Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Submitting an application for approval to use a restricted representation

Using a restricted representation under Section 42DF of the Therapeutic Goods Act 1989

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What is a restricted representation?

A restricted representation is a representation that refers, whether expressly or by implication, to a serious form of a disease, condition, ailment or defect. The concept of a 'serious form' is defined in the Therapeutic Goods Advertising Code (the **Code**). See What is a restricted representation? for more information.

When can I use a restricted representation?

Before a restricted representation can be used in an advertisement (including labelling), the representation must be either:

- approved by the Secretary under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**)

- permitted by the Secretary under section 42DK of the Act.

Approval to use a restricted representation under section 42DF of the Act can only be granted following a successful application from the advertiser. However, the Secretary can permit all advertisers to use a particular restricted representation under section 42DK of the Act without receipt of an application.

Can the use of restricted representations be approved for the advertising all types of therapeutic goods?

Approval for the use of a restricted representation will only be granted in relation to therapeutic goods that:

1. can be lawfully advertised to the public (e.g. not prescription medicines), and
2. are either entered, or exempt from inclusion, in the Australian Register of Therapeutic Goods (ARTG).

Any proposed restricted representation must be consistent with both:

1. the good's accepted indications or intended purpose, as per its ARTG entry
2. any mandatory warning or cautionary statements which are required to be included in the product packaging/labelling in order to satisfy other regulatory requirements.

The permitted indications for listed medicines generally do not allow for the use of restricted representations. As such, restricted representation applications for approval in relation to indications are unnecessary. Required warning statements that include restricted representations do not need approval.

What information and documentation do I need to submit in the application?

In order to submit an application for approval to use a restricted representation in advertising therapeutic goods to consumers, the following information must be provided:

- the name of the business seeking approval to use the restricted representation
- details for the primary contact for the application (i.e. name, email, phone number and postal address)
- the name of the therapeutic good, as included on the ARTG
- the serious disease, condition, ailment and/or defect that will be referred to in the representation
- the proposed restricted representation(s) that you are applying for approval to use (e.g. product X may relieve the pain associated with rheumatoid arthritis, or product X will not aggravate asthma).

With some limited exceptions, you will also need to submit supporting documentation to assist the TGA in assessing your application against the criteria set out in section 42DF of the Act, including:

- the ARTG certificate (if applicable)
- a statement as to why you consider the proposed representation is accurate, balanced and not misleading or likely to be misleading, referenced to appropriate supporting evidence
- a statement as to why you consider the proposed representation meets the public interest criteria.

To assist you in the preparation of the necessary information prior to commencing your application to use a restricted representation in advertising therapeutic goods to consumers, please refer to the restricted representation application checklist.

Do I need to provide specific examples of advertising with my application?

No, there is no requirement to provide specific examples of advertising; however, it may be beneficial to provide specific examples with your application if they will support and give context in relation to the proposed use of the restricted representation.

What criteria are applications assessed against?

When the TGA assesses an application to use a restricted representation, we consider whether the proposed representation is accurate, balanced and not misleading or likely to be misleading, in accordance with section 42DF of the Act. In forming a view about these requirements, we consider various factors including:

- the context in which the proposed representation will be used
- the actual wording of the proposed representation
- substantiating evidence provided to justify the use of the proposed representation and to satisfy the TGA that the use of the representation will be accurate
- any relevant information the decision maker may be aware of
- the public interest criteria specified in the Code.

You do not need to provide specific examples of the proposed advertising; however, it may be beneficial to provide specific examples with your application if they will support your application and give context in relation to the proposed use of the restricted representation.

It is important to note that any advertisements submitted are only considered in relation to the restricted representation application and are not an approval by the TGA for the entirety of the advertisement. Only the use of the restricted representation within an advertisement is approved.

What are the public interest criteria referred to in the application form?

Section 42DF of the Act requires that the Secretary (or delegate) take into consideration the public interest criteria set out in the Code when deciding whether to approve, or refuse to approve, the use of a restricted representation in advertising.

The public interest criteria contemplate 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 at an appropriate time; and
- have a negative impact on public health.

The Secretary (or delegate) can also take into account other aspects of public interest that they consider may be appropriate.

The public interest criteria provide a framework against which the Secretary (or delegate) can assess the suitability of the restricted representation for use in advertising to consumers. Therefore, it is important that your application includes a statement to explain to the TGA how your proposed representation and advertising addresses the public interest criteria. Addressing the public interest criteria may also reveal changes in wording or approach you may need to make in your proposed representations.

Do I need restricted representation approval or permission for label warnings or contraindications?

Restricted representation approval or permission is not required for warnings, contraindications or advisory statements that refer to serious forms of diseases, ailments, defects or conditions, provided that the warning, contraindication or advisory statement is required under the therapeutic goods legislation to be included in that form of advertising. This includes:

- a health warning, as prescribed by the Code for the advertised medicine, when used in advertising other than labels and packaging
- an advisory statement on a medicine's label or packaging that has been prescribed for that medicine in a condition of the registration or listing of a medicine
- an advisory statement on a medicine's label or packaging that has been prescribed for that medicine in the applicable version of any of the following:

- the Required Advisory Statements for Medicine Labels;
- the Permissible Ingredients specification;
- the Permissible Indications specification;
- the Poisons Standard;
- a standard that applies to the medicine (for example, Therapeutic Goods Orders 69 and 92).

This advice only applies in relation to the use of such statements in advertising when that use is required under one or more of the measures noted above. The use of such statements in these contexts is required in order to provide and highlight critical safety information for consumers. However, if used inappropriately and not in a manner to highlight that safety information, these statements may have unintended consequences.

If such statements are used outside of the contexts listed above, the Secretary's approval or permission will be required prior to their use. In the absence of such approval or permission, criminal offences or civil penalties in the Act may apply.

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

The approval or permission for the use of a restricted representation may be given to advertisements for:

- a group of products, e.g. condoms, broad spectrum 30+ sunscreens, meters for monitoring blood glucose levels
- products containing a particular substance, e.g. vitamin D
- a substance limited to a specific company for some products, e.g. paracetamol-only products sponsored by company X
- a specific product, e.g. Mediflexor Calf Carer, Diflucan Duo

Applicants, therefore, need to carefully consider the scope of the restricted representation they wish to make, e.g. either a category or limited to a particular brand/product. If the applicant wishes to confine the restricted representation to a particular brand/product, it may be helpful for the submission to include some justification for doing so.

Applicants should be aware that the Secretary may decide to issue a category exemption, even where the application is made for a particular product.

Who makes the decision to approve or refuse an application?

The decision to approve, or to refuse to approve, an application is made by the Secretary of the Department of Health (or their delegate). The Secretary must approve the use of the restricted representation if they are satisfied that:

- the representation is accurate and balanced; and
- the representation is not misleading or likely to be misleading.

Approvals may be subject to conditions.

Where the Secretary is not satisfied that the application satisfies the above criteria, they must refuse to approve the use of the restricted representation.

In deciding whether to approve or refuse to approve the use of a restricted representation, the Secretary must take into consideration:

- the public interest criteria mentioned in the part of the Code dealing with restricted representations, and
- any advice the Secretary may have sought from:
    - Advisory Committee on Medicines;

- Advisory Committee on Complementary Medicines;
- Advisory Committee on Medical Devices; or
- Advisory Committee on Vaccines.

What if I disagree with the decision?

Applicants that are not satisfied with the decision in relation to an application can seek a review of that decision. Details on how to seek a review will be set out in the decision letter issued by the TGA.

Alternatively, the decision letter may identify issues that could be addressed by amending the proposed representation(s), advertising and/or supporting documentation to allow the lodgement of a new application.

Topics: Advertising Complementary medicines Labelling and packaging Listed medicines Prescription medicines In Vitro Diagnostic medical devices (IVDs)