



Australian Government

Department of Health

Therapeutic Goods Administration

Guidelines for using the TGA assessed claim on medicine labels

Assessed listed medicines and registered
complementary medicines

Version 1.1, August 2020

TGA Health Safety
Regulation



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Overview

This document provides sponsors of assessed listed medicines and registered complementary medicines guidance on:

- what the TGA assessed claim is
- how the TGA assessed claim can be used on medicine labels and in other advertising
- how to apply to use the TGA assessed claim

For more information, see [TGA assessed claim for assessed listed and registered complementary medicines](#).



Please note the examples of product labels in this document are intended to provide guidance on the presentation of the TGA assessed claim only. They do not represent actual products, nor necessarily meet the requirements of the therapeutic goods labelling order or advertising requirements. For information on requirements for labelling refer to [Labelling & Packaging](#) and for information on advertising refer to the [Advertising hub](#) on the TGA's website.


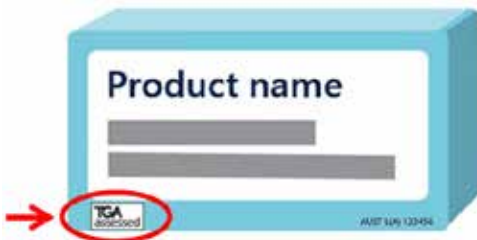
The TGA assessed claim

The TGA assessed claim can be used to indicate that a medicine has had the efficacy of its indications assessed by the TGA. The claim must only be used in relation to assessed listed medicines or registered complementary medicines. The claim must be displayed as the approved TGA assessed statement, with or without the approved TGA assessed symbol.

The TGA assessed symbol is the subject of an application for a certification trade mark that is currently being considered by the Registrar of Trade Marks under the *Trade Marks Act 1995*. It is anticipated that the application will be determined in the near future, at which time these guidelines will be revised. Once registered, use of the certification trade mark will be governed by accompanying certification rules, which will reference these guidelines.


The TGA assessed symbol and statement are shown below.

The TGA assessed symbol

TGA assessed symbol	Example label with symbol
	

If the symbol is used, a statement authorised by the TGA must also be used (see below).

The TGA assessed statement

TGA assessed statement	Example label with statement
Evidence for the approved indications has been assessed by the TGA.	

The statement may be used on its own without the TGA assessed symbol. The wording of the TGA assessed statement must not be changed.

Examples of compliant and non-compliant statements

Compliant: Evidence for the approved indications has been assessed by the TGA.

Non-compliant: The TGA has assessed our evidence and has approved all of our indications.

Using the TGA assessed claim on product labels

The TGA assessed claim may only be used in relation to a medicine when that use has been authorised by the TGA.

Authorisation to use the TGA assessed claim will only be issued for assessed listed medicines and registered complementary medicines that have undergone a pre-market assessment of efficacy by the TGA. The TGA assessed claim must be easily identifiable on medicine labels. The label of the medicine that will display the TGA assessed claim is also assessed as part of this process.

The TGA assessed symbol and statement are standardised for easy identification on different product types. The requirements for using the TGA assessed claim on a medicine label are provided below.

Location of the TGA assessed claim on a product label

The TGA assessed claim (the TGA assessed statement, with or without the TGA assessed symbol) can be displayed anywhere on the label, including the primary pack. The TGA assessed claim must be balanced against other information on the main label and primary pack to assist consumers in selecting and using a medicine. The size of the TGA assessed claim must not be more prominent than required label information. For more information on labelling requirements refer to [Medicine labels: Guidance on TGO 91 and TGO 92](#).



Section 3(1) of the *Therapeutic Goods Act 1989* provides the following definitions of primary pack and label:

primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

label, in relation to therapeutic goods, means a display of printed information:

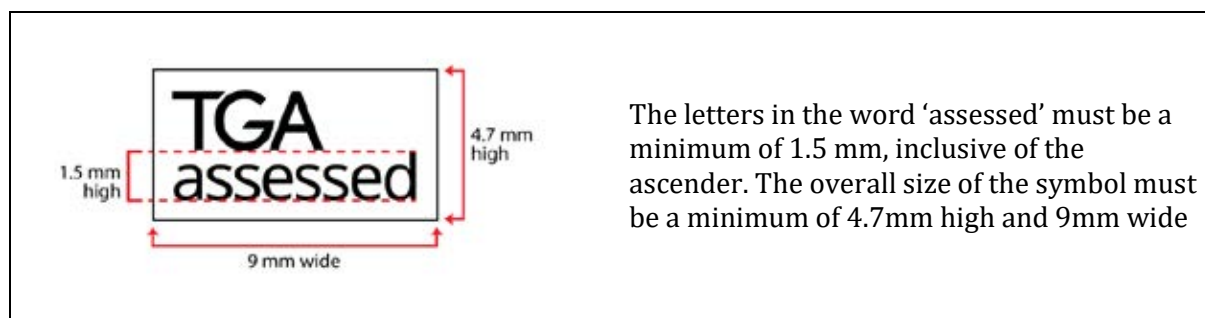
- (a) on or attached to the goods; or
- (b) on or attached to a container or primary pack in which the goods are supplied; or
- (c) supplied with such a container or pack.

Text size of the TGA assessed claim

Text size for the TGA assessed symbol

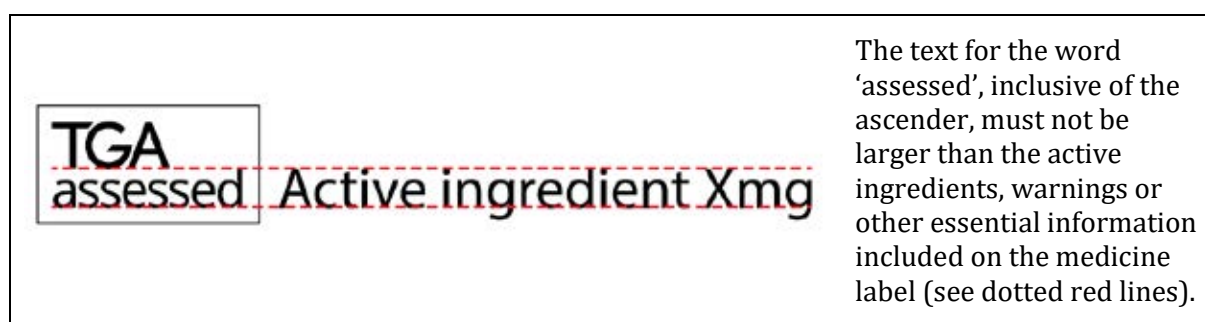
Minimum text size for the TGA assessed symbol

The minimum text size for the letters in the word 'assessed' included in the TGA assessed symbol is 1.5 millimetres, inclusive of the ascender. Therefore, the minimum overall size of the symbol/information box is equivalent to 4.7 mm high and 9 mm wide.



Maximum text size for the TGA assessed symbol

The maximum text size for the word 'assessed', inclusive of the ascender, is no more than the text size of the letters for the active ingredients, warnings or other essential information included on the medicine label.



Text size for the TGA assessed statement

Minimum text size for the TGA assessed statement

The minimum text size for the TGA assessed statement is 1.5 millimetres.

Maximum text size for the TGA assessed statement





The maximum text size for the TGA assessed statement is no more than the text size for the names and amounts of active ingredients, warnings or other essential information included on the medicine label.

Font style and colour of TGA assessed claim

TGA assessed symbol font style and colour

The TGA assessed symbol must be presented in black ink on a white background and surrounded by a black outline (as provided to the sponsor in an '.eps' file by the TGA).

Examples of compliant and non-compliant TGA assessed symbols

			
<p>Compliant Do present the symbol in black with a white background and a black outline.</p>	<p>Non-compliant Do not change the colour of the symbol or the outline. Do not invert the symbol.</p>	<p>Non-compliant The symbol must be presented on a white background.</p>	<p>Non-compliant Do not change the shape of the symbol or any of its elements, do not stretch or skew the symbol.</p>

TGA assessed statement font style and colour

To allow sponsors some flexibility in label design, you can choose the font style and colour for the TGA assessed statement; however, it must:

- be presented in a colour that contrasts strongly with the background it is printed on; and
- be consistent with the font style, colour and prominence of the surrounding label text, warnings or other essential information.

The sentence must be written in lower case, with the exception of the first letter of the sentence and TGA, as shown below.

Examples of compliant and non-compliant statements

Compliant: Evidence for the approved indications has been assessed by the TGA.

Non-compliant: EVIDENCE FOR THE APPROVED INDICATIONS HAS BEEN ASSESSED BY THE TGA.

Examples of TGA assessed claim (symbol and statement) on labels

		
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Using the TGA assessed claim in other advertising materials

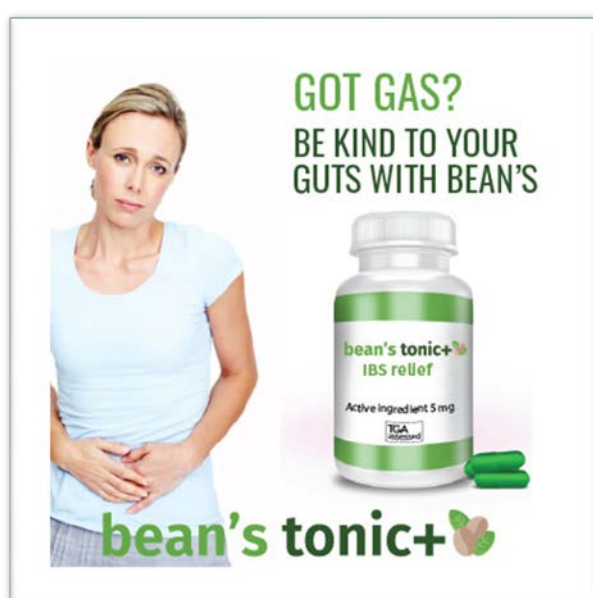
Advertisements may show images of the medicine label, including the TGA assessed claim (the TGA assessed statement with or without the TGA assessed symbol), but must not use the TGA assessed symbol or statement other than on the image of the label in the pack shot. An advertisement must not include any audible commentary or further written commentary on the TGA assessed claim.

The TGA assessed claim must not be more prominent than the mandatory statements in an advertisement.

The use of the TGA assessed claim in any advertising must comply with the advertising requirements set out in the [Therapeutic Goods Act 1989](#) and the [Therapeutic Goods Advertising Code](#), as amended from time to time.

The advertising **must not imply that the TGA recommends** the medicine or advocates the use of the medicine above other medicines that do not use the TGA assessed claim.

Examples of TGA assessed claim in other advertising materials



ALWAYS READ THE LABEL. FOLLOW THE DIRECTIONS FOR USE. IF SYMPTOMS WORSEN OR CHANGE UNEXPECTEDLY TALK TO YOUR HEALTH CARE PROFESSIONAL



Applying to use the TGA assessed claim

You can request the TGA assessed symbol file by emailing:

complementary.medicines@health.gov.au. The file will be provided in an '.eps' format.

Copies of proposed labels displaying the TGA assessed claim must be provided to the TGA with an application:

- for a new assessed listed medicine or a new registered complementary medicine; or
- to vary the labelling of a registered complementary medicine or assessed listed medicine included in the Australian Register of Therapeutic Goods.

In considering a label in relation to a medicine, the TGA will consider all aspects of the medicine's presentation for compliance with the various legislative requirements. Authorisation to use the TGA assessed claim will not be given in relation to a medicine where the presentation of that medicine (with the TGA assessed claim) is not acceptable—refer to the [Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines](#).

Version history

Version	Description of change	Author	Effective date
V1.0	Initial publication	Complementary and OTC Medicines Branch, TGA	October 2019
V1.1	<ul style="list-style-type: none">• Clarification of measurement of the text height in line with existing TGO 92 guidance.• Revision of minimum TGA assessed symbol dimensions to allow sponsors to use a smaller symbol, if the mandatory label information text is at the minimum height required by TGO 92.• Updated link to the Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines.• Addition of information regarding certification trade mark.	Complementary and OTC Medicines Branch, TGA	August 2020

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

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