act. The approval can only be given to the applicant for a specific product/s. The TGA notifies the applicant of the result of their application as required under section 42DG of the Act.

The Secretary can however choose to issue a permission under section 42DK of the Act that permits the use of the restricted representation by a group of permitted advertisers, not only the applicant, where it is in the public interest for this to occur.

Examples of section 42DK permissions that have been issued include for the following classes of therapeutic goods:

- condoms
- broad spectrum 30+ sunscreens
- meters for monitoring blood glucose levels
- vitamin D supplements
- iron supplements
- calcium supplements

- rapid antigen tests for COVID-19
- low-dose aspirin products.

The TGA publishes approvals and permissions for both 'restricted' and 'prohibited' representations on its website at Notices of approved and permitted restricted representations.

Example

Albus applies to use the following statement in his advertising for the (fictional) Beans Tonic Lung Formula.

May assist with symptoms of cystic fibrosis by loosening and clearing lung mucus.

The ARTG indication for the product includes clearing mucus and supporting the immune system, however

- the applicant did not provide any justification that the representation is balanced and not misleading
- there is no evidence to support use of the product in any specific disease or condition.

The application is refused under section 42DF(2) of the Act. The delegate is not satisfied that the restricted representation is accurate, balanced and not misleading or likely to be misleading.

Example

Mohammad applies on behalf of a pharmacy marketing group to advertise an automated external defibrillator. The representation he proposes to use has already been permitted under a section 42DK of the Act. The TGA informs Mohammad of the existing s42DK permission. He withdraws his application.

What are prohibited representations?

Prohibited representations must not be used in advertising unless permitted by the TGA.

Prohibited representations are those representations that refer to the following:

- neoplastic diseases (e.g. all types of cancer)
- sexually transmitted diseases
- HIV/AIDS
- Hepatitis C virus
- mental illness
- an abortifacient action.

Other prohibited representations apply to other specific types of therapeutic goods including:

- analgesics
- disinfectants and antiseptics

- vitamins and minerals.

For details about prohibited representations refer to Schedule 2 of the Regulations. Schedule 2 applies to all advertising of therapeutic goods.

The TGA publishes approval and permissions for both ‘restricted’ and ‘prohibited’ representations on its website.

When can a prohibited representation be used?

In limited circumstances, the TGA may permit the use of prohibited representations if the representation is:

- in the interest of public health

  OR

- necessary for the appropriate use of the goods
  - this applies to packaging, labelling or material included with the goods.

Examples of section 42DK permissions that have been issued for prohibited representations include:

- Sunscreens
- Condoms
- HIV self-test kits.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising and Compliance Education and Policy Section Regulatory Compliance Branch	June 2022
V1.1	Minor editorial changes Additional clarification that permission or approval to use a restricted representation is not required for warnings or contra-indications that are required by a legislative instrument Guidance on Samples and incentives (Part 7) and Pricing information (Part 9) published in separate documents.	Advertising and Compliance Education and Policy Section Regulatory Compliance Branch	February 2023

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