Australian Government
Department of Health
Therapeutic Goods Administration

Restricted representation application checklist

This checklist assists applicants to assemble the necessary information and supporting documentation to lodge an application with the TGA for approval to use restricted representations in consumer advertising under section 42DF of the *Therapeutic Goods Act 1989* (the Act).

Preparing your application in accordance with the checklist will assist in producing a high quality application that will minimise the time required for the TGA's assessment. This checklist should be considered in conjunction with the Guidance for submitting an application for approval to use a restricted representation.

Scope of application

Before lodging, you should carefully consider the scope of your application in the context of the following principles for a high quality application.

Principle	Description	Check
The therapeutic goods must be able to be advertised to consumers	Ensure that the goods concerned can be lawfully advertised to consumers – e.g. applications for prescription medicines and biologicals will not be progressed as they cannot be advertised to consumers. Refer to the decision tree Can I advertise this therapeutic good to the public?.	☐
Scope of application is clear, defined and reasonable	Consider the therapeutic goods, the associated restricted representations for which you would like approval and the evidence that you will need to provide to support your case for approval. Large and complex applications (such as those involving multiple and unrelated diseases and multiple representations with multiple sets of efficacy data) generally require more extensive consideration by the TGA and tend to take longer to decide. As such, it is preferable to lodge multiple, discrete applications. To ensure the most efficient consideration of applications, applicants should limit the scope of their applications to a single concept. For example: • A single medicine to be promoted for assisting with multiple related conditions with a common supporting data set is suitable for a single application. • Two related devices under a common ARTG entry to be promoted for assisting with a single condition with a common supporting data set (e.g. nebulisers under a particular ARTG entry for delivery of medication to relieve asthma) would also be suitable for a single application. • A single device for use in relieving multiple health conditions with a different set of clinical trials for each condition would best be presented as one application per condition. If you are unsure of whether multiple applications may be needed, please contact us for advice.	☐

Principle	Description	Check
Wording of proposed representations	To minimise application handling times, the representations included in your application should be limited to statements about the goods that are: • factual • unembellished • capable of complying with the Therapeutic Goods Advertising Code (the Code). This does not prevent marketing claims being used in conjunction with approved restricted representations in advertising, provided: • the advertiser can substantiate the claims • the claims comply with the Act and the Code • the use complies with any conditions imposed on the use of the restricted representation Restricted representations that include marketing representations where accuracy cannot be definitively established (including because of the subjectivity of the representation) cannot be approved. For example, the adjectives in the claim “The best and fastest imaging for anterior cruciate ligament tears” are subjective and would be difficult to establish. Including such a representation in an application would likely result in the TGA contacting the applicant to explain the issues, waiting for the applicant to consider them and possibly amend their application, leading to delays before the application is decided. However, the core representation that the good can provide “imaging for anterior cruciate ligament tears” could be more readily approved, subject to appropriate corroborating evidence. Similarly, a representation that a good is “the safest imaging device for anterior cruciate ligament tears” could not be approved as it would breach the Code prohibition on advertising goods as “safe” and therefore mislead consumers (see Are the proposed restricted representations accurate, balanced and not misleading or likely to be misleading? below).	☐

Lodging your application

The online application form requires you to input information and attach documents to support your application. The following part of the checklist provides information to assist you in preparing the information and attachments.

* denotes mandatory information

Applicant details

Requirement	Description	Check
Business name*	This is the name of the business applying for approval to use the restricted representation – if approval is given, it will be given to this entity.	☐
Primary contact details: • Name* • Email address* • Phone number • Postal address	This is the person that we should contact with any questions or correspondence about the application. It may be the details of a regulatory affairs consultant who is completing the application on behalf of the business identified above or it may be the contact details of someone employed by the business itself. Providing an Australian phone number where possible will enable the TGA to contact you promptly regarding the application.	☐

Details about the therapeutic goods to be advertised

Requirement	Description	Check
Product*	Where the goods to be advertised are in the ARTG, you will need to select them from a list in the online form. While you can search for the goods using either the name or ARTG number, ensure you have the ARTG number (or numbers) for the goods ready to confirm you have selected the correct goods. For goods exempt from inclusion in the ARTG, record the name of the goods as they appear on the label or in the instructions for use. Before lodging an application relating to goods currently being evaluated by the TGA (e.g. through the registered medicines pathway), please contact us for advice. Multiple products can be added to the application if necessary.	☐
Indication/intended purpose*	For goods entered in the ARTG, you will need to record the indications in the form as specified on the ARTG entry (the indication is not automatically pre-populated from the ARTG entry). For goods exempt from inclusion in the ARTG, record the indications as they appear on the label or in the instructions for use.	☐
What is the serious disease(s), condition(s), ailment(s) and/or defect(s) that will be referred to in the advertising to consumers?*	Record the serious disease(s), condition(s), ailment(s) and/or defect(s) relevant to your application. For example: rheumatoid arthritis. Note that a serious disease, condition, ailment or defect can be referred to by implication. For example, a serious form of arthritis could be referred to by pictorial representation of swollen and inflamed hands. If you are unsure whether the disease, condition, ailment or defect you want to refer to is a restricted representation, please contact us for advice.	☐
How do you propose to use the reference to the serious disease(s), condition(s), ailment(s) and/or defect(s) that will be referred to in the advertising to consumers?*	Set out the proposed restricted representation. This may be in the form of a therapeutic claim (whether express or implied) or other representation about the therapeutic good. For example: *product X may relieve the pain associated with rheumatoid arthritis; product X will not aggravate asthma.*	☐

Supporting information – all applications

Requirement	Description	Check
ARTG certificate	For therapeutic goods that are entered in the ARTG, you will need to attach a copy of the ARTG certificate(s) to your application.	☐
Are the proposed restricted representations accurate, balanced and not misleading or likely to be misleading? (Section 42DF(1) of the Act)	It is important that you provide a written explanation and supporting evidence (where applicable) to address these criteria. This is your opportunity to highlight to the TGA why the representations should be considered to meet the legislative criteria in section 42DF of the Act. When assessing an application against the legislative criteria, the TGA considers information including (without limitation): • for goods in the ARTG - whether the proposed representations are consistent with the indications or intended purpose accepted in relation to the ARTG entry • any applicable scientific studies (to support the TGA's assessment, your explanation should cross-reference the applicable pieces of evidence and you should provide a clinical evaluation report for the studies) • consistency with current applicable public health campaigns, government policies and contemporary clinical guidance (where available)	☐

Requirement	Description	Check
	The evidence needed to support the accuracy of the representation will depend on the nature and strength of the representation. Refer to the guidance on section 9 of the Code for further information. In preparing your explanation, you should also consider whether the proposed representations are capable of complying with all relevant Code provisions. For example, a restricted representation that contravenes section 16 of the Code because it includes a government endorsement would not meet the requirements for approval as it would be considered misleading.	
Does the proposed representation meet the public interest criteria set out in section 29 of the *Therapeutic Goods Advertising Code (No.2) 2018*? (Section 42DF(4)(c) of the Act)	It is important that you provide a written explanation and supporting evidence (where applicable) to address these criteria. This is your opportunity to highlight to the TGA why the representations should be considered to not raise any concerns in relation to the public interest criteria. In order to satisfy these criteria, advertisers should have regard to whether the proposed representation: (a) is likely to take advantage of vulnerable consumers, or particular groups of consumers, when faced with the disease, condition, ailment or defect; (b) is likely to result in consumers not seeking professional medical advice; (c) when considered alone, through repetition, or together with other references, is likely to have a negative impact on public health; and (d) any other relevant public interest concerns.	☐

Supporting documentation for applications relating to medical devices

Requirement	Description	Check
Product information	You will need to provide clear, legible and colour copies of the following: • information that describes the device and explains how the device can be used safely • any labelling for the device • the instructions for use • any existing advertising material for health professionals and consumers • the manufacturer's specifications.	☐
Additional documents for custom made devices	Examples of custom made medical devices can include dental appliances, prosthetic limbs and prescription glasses. For these types of devices, you will need to attach a copy of the declaration issued under part 7.2 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* to your application.	☐

Supporting documentation for applications relating to medicines

Requirement	Description	Check
Product labels and packaging	You will need to attach copies of the medicine label and packaging with your application. Please ensure they are in colour and legible scans or images.	☐
Has the TGA previously granted a permission under section 42DK of the Act for a similar product?	If yes, you may wish to provide copies of any previously granted permissions.	☐