Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Regulatory options to potentially allow references to the TGA in therapeutic goods advertising

Consultation paper

Version 1.0, August 2022

TGA Health Safety Regulation

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Purpose and scope

The Therapeutic Goods Administration (TGA) is considering regulatory options to allow advertisers, including product sponsors, to make references to the TGA in advertising (including on product labels).

The driver of this proposal is to support consumers to more easily identify products than can be lawfully supplied in Australia and to make more informed healthcare decisions when self-selecting medicines and medical devices. Secondary interests include the advertiser's ability to indicate their product has been subject to regulation. It will also potentially simplify TGA's compliance and enforcement activities by removal of doubt over whether a particular product has been included on the ARTG.

The purpose of this consultation paper is to seek feedback on:

- whether references to the TGA should be allowed in therapeutic goods advertising
- the class or classes of therapeutic goods, if any, that should be allowed to refer to the TGA
- options for what a reference to the TGA could look like
- options for how an authorised reference to TGA may be used in advertising
- whether references to TGA should be optional or mandatory for advertisers.

Prescription-only and certain pharmacist-only medicines that cannot be advertised to consumers are excluded from consideration in this proposal and consultation as, generally, advertising of these medicines is not permitted. Where advertising of these medicines is specifically authorised, the authorisation will describe the conditions under which that advertising is to take place, including approved claims.

Background

The TGA, part of the Australian Government Department of Health and Aged Care, is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. These include goods Australians rely on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, blood products, surgical implants and products used to test for diseases, such as blood tests.

The TGA regulates therapeutic goods through the administration of the *Therapeutic Goods Act 1989* (Act), the *Therapeutic Goods Regulations 1990* (Regulations), the Poisons Standard, and other relevant subordinate legislation. These instruments establish a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods. A general rule is that therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG), or otherwise subject to an exemption, approval or authority, before being lawfully supplied in, imported to, exported from or advertised in Australia.

The TGA also regulates the advertising of therapeutic goods in Australia through a combination of measures prescribed under the Act and Regulations and the Therapeutic Goods Advertising Code.

Advertising to the public is permitted for the majority of medical devices, as well as most medicines available for over-the-counter sale. The advertising of prescription-only and certain pharmacist-only medicines to the public is prohibited.[1]

The regulation of advertising contributes to the safe use of therapeutic goods by supporting the general public to receive accurate and balanced information about their proper use, quality, safety and efficacy. It is essential that consumers receive credible information in advertisements so that they can make informed decisions regarding the suitability of the goods for their health needs, and do not delay seeking care from a health professional when appropriate.

Risk based approach to regulation

The level of TGA regulatory control increases with the level of risk the medicine or device can pose and determines how consumers can access these goods.

This risk-based approach impacts the types of products for which references to the TGA in advertising may be suitable and what references may be considered appropriate, as presented in the options below.

For information on how different types of products are classified and regulated, please see Appendix 1.

Advertising prohibition on government endorsements

The Act[2] and the Advertising Code[3] currently prohibit advertisements to the public that suggest or imply that a product has been approved or endorsed by a government agency, such as the TGA, without authorisation.

The TGA publication The claim 'TGA approved' must not be used in advertising provides guidance on the current regulatory requirements. In summary:

- inclusion of a therapeutic good in the ARTG is not an endorsement of that good by the TGA
- advertisers are permitted to include a statement of the registration number, listing number or device number of the goods, such as 'Product X is included in the ARTG, (ARTG number)'
- statements such as ‘TGA approved’ or ‘TGA registered’ are considered to be endorsements and must not be used in therapeutic goods advertising, including on labels or packaging
- advertisers should not make a broad statement that a therapeutic good is listed, registered, or included in the ARTG unless it includes the ARTG number.

Endorsements about therapeutic goods can influence consumers' decisions regarding the suitability of the goods for their health needs. Therefore, endorsements from government agencies are prohibited to enable consumers to choose the medicine or medical device suitable for their circumstances and not be swayed toward a particular product because of the status or perceived expertise of the person or organisation endorsing it.

[1] Note that price information for prescription medicines can be advertised, with the Advertising Code setting out the conditions under which this may occur.
[2] Sections 42DL(9) and 42DLB(6) of the Act prohibit an advertisement for therapeutic goods from containing a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority unless the statement is in relation to the availability of the goods as a pharmaceutical benefit or otherwise authorised.
[3] Advertising therapeutic goods to the public with a Government endorsement is also prohibited under paragraph 24(6)(a) of the Advertising Code.

There are mechanisms in the Act to allow the TGA to authorise statements and representations that therapeutic goods are approved by a government agency. For example, the 'TGA assessed'[4] claim in labelling is authorised for assessed listed medicines and registered complementary medicines that have undergone pre-market assessment by the TGA. This is intended to:

- improve the transparency about the efficacy claims made about complementary medicines for consumers
- provide an incentive to the industry to improve the evidence base for complementary medicines.

Therapeutic Goods Advertising Consultative Committee

The Therapeutic Goods Advertising Consultative Committee (TGACC) is a forum through which the TGA consults with the therapeutic goods industry, and media, publishing and broadcasting bodies involved in the advertising of therapeutic goods to the public. The TGACC also includes membership from government, and consumer and health professional representative bodies.

At the 21 March 2022 TGACC meeting, the TGA sought comments on the merits of the options proposed in this consultation paper. The Committee discussed the risks and benefits of the proposals including the potential impacts for consumers and advertisers.

The commentary included in this consultation paper considers feedback received from the TGACC.

Reading this consultation paper

This proposal on options to allow references to the TGA in advertising must consider:

- should references to the TGA be allowed
- if so, what goods should be able to make such a reference
- what should that reference be
- in what advertising can the reference be made
- should it be optional or mandatory.

You may choose to support more than one solution. For example, allowing advertisers to put 'TGA' in front of the ARTG number, plus a prescribed statement in relation to the advertising of only certain goods in certain circumstances as determined by the TGA using published guiding criteria.

Therefore, we recommend reading this paper in full before coming back to each section to consider the questions posed and the combination of options that you support.

Consultation submissions

The TGA welcomes feedback on the options presented in this paper and encourages alternative suggestions that may assist. We have posed questions within the paper to help structure your submission, these are not compulsory, and no set format is required for your submission.

[4] Therapeutic Goods (TGA Assessed Claim) Authorisation 2020

Should references to the TGA be allowed in therapeutic goods advertising?

It is important that Australian consumers can easily identify if a product they are considering purchasing has met the regulatory requirements and is being lawfully advertised and sold.

The supply of illegal goods poses significant risks to consumers. These products have not been assessed by the TGA, meaning they do not come with the same assurances of safety, effectiveness and quality as those that have met Australian regulatory requirements. Simply put, unapproved versions may not work as expected, or work at all or may be harmful.

The presence of an ARTG number on the packaging of medicines may provide some assurance to informed consumers that the product has been subject to the regulatory processes managed by the TGA. However:

- while it is a requirement that all medicine labels display the medicine's AUSTL or AUSTR number, there is no equivalent requirement for medical devices
- despite the TGA's educational efforts over many years, many consumers seem not to recognise or understand the meaning of AUSTL, AUSTR and ARTG numbers.

The COVID-19 pandemic, in particular, has highlighted the challenges consumers face in identifying whether particular personal protective equipment (PPE) such as facemasks and gloves, disinfectants, and testing products have been included on the ARTG.[5]

A recent case study – COVID-19 Rapid Antigen Tests (RATs)

Since late 2021, RATs have become a key part of the Commonwealth, state and territory government's public health response. They are a quick and convenient way for consumers to detect potential COVID-19 infection.

As soon as RATs first became available in Australia for self testing, consumers were trying to purchase them in large numbers in order to follow public health directions. Consumers were advised that only tests approved by the TGA should be sold by retailers, however, uninformed or unscrupulous suppliers were seeking to profit from supplying unapproved products.

The challenge in identifying whether particular COVID-19 RATs have been approved by the TGA for supply in Australia and appear on the ARTG was raised with the TGA by several healthcare professional, government, industry and consumer groups. Consumers and health care professionals were looking for reassurance that they were buying products approved by the TGA.

In response, the TGA has:

- targeted unlawful imports, advertising and supply of unapproved RATs[6]
- published a list of COVID-19 rapid antigen self-tests that are approved in Australia.

Additionally, claims to the effect that a product is 'TGA approved' are a frequently encountered contravention of the Act,[7] yet they are arguably low risk in terms of potential harm to consumers (provided the medicine or device is included in the ARTG).

[5] Since May 2020 the TGA has issued at least 53 infringement notices for the unlawful promotion of goods not entered on the ARTG.
[6] See for example, Import, Advertising and Supply Compliance Priorities 2022-23.
[7] The TGA has issued at least 20 infringement notices for this alleged contravention since May 2020.

With this in mind, we are seeking stakeholder, including consumer, comment on whether 'TGA approved' type claims should be allowed in advertising for some or all products.

Option 1: Allow advertisers to make references to the TGA in therapeutic goods advertising

Under this option, the TGA would authorise advertisers to make references to the TGA in advertising of some or all therapeutic goods (including on product labels).

A reference to the TGA may:

- support consumers to make better informed health decisions by more clearly identifying products that have met the regulatory requirements and are being lawfully advertised and sold
- help address the current gap in consumer knowledge about the TGA and the meaning of AUSTL, AUSTR and ARTG numbers on product labels and in advertising.

The TGA's compliance and enforcement activities may also be simplified if by doing so it was clearer which products were on the ARTG (see What could references to the TGA look like? below). Although it is noted that unscrupulous advertisers could seek to illegally use any such claim to market unapproved products, if reference to an ARTG number were required as part of the policy change it would be straightforward to determine whether a particular product was indeed included on the ARTG.

Option 2: Maintain the prohibition on references to the TGA in advertising (status quo)

Under this option, the existing advertising prohibition on government endorsements would be maintained.

As is the case currently, advertisers could not make any reference to indicate that a therapeutic good is approved, listed or included on the ARTG by the TGA. However, they would continue to be permitted to include a statement of the ARTG entry number of the goods.

1. Should the TGA allow references to the TGA in therapeutic goods advertising to identify whether certain products have met regulatory requirements?
2. Do you think a reference to the TGA would support consumers to better identify those products that can be legally supplied in Australia?

Which types of products should be able to refer to the TGA in advertising?

A reference to the TGA in therapeutic goods advertising could be considered misleading and inappropriate where the TGA has not evaluated the particular product prior to entry in the ARTG (such as for listed complementary medicines and Class I medical devices) (refer to Appendix 1 for information on the different levels of regulation undertaken by product class).

At the other extreme, for products that can only be accessed by consumers following a consultation with a doctor, pharmacist or other healthcare professional (and are not available for self-selection), a 'TGA approved' claim may be of little value to consumers. So, it could be

argued that reference to the TGA is most relevant for products that are able to be selected by the consumer such as COVID-19 or pregnancy test kits or over the counter medicines.

With this in mind, we are seeking stakeholder comment on the classes of therapeutic goods that should be allowed to make 'references to the TGA' in advertising were a proposal of this kind to go forward.

Option 1: Allow references to the TGA for *all* approved (ARTG) products that can be advertised to the public

Under this option, references to the TGA would be allowed for all therapeutic goods for which advertising to the public is permitted. This would include the majority of medical devices, as well as most medicines available for over-the-counter sale.

Some therapeutic goods are exempt from the requirement to be included on the ARTG (in some cases the exemption may be subject to compliance with certain conditions). References to the TGA would only be permitted for products that are included on the ARTG.

Because listed complementary medicines and Class I medical devices only undergo either no assessment, or limited assessment by the TGA before they are entered in the ARTG, allowing these products to refer to TGA in advertising, depending on the nature of the reference (see What could a reference to the TGA look like? below), may not be accurate and could add to consumer confusion. Therefore, it is proposed under this option that a reference to the TGA for listed medicines and Class I medical devices should **only** be considered in conjunction with the ARTG number format (see Option 1: Indicating TGA approval through the ARTG number below).

Option 2: Only allow references to the TGA for products that have undergone pre-market assessment

Under this option, references to the TGA would be allowed for products that have undergone assessment by the TGA before they are included in the ARTG, but not products that are not self selected by consumers, such as implantable medical devices. Primarily these are:

- registered Schedule 3, Schedule 2 and general sale OTC medicines
- listed assessed and registered complementary medicines
- listed surface disinfectants
- Certain class IIa, IIb and III medical devices
- Class 3 IVDs.

This option would also be consistent with the implementation arrangements for the 'TGA assessed' claim which only applies to a medicine that has undergone pre-market evaluation by the TGA and where the label has been considered and agreed to as part of the assessment.

Option 3: Allow references to the TGA only for specific products

Under this option, the TGA may specify a particular type or class of products about which references to the TGA could be made to address particular public health needs.

This might be appropriate where there is a high risk of unlawful promotion or marketing of unapproved products that have public health importance and a reference to the TGA may help consumers to quickly and easily identify that they are buying products that are approved, listed or included, by the TGA.

For example, the TGA could in future consider authorising references to the TGA in relation to advertising for COVID-19 RATs because of the pressing need to distinguish the TGA approved RATs from the RATs being illegally promoted and supplied (see A recent case study – COVID-19 Rapid Antigen Tests (RATs)).

This authorisation could happen on an as-needs basis (i.e. the instrument of authorisation could be modified periodically as appropriate, for example as a public health need arises in relation to a particular good), and the authorisation for that particular good or category of goods could be time-limited, and/or be written with conditions.

3. What is your preferred option for the types of products, if any, that that should be able to refer to the TGA in advertising?
4. Under option 3, which class or classes of products should be able to make references to the TGA in advertising? It is important to consider this question in conjunction to the type of claim you support after reading the next section.

What could a reference to the TGA look like?

To achieve the objective of enabling consumers to more easily identify products that have met the regulatory requirements and are being lawfully advertised and sold, references to the TGA should:

- be informational rather than promotional
- accurately reflect the level of assessment of the product by the TGA, i.e. for products such as listed complementary medicines that are not subject to pre-market review by the TGA, use of a term such as "TGA approved" would be both misleading and legally incorrect.

Three options are proposed below for how references to the TGA in advertising could be implemented – you are welcome to propose alternative options or additional ideas.

Option 1: Indicating TGA approval through the ARTG number

In keeping with the current system of therapeutic goods identification, under this option advertisers would be permitted to insert 'TGA' ahead of the ARTG number. For example:

- TGA ARTG 12345 (e.g. could be used for medical devices, which are neither 'listed' nor 'registered' in law)
- TGA approval number AUST R 12345 (for products such as registered medicines that have been through a pre-market approval process)

This reference could be used in respect of **all** therapeutic goods entered in the ARTG, i.e. including Class 1 medical devices and listed medicines (see Option 1: Allow references to the TGA for all approved products that can be advertised to the public above), or a subset of goods.

Allowing advertisers to more clearly link the 'TGA' to the AUST L, AUST R and ARTG numbers in advertising and on product labels may:

- help improve consumer knowledge about the TGA and the meaning of ARTG numbers on product labels and in advertising

- provide a way for consumers to quickly and easily identify whether particular products available for self-selection have been approved by the TGA
- by providing the ARTG number, assist consumers in obtaining additional information about the particular product from the ARTG (which is on the TGA website).

An important consideration here is that the ARTG number for medical devices is not currently required in any advertising, including product labelling and packaging.

Option 2: Authorisation of a statement

Under this option, the TGA would authorise advertisers to use a statement to indicate that their product has been subject to TGA regulation in their advertising (including product labels).

This could include, for example:

- 'TGA approved'
- 'TGA registered'
- 'TGA regulated'

The statement 'TGA approved' may be the simplest and easily understood by average consumers. However, as outlined above, claims such as 'TGA approved' (and similar) are problematic in relation to certain product categories (such as listed medicines and Class I medical devices) as they may imply that the TGA has carried out an evaluation of the product. It would therefore be incorrect in law to apply it to these products.

The alternative 'TGA registered' overcomes this problem although in law medical devices on the ARTG are 'included' rather than registered. 'TGA regulated' overcomes this but in the strict sense it could also be misleading, as all medicines and medical devices in Australia are understood to be TGA regulated in general, but a particular product may not be on the ARTG.

Whichever statement is used, there may be a greater risk of false assurance for consumers if the statement is not linked to the ARTG number, and a temptation by certain marketers to make this general claim for products that are not on the ARTG (as some do now, illegally). Implementation of a 'TGA approved/registered/regulated' statement could therefore be used in conjunction with the ARTG number format (see Option 1: Indicating TGA approval through the ARTG number above).

Option 3: Authorisation of a logo or symbol

Under this option, the TGA would authorise advertisers to refer to the TGA by using a simple text based logo or symbol in advertising (including on product labels). The use of government crests or embellishment would not be permitted.

As outlined above, we are aware that most consumers are unaware of the presence or meaning of ARTG identifiers (i.e. AUST L and AUST R) on medicine labels. A text-based logo or symbol on its own or with an authorised statement (see Option 2: Authorisation of a statement above) may therefore allow consumers to quickly and easily identify products that are being lawfully supplied. However, there is risk of false assurance if the claim is not linked to a TGA ARTG number.

Like the 'TGA assessed' symbol that is already available for listed assessed complementary medicines (see Figure 1 below) it may be beneficial to have a single authorised symbol that could be used to build consumer recognition and confidence in the scheme – although the wording would likely need to be different if the scheme encompassed products that have not been assessed by the TGA prior to marketing.

Figure 1: TGA assessed claim

TGA assessed symbol	TGA assessed statement
	**"Evidence for the approved indications has been assessed by the TGA".**

5. What is your preferred option for the presentation of references to the TGA?
6. Do you have any alternative options for the statement?

How could references to the TGA be used in advertising?

Option 1: On product labels and in pack shots only

Under this option, an authorised reference to the TGA could be displayed anywhere on the product label, provided it does not detract from or be more prominent than mandatory product information.

Advertisements could show images of the product label, including the reference to the TGA, but must not make a reference to the TGA other than on the image of the label in a pack shot.

An advertisement would not be permitted to:

- include any audible commentary or further written commentary that refers to the TGA
- imply that the TGA recommends the medicine or advocates the use of the medicine above other products.

This option is intended to support consumer confidence and assist the TGA's regulatory compliance efforts by helping ensure that:

- any references to the TGA made by advertisers are consistent with those made by the product sponsor
- any references to the TGA are considered and agreed to as part of the inclusion of the product in the ARTG.

This option would also be consistent with the implementation arrangements for the 'TGA assessed'.

Option 2: In broader advertising

Under this option, an authorised reference to the TGA could be used in any advertising provided it complied with the rules of the authorisation.

This option recognises that an appropriate reference to the TGA is arguably low risk in terms of potential harm to consumers when the medicine or device is included in the ARTG.

This option would be more suitable for digital devices such as software and apps that don't have physical packaging.

7. Should references to the TGA in therapeutic goods advertising be allowed only on product labels and pack shots, or in broader product advertising?

Should the scheme be optional or mandatory?

Voluntary use of a statement:

- has the potential for negative consumer perceptions is it may be incorrectly assumed that products that do not make the resulting claim have not been included on the ARTG
- could make recognition by consumers and enforcement by the TGA more challenging.

On the other hand, a mandatory statement or reference may better support consumers to more easily identify products that have met the regulatory requirements and are being lawfully advertised and sold. However, it is recognised that this involves impost on sponsors, and a significant transition period (several years) would be required for its implementation.

An additional and important factor to consider under this option is whether there would be benefits to requiring, as mandatory, the ARTG number in advertising. ARTG numbers are already required on the labels of medicines, but while they all have ARTG numbers, there is no equivalent requirement for medical device labels.

It is likely that the TGA's compliance would be assisted if the ARTG number was shown, for example on medical device labelling and packaging, which could deter 'copy-cat' companies from making a 'TGA approved' type statement on unapproved products which do not have a valid ARTG number.

8. If implemented, should use of authorised references to the TGA in advertising be optional or mandatory for advertisers?
9. Do you think it should be mandatory for advertisers to display the product's ARTG number in advertising?

Implementation

After this consultation, feedback received will be considered to determine the preferred approach, and policy options considered by the Government.

Depending on the options chosen, the TGA may need to specify the circumstances in which references to the TGA can lawfully be used in an advertisement in an instrument of authorisation that will be made under the Act (although changes to the Act itself would not be required). Transitional arrangements and assessments of regulatory impact would depend on the particular options that are taken forward for further consideration.

A legal authorisation to refer to the TGA would be required because a claim that suggests or implies that goods have been recommended, approved or endorsed by the TGA, as outlined at the beginning of this paper, would, unless authorised, breach the Act and the Advertising Code, which could result in criminal and/or civil penalties, and/or cancellation of the good from the ARTG.

Education

In order to foster improved consumer understanding of the therapeutic goods regulatory framework, any authorisation of references to the TGA in advertising would be supported by:

- consumer and healthcare professional education to assist with interpretation of the reference
- updated industry, healthcare professional and consumer guidance on the TGA website.

Appendix 1: Regulation of different product types by the TGA: Risk based approach

The Australian regulatory regime for therapeutic goods regulates products according to risk, and the nature of regulation is set down in the Act and Regulations.

The higher the potential risks of a product, the more they are reviewed prior to inclusion on the ARTG. The level of risk that is identified determines:

- what type of assessment the TGA carries out
- the amount and type of information the TGA reviews
- the degree of scrutiny necessary **before** the product can be made available in Australia.

In summary:

- Medicines containing low-risk ingredients, including most complementary medicines, are listed (AUST L) on the ARTG rather than assessed by the TGA. Listed medicines are entered in ARTG on the basis of certifications by the product sponsors and undergo no or limited assessment by the TGA before they can be supplied in Australia.
- Medicines carrying a higher risk, which include all prescription and many over the counter medicines, receive a higher degree of scrutiny and, if found to comply, are registered (AUST R) on the ARTG. Registration involves an independent assessment of data related to safety, quality and efficacy of the product by the TGA.
- A similar risk-based approach is taken with the assessment of evidence related to medical devices and in vitro diagnostic medical devices (IVDs) included on the ARTG. Low-risk devices (such as bandages and IVDs for performing a liver function test) rely on certification by sponsors (Class I devices and Class 1 and 2 IVDs), whereas higher-risk devices and IVDs (such as pacemakers or tests for serious diseases) involve independent assessment of the available evidence by the TGA (Class III devices and Class 3 and 4 IVDs).

Version history

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