



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

# Advertising compliance self-assessment checklist

## Consumer advertising

This checklist has been designed to assist advertisers to self-assess their consumer advertising for compliance with the [Therapeutic Goods Act 1989](#) (the Act), the [Therapeutic Goods Regulations 1900](#) (the Regulations) and the [Therapeutic Goods Advertising Code 2021](#) (the Code).

This checklist should be used in conjunction with reading the Act, the Regulations, the Code and published [guidance](#). It will help you identify which parts of the Code are relevant to your advertisement and where you can get more information.

The guidance was created to help advertisers consider how to comply with the Code as there are some fundamental requirements when advertising any therapeutic good. You may also wish to use [decision trees](#) to aid you during the checklist.



The use of this checklist to assess an advertisement for compliance is not a guarantee of compliance or protection from [compliance action](#).

The TGA will however consider the appropriate use of the checklist in relation to an advertisement as a demonstration of an advertiser's willingness to comply.

When assessing compliance, an advertisement is considered in terms of:

- the total presentation and context, including the target audience
- the likely impact on the reasonable consumer within the target audience for the advertisement.

There are 3 parts to this checklist.

You should review each before making a final assessment that your advertising is compliant.

## 1. Can I advertise this product to the public?

Section 42DL of the Act prohibits certain types of products from being advertised to the public. Use the [Can I advertise this therapeutic good to the public?](#) decision tree to help you assess whether your advertising can be directed to the public.

If you are sure that you can advertise your product to the public, then proceed with this checklist.

## 2. Does the Code apply to your advertising?

This section takes you through Part 2, Section 6 of the [Code](#) to help you assess whether the Code applies to your advertisement.

If you answer '**yes**' to any of the following questions, then it is likely that the Code **does not apply** to your advertisement.

If you answer '**no**' to all questions, then the Code **applies** to your advertisement, and you should continue with Section 3 of the checklist (below) to assess your compliance with the Code rules.

Question	Yes	No
1. Is your advertisement directed exclusively to health professionals or other persons listed in section 42AA of the Act?  <small>For more information see <a href="#">Advertising to health professionals</a>.</small>	<input type="checkbox"/> The Code does not apply	<input type="checkbox"/> Go to next question
2. Is your advertisement part of, or otherwise comprises of, a public health campaign?  <small>For more information refer to Part 2, section 6(1)(b) of the <a href="#">Code</a></small>  <small>The following resources may be helpful in answering this item:</small>  <a href="#">Department of Health Public health Campaigns</a>  <a href="#">Australian Government Department of Health Programs &amp; Campaigns</a>	<input type="checkbox"/> The Code does not apply	<input type="checkbox"/> Go to next question
3. Is your advertisement about a COVID-19 vaccine and is it made in accordance with the <a href="#">Therapeutic Goods (Restricted Representations - COVID-19 Vaccines) Permission 2022</a> ?  <small>For more information see <a href="#">Communicating about COVID-19 vaccines</a></small>	<input type="checkbox"/> The Code does not apply	<input type="checkbox"/> Go to next question
4. Does your advertisement only contain price information about a registered medicine containing a substance in schedule 3, 4 or 8 to the current Poisons Standard (other than a substance included in Appendix H)?  <small>For more information see <a href="#">Part 9 of the Code – Price information</a></small>	<input type="checkbox"/> Part 9 of the Code applies. Go question 31 in section 3 of this checklist (below)	<input type="checkbox"/> Go to next question

	Question	Yes	No
5.	<p>Is the information that you intend to publish or otherwise disseminate genuine news that is broadcast or published by:</p> <ul style="list-style-type: none"> <li>• a broadcaster</li> <li>• a datacaster</li> <li>• the SBS</li> <li>• a publisher of a print or digital edition of a newspaper or magazine that is or was available to the public by way of purchase in Australia?</li> </ul> <p>Note: information that is disseminated via social media, magazines, posters and flyers is likely considered advertising and not genuine news.</p> <p>For more information see <a href="#">Activities that represent advertising</a>.</p> <p>For more information refer to Part 2, section 6(3) of the <a href="#">Code</a> and Code guidance – Part 2 – <a href="#">Application of this code</a></p>	<input type="checkbox"/> The Code does not apply	<input type="checkbox"/> Proceed to the next section

### 3. Does your advertisement comply with the Advertising Code?

This section leads you through the sections of the Code to help you to assess whether your advertisement is likely to be compliant with the Code rules.

For every answer that highlights a compliance issue, you should review and amend your advertisement then reassess compliance. Once sure, continue with the checklist in full prior to the advertisement being published or otherwise disseminated.

	Question	Yes	No
1.	<p>Is your advertisement accurate, balanced and not misleading or likely to be misleading to consumers?</p> <p>For more information refer to Part 3, section 8(1) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Amend advert to meet requirement
2.	<p>Can you substantiate all information and claims you intend to make about the product(s) in the advertisement?</p> <p>For more information see the TGA's published evidence guidelines for <a href="#">listed medicines</a>, <a href="#">assessed listed medicines</a>, <a href="#">over-the-counter (OTC) medicines</a>, <a href="#">medical devices</a>.</p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Substantiate claims before publishing or disseminating

	Question	Yes	No
3.	<p>Are the claims made in the advertisement consistent with the indications or the intended purpose for the product(s) as it appears in the Register (if applicable)?</p> <p>You should review the product's entry on the <a href="#">Australian Register of Therapeutic Goods</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Amend claims to ensure they are not inconsistent with indications or intended purpose
4.	<p>Does your advertisement represent the product(s) as being:</p> <ul style="list-style-type: none"> <li>safe, without harm or side-effects</li> <li>effective in all cases</li> <li>a guaranteed cure</li> <li>infallible, unfailing, magical or miraculous?</li> </ul> <p>For more information refer to Part 3, Section 9(1) of the <a href="#">Code and Code guidance – Part 3 – General requirements</a></p>	<input type="checkbox"/> Remove any representation that contravenes this provision	<input type="checkbox"/> Go to next question
5.	<p>Is your advertisement likely to cause undue alarm, fear or distress in consumers?</p> <p>For more information refer to Part 3, Section 9(2)(a) of the <a href="#">Code and Code guidance – Part 3 – General requirements</a></p>	<input type="checkbox"/> Remove statements or implications that may cause undue alarm, fear or distress	<input type="checkbox"/> Go to next question
6.	<p>Does your advertisement contain a representation to the effect that not using the product may result in harmful consequences?</p> <p>For more information refer to Part 3, Section 9(2)(b) of the <a href="#">Code and Code guidance – Part 3 – General requirements</a></p>	<input type="checkbox"/> You cannot advertise in this way without a <a href="#">section 42DF approval</a> or <a href="#">section 42DK permission</a>	<input type="checkbox"/> Go to next question
7.	<p>Does your advertisement contain any statement or claim that is inconsistent with the product(s):</p> <ul style="list-style-type: none"> <li>label</li> <li>directions for use</li> <li>consumer medicine information</li> <li>instructions for use</li> <li>patient information leaflet?</li> </ul> <p>For more information refer to Part 3, Section 9(3)(a) of the <a href="#">Code and Code guidance – Part 3 – General requirements</a></p>	<input type="checkbox"/> Alter advertisement to make it consistent with the information pieces	<input type="checkbox"/> Go to next question

	Question	Yes	No
8.	<p>Does your advertisement contain any claim or statement that is likely to result in a consumer delaying or being discouraged from:</p> <ul style="list-style-type: none"> <li>seeking out medical attention, or</li> <li>using a treatment prescribed by a medical practitioner?</li> </ul> <p>For more information refer to Part 3, Section 9(3)(b) and (c) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> Alter advertisement to meet requirement	<input type="checkbox"/> Go to next question
9.	<p>Does your advertisement contain a claim or statement that exaggerates the efficacy or performance of your product(s)?</p> <p>For more information refer to Part 3, Section 9(3)(d) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> Alter advertisement to meet requirement	<input type="checkbox"/> Go to next question
10.	<p>Does your advertisement contain a statement or claim that is likely to encourage inappropriate or excessive use of the advertised product(s)?</p> <p>For more information refer to Part 3, Section 9(3)(e) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> Alter advertisement to meet requirement	<input type="checkbox"/> Go to next question
11.	<p>Does your advertisement compare the product to other therapeutic goods or therapeutic services, including suggesting that these other goods or services are harmful or ineffective?</p> <p>For more information refer to Part 3, Section 9(3)(f) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> Alter advertisement to meet requirement	<input type="checkbox"/> Go to next question
12.	<p>Is your advertisement consistent with a current public health campaign?</p> <p>For more information refer to Part 3, Section 10 of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p> <p>The following resources may also be of assistance in answering this item:</p> <p><a href="#">Department of Health Public health Campaigns</a></p> <p><a href="#">Australian Government Department of Health Programs &amp; Campaigns</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Alter advertisement to meet requirement
13.	<p>Does your advertisement make a scientific or clinical representation where both:</p> <ul style="list-style-type: none"> <li>the terminology is clearly communicated and can be readily understood by the target audience; AND</li> <li>the representations are consistent with the body of scientific or clinical evidence available?</li> </ul> <p>For more information refer to Part 3, Section 11(2)(a) and 11(2)(b) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a> and <a href="#">scientific citations</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Alter advertisement to meet requirement

	Question	Yes	No
14.	<p>If your advertisement refers to scientific or clinical research, have you:</p> <ul style="list-style-type: none"> <li>• identified the researcher, AND</li> <li>• identified the financial sponsor of the research (where you reasonably ought to know this information), AND</li> <li>• cited the research in a way that enables a consumer to access that research?</li> </ul> <p>For more information refer to Part 3, Section 11(3) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a> and <a href="#">scientific citations</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Alter advertisement to meet requirement
15.	<p>Is your advertisement directed to children <u>under</u> 12 years?</p> <p>For more information refer to Part 3, Section 12 of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> You cannot advertise to children <u>under 12 years</u> . Amend your advertisement to meet the requirement.	<input type="checkbox"/> Go to next question
16.	<p>Is your advertisement directed to children 12 years and <u>over</u>?</p> <p>For more information refer to Part 3, Section 12 of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Go to question 18
17.	<p>An advertisement may only be directed to children 12 years and over if:</p> <ul style="list-style-type: none"> <li>• the product(s) is mentioned in Annexure 1 of the Code and it complies with conditions for that item (if any), AND</li> <li>• the product does not contain a substance included in Schedule 2, 3, 4 or 8 to the current <a href="#">Poison Standard</a>.</li> </ul> <p>Does your advertisement meet these requirements?</p> <p>For more information refer to Part 3, Section 12(3) of the <a href="#">Code</a> and Code guidance – Part 3 – <a href="#">General requirements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> You cannot advertise to children 12 years and over. Amend your advertisement and recheck your compliance
18.	<p>Does your advertisement contain the mandatory statements and other required information for the type of product you are advertising?</p> <p>For more information refer to Part 4 of the <a href="#">Code</a> and Code guidance – Part 4 – <a href="#">Mandatory statements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Apply relevant mandatory statement and other required information
19.	Does your advertisement use a testimonial or endorsement about therapeutic goods?	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Go to question 27

	Question	Yes	No
20.	<p>Is the testimonial or endorsement used in your advertisement consistent with the following materials?</p> <ul style="list-style-type: none"> <li>the label of the good</li> <li>the directions or instructions for use for the goods</li> </ul> <p>For more information refer to Part 6, Section 24(2)(a)(b) of the <a href="#">Code</a> and <a href="#">Code guidance – Part 6 – Testimonials and endorsements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Remove the inconsistent testimonial or endorsement
21.	<p>Do any claims used in a testimonial or endorsement in the advertisement for the product meet the following requirement?</p> <ul style="list-style-type: none"> <li>For products that <b>are included on the Register</b>:           <ul style="list-style-type: none"> <li>the claims are not inconsistent with the indications or intended purpose for the product as accepted in the Register, OR</li> </ul> </li> <li>For products <b>not on the Register and are not required to be</b>:           <ul style="list-style-type: none"> <li>claims made are not inconsistent with the indication or intended purpose as displayed on the label of the products or direction or instructions for use.</li> </ul> </li> </ul> <p>For more information refer to Part 6, Section 24 (2)(c)(i) and 24(2)(c)(ii) of the <a href="#">Code</a> and <a href="#">Code guidance – Part 6 – Testimonials and endorsements</a> and the <a href="#">Register</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Remove the inconsistent testimonial or endorsement
22.	<p>A testimonial or endorsement used in an advertisement that refers to a health benefit must be typical of the benefit expected from the goods when used in accordance with:</p> <ul style="list-style-type: none"> <li>the label</li> <li>the directions for use or instructions for use</li> <li>the indications or intended purpose accepted in relation to the inclusion in the ARTG (where applicable).</li> </ul> <p>Does your advertisement comply with this requirement?</p> <p>If this question does not apply to you, please go to next question</p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Remove the testimonial or endorsement that does not meet the requirements
23.	<p>For any testimonial used in your advertisement, have you ensured that it was not made by a person or organisation that is excluded for the purposes of Part 6 of the Code?</p> <p>For more information refer to Part 6, Section 24(4) of the <a href="#">Code</a> and <a href="#">Code guidance – Part 6 – Testimonials and endorsements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Check. Then remove any testimonial from advertisement that does not comply

	Question	Yes	No
24.	<p>For any testimonial used in your advertisement, have you verified:</p> <ul style="list-style-type: none"> <li>• that person's identity</li> <li>• that they have used the advertised product</li> <li>• the content of their testimonial?</li> </ul>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Remove testimonial where you cannot verify the required details
25.	<p>For any endorsement intended to be used in your advertisement, have you ensured that it was NOT made by a person who is excluded from being able to make an endorsement for the purposes of the Code?</p> <p>For more information refer to Part 6, Section 24(6) of the <a href="#">Code and Code guidance – Part 6 – Testimonials and endorsements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Remove non-compliant endorsements
26.	<p>Where your advertisement contains an endorsement made by an organisation that represents interests of healthcare consumers or interests of current or former health professionals or medical researcher, have you ensured that it discloses:</p> <ul style="list-style-type: none"> <li>• the name of the organisation, AND</li> <li>• any valuable consideration received for the endorsement?</li> </ul> <p>For more information refer to Part 6, Section 24(6)(f) of the <a href="#">Code and Code guidance – Part 6 – Testimonials and endorsements</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Either remove endorsement OR Include required disclosures
27.	<p>Does your advertisement contain or consist of a sample, or offers a sample of a therapeutic good?</p> <p>For more information refer to Part 7, Section 25 (1) of the <a href="#">Code and Code guidance – Part 7 – Samples and incentives</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> I am not offering a sample in my ad.  Go to question 29
28.	<p>If your advertisement offers a sample of a therapeutic good, are you satisfied that each of the following is met?</p> <ul style="list-style-type: none"> <li>• the product is mentioned in <a href="#">annexure 2</a> and complies with any conditions for that item (if any)</li> <li>• the product does not contain substances included in Schedule 2, 3, 4 or 8 to the current <a href="#">Poison Standard</a></li> <li>• the samples are contained in an original pack accepted in relation to the inclusion of the goods in the ARTG (if applicable).</li> </ul> <p>For more information refer to Part 7, Section 25 (1) of the <a href="#">Code and Code guidance – Part 7 – Samples and incentives</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> If the answer is no to any of the points, then you cannot offer this sample in your advertisement

	Question	Yes	No
29.	<p>Does your advertisement offer any incentive or commission to a pharmacy assistant or retail salesperson (who is not a health professional) in exchange for recommending or supplying the products?</p> <p>For more information refer to Part 7, Section 26 of the <a href="#">Code</a> and Code guidance – Part 7 – <a href="#">Samples and incentives</a></p>	<input type="checkbox"/> Remove any incentives or commissions from the advertisement	<input type="checkbox"/> Go to next question
30.	<p>Does your advertisement contain a <a href="#">prohibited or restricted representation</a> that has not been <a href="#">permitted</a> or approved by the TGA?</p> <p>A representation in an advertisement about therapeutic goods that refers to a serious form of a disease, condition, ailment or defect is a <b>restricted representation</b>. Under section 42DL of the Act, they can only be used with prior <a href="#">approval or permission</a> from the TGA. If there is no existing permission in place, Approval to use a restricted representation under section 42DF of the Act can be granted following a successful application from the advertiser.</p> <p>Additionally, certain representations are <b>prohibited representations</b> in advertising. See Schedule 2, Part 1 of the <a href="#">Regulations</a> for full details. These include references to abortifacient action, the treatment or prevention of cancer, sexually transmitted diseases, HIV/AIDS, hepatitis C and mental illnesses.</p> <p>Prohibited representations must not be used in advertising unless permitted by the TGA.</p> <p>For more information refer to Part 8 of the <a href="#">Code</a> and Code guidance – Part 8 – <a href="#">Restricted representations</a></p> <p>For more information see <a href="#">Apply to use the restricted representation in advertising</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> Remove the unapproved prohibited/ restricted representation
31.	<p>Does your advertisement <b>only</b> contain price information about a registered medicine containing a substance included in schedule 3, 4 or 8 to the current Poisons Standard (other than a substance included in Appendix H)?</p> <p>For more information refer to Part 9 of the <a href="#">Code</a> and Code guidance – Part 9 – <a href="#">Price information</a></p>	<input type="checkbox"/> Go to next question	<input type="checkbox"/> If you are sure that your advert is compliant with all of the above requirements, and your information is not intended to be price information only, then it is likely that you can publish or disseminate your advertisement
32.	<p>Does your advertisement comply fully with Part 9 of the <a href="#">Code</a></p> <p>For more information refer to Part 9 of the <a href="#">Code</a> and Code guidance – Part 9 – <a href="#">Price information</a></p>	<input type="checkbox"/> It is likely that you can publish or disseminate your advertisement	<input type="checkbox"/> Either comply with Part 9 of the Code or you cannot publish the price information list

## Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Education and Compliance Branch	July 2018
V2.0	Substantial update to checklist including to include content consistent with the 2021 Code	Advertising and Compliance Education and Policy Section Regulatory Compliance Branch	November 2023