



# Therapeutic goods advertising: Ensuring 'natural' claims are not misleading

Guidance on how advertisers can use terms such as 'natural' without misleading consumers.

## Last updated:

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## Introduction

The use of the term 'natural' (and related terms such as 'naturally derived', 'sourced from nature', 'all natural') in therapeutic goods advertising is regulated by the Therapeutic Goods Administration (TGA) to the extent that the *Therapeutic Goods Advertising Code (No.2) 2018* (**'the Code'**) prohibits claims from being misleading and requires claims to be truthful, valid, accurate and substantiated.<sup>[1].([#fn1](#))</sup>

While it is ultimately the responsibility of the advertiser to ensure advertising claims are not misleading, a guideline for industry and consumers is useful to clarify the TGA's interpretation of the meaning of 'natural' in the context of therapeutic goods, including how the claim will be assessed in compliance reviews.

This guidance provides information for industry on how claims about the 'naturalness' of a particular therapeutic good and/or its ingredients can be made without misleading consumers.

For a proportion of consumers, a claim that a therapeutic good is natural or its ingredient/s are natural will be material to purchasing choices. This may be because the consumer perceives the natural good or ingredient to be safer than another good or ingredient, or in some other way superior to a good or ingredient not represented as 'natural'.

While it is clear that a therapeutic good cannot be 'natural' in the way a whole food can be, consumers are likely to reasonably understand that a 'natural' therapeutic good or ingredient is one that is obtained from a natural source and has undergone only minimal processing.

Providing insufficient or no information about the meaning of a claim, when the meaning is open to various interpretations (as is the case with 'natural' claims), will result in consumers being misled. As noted by the Australian Competition and Consumer Commission ('ACCC')<sup>[2]</sup><sup>(#fn2)</sup> in relation to 'natural' claims on food labels:

Consumers may view what is 'natural' differently to manufacturers and food technologists. When providing a label with a claim that the product is 'natural', thought should be given to what the consumer would think. In those cases where the term 'natural' meets a technical definition, a code or a standard, and this information is not available to the consumer, the consumer is left to draw their own conclusion and may therefore be misled.

The TGA recognises that imparting potentially lengthy explanations in an advertisement (including on the label when such claims are used in that context) may not be feasible and may detract from other important information required to be conveyed in the advertisement. Therefore the advertiser must ensure that any claims relating to the 'naturalness' of therapeutic goods are either consistent with these guidelines or satisfactorily explained in the advertising. This will enable consumers to have access to information that will assist them in understanding the meaning of such claims and will assist advertisers in knowing how, and in what contexts, such claims can be made and therefore avert compliance concerns.

The following information relates to claims made about specific goods. In instances where the references to 'natural' are not made in the context of a direct claim about a particular good, such as when marketing goods under a company or brand name, the onus is on the advertiser to ensure the consumer is not led to the view that all the products advertised under that name have various qualities of 'naturalness' if that is not the case. This may be achieved in various ways, for example by minimising prominence of the brand name in advertisements for therapeutic goods that are not 'natural' (including on labels) or by explicitly stating the synthetic ingredients in the product.

## Definition of 'natural'

Natural is defined in the Macquarie Dictionary as:

'existing in or formed **by nature; not artificial**'<sup>[3]</sup><sup>(#fn3)</sup> and **not synthetic**'<sup>[4]</sup><sup>(#fn4)</sup>

Recognising that all therapeutic goods have had the raw starting material (unprocessed material) transformed through manufacturing processes into the final product (such as tablets, capsules, tinctures, topical creams and ointments, herbal extracts), as well as acknowledging that many synthetic pharmaceutical medicines are originally derived from a variety of natural sources<sup>[5]</sup><sup>(#fn5)</sup>

5), the TGA has focussed on the processing steps involved in the transformation of the raw material to the finished good in defining the term natural when it is used in the context of promoting therapeutic goods.

## Form found in nature

The starting, or 'raw material' from which the 'natural' therapeutic good (or therapeutic good ingredient) is derived must be a form physically found in nature - plants, (and other organisms that are treated as plants in the International Code of Botanical Nomenclature (<https://archive.bgbm.org/iapt/nomenclature/code/SaintLouis/0001ICSLContents.htm>), such as fungi, algae and yeast), animal, marine, mineral or bacterial.

## Processing/manufacturing steps

The manufacturing of the therapeutic good to produce a finished dosage form must involve 'minimal processing'. The production steps to achieve 'minimal processing' can include:

- freezing
- drying
- filtering
- grinding and powdering
- fermentation
- boiling and primary distillation
- solvent extraction
- concentration, or
- fractionation.

## Same chemical identity

In addition to the 'minimal processing' requirement, the substances occurring in the starting material **must**:

- be chemically identical; and

**must not:**

- have undergone any chemical conversion or modification - for example, to become a derivative or salt form.

### Example 1: Vitamin E

- ✓ Vitamin E (d-alpha-tocopherol) isolated from soybean is natural.
- The derivative, d-alpha-tocopheryl acetate, produced via chemical modification of
- ✗ vitamin E from soybean, is not natural, nor is the totally synthetic dl-alpha-tocopheryl acetate.

**As a synthetic substance may be chemically identical to a naturally-occurring substance**, for an ingredient to be 'natural' it must meet **both** the requirement to be 'minimally processed' AND the requirement to be chemically identical.

An advertiser seeking to claim that a particular therapeutic good is 'natural', should ensure that:

1. the starting or 'raw material' from which the natural therapeutic good is derived must be a form found in nature, and
2. the therapeutic good or therapeutic ingredient must have only undergone 'minimal processing', and
3. the finished therapeutic good ingredient must not have become a new chemical identity.

## Example 2: Synthetic Vitamin C

The vitamin C obtained from chemical synthesis is chemically identical to that derived from food. Most vitamin C supplements however are more than minimally processed - they are wholly made in a laboratory/factory.

Food-derived vitamin C supplements use a food source (such as rosehips or acerola) and manufacture the finished dosage form using manufacturing steps, such as extraction and drying, that would reasonably be considered to meet the definition of 'minimally processed'.

- ✗ Synthetic vitamin C cannot be described as natural as, while chemically identical to vitamin C derived from food, it has not been minimally processed
- ✓ Food derived vitamin C can be described as natural where it has only undergone extraction and drying

# Representing a therapeutic good in its entirety as natural

Only in very limited circumstances would a claim (without qualification) that a product in its entirety is 'natural' not be misleading. For a therapeutic good to be advertised without qualification as 'natural', every ingredient in that good:

- must be only minimally processed from the form found in nature (such as a whole food or plant), AND
- must not have been transformed (for example, synthetically modified) to an extent that the ingredient is a different chemical substance.

In such cases it may be obvious to the consumer how such a product is 'natural', however the advertiser is at liberty to explain the claim further by including information drawn from the definition of 'natural' as articulated in this Guidance.

## **Example 3: Entirely natural products**

Dried, powdered and encapsulated turmeric root:

- ✓ 'Natural turmeric - does not contain artificial colours, chemical preservatives or any other synthetic ingredients'

If a therapeutic good contains both 'natural' ingredients and chemically synthesised active substances (including synthetic compounds as an active ingredient or excipient), the term 'natural' may still be used. However it must be qualified to ensure the consumer would not be led to the view that every ingredient in the therapeutic good is natural. The advertiser may choose to specify which ingredients in the therapeutic good are natural or may choose to identify the synthetic 'non-natural ingredients', or both.

## **Example 4: Therapeutic goods containing both natural and chemically defined substances**

For example, any of the following would be acceptable:

- ✓ '[product name] contains 60% natural [name of ingredient]'
- ✓ '[product name] contains natural [name of ingredient], preserved with sodium benzoate'
- ✓ '[product name] contains [name of ingredient], a natural active ingredient'
- ✓ '[product name] contains the natural active ingredients [name of ingredient] and [name of ingredient]'

## 'Natural' references in other contexts

The TGA recognises that a number of existing businesses, particularly within the complementary medicines industry, operate under company or trading names referencing 'natural' or refer to 'natural' within brand or range names. We acknowledge that such references to 'natural' within a trading name would not by itself, **automatically** lead consumers to a view that all therapeutic goods marketed by that company are claiming to be 'natural'. However, the advertiser must ensure that it is clear to a consumer that a company name (and any associated taglines or logos) relate to the company and not to the specific therapeutic goods marketed under that trading name. A high degree of caution is required if the actual name of the product includes the word 'natural' as it could imply to consumers that the product is wholly natural or contains natural ingredients.

**Example 5: Complaints Resolution Panel - Complaint number 2017-09-001 ([http://www.tgacrp.com.au/complaint-register/?\\_year=2017&\\_search=2017%2F09%2F001&\\_id=3282](http://www.tgacrp.com.au/complaint-register/?_year=2017&_search=2017%2F09%2F001&_id=3282))**

**Product:** Botani Phytoseptic Natural Anti-Fungal Skin Cream

**Issue:** use of 'Natural' in product name

The complaint before the Panel was in relation to allegedly overstated and misleading claims within an internet advertisement. In addition, the Panel raised possible breaches of paragraph 4(1)(b)<sup>[6]</sup><sub>(#fn6)</sub> and 4(2)(c)<sup>[7]</sup><sub>(#fn7)</sub> of the Therapeutic Goods Advertising Code 2015 ('2015 Code') by the use of 'Natural' within the name of the product.

The product sponsor refuted the alleged breaches on the basis that:

- the active ingredient was an extract of *Hydrastis canadensis*
- the "vast majority of the other ingredients in the product were herbal extracts", and
- the advertisement didn't claim "all natural" or "100% natural".

The Panel noted that the inclusion of the word 'Natural' as part of the name and as a claim of benefit would lead any reasonable consumer to the view that the product comprised only ingredients that are natural (active and excipient).

In reviewing the ingredients of the product, the Panel was satisfied that some of the ingredients were not natural. They found that the claim implied the product was wholly natural, not just some of the ingredients, and therefore the claim was not valid and was found to be misleading in breach of sections 4(1)(b) and 4(2)(c) of the 2015 Code.

**How could the advertising be made compliant?**

As noted in this guidance, the concerns of the Panel could have been overcome by the advertiser explicitly stating the synthetic ingredients in the product, wherever the natural claim was made (see [Definition of 'natural' \(#definition-natural\)](#), below).

## Therapeutic goods with a natural mode of action

Some advertisers use claims to the effect that an advertised therapeutic good has a 'natural mode of action'. The TGA considers that these claims will convey to the consumer a process which is, or mimics, a normal physiological process in the body. For example 'works naturally' and 'acts naturally'. It is, for example, reasonable to claim that a bulk forming laxative acts naturally to the extent that it invokes a normal physiological process. However, advertisers need to exercise caution to ensure they do not imply that the good itself is natural, if this is not the case. Advertisers should ensure that sufficient justification for making natural mode of action claims are provided to consumers, within the body of the advertisement or by reference to further information, to ensure that ordinary consumers are not misled. Further, as most medicines act on the physiology of the body, it may mislead consumers to state or imply a medicine has a natural mode of action.

## Safety and efficacy

Notwithstanding that the Code prohibits claims in advertisements to the public that the advertised good is safe or free from side effects, there are risks of consumer misperceptions that 'natural' means 'safe'.

While claims that a therapeutic good is natural or that it contains natural ingredients are not prohibited, care must be taken to ensure the 'natural' qualities of the goods are not correlated, expressly or by implication, with other qualities such as safety and/or efficacy.

### **Example 6: Inappropriate safety and efficacy claims**

Advertisers should ensure that 'natural' claims about therapeutic goods do not imply that they are safer or more efficacious than other therapeutic goods. The types of claims that are likely to correlate 'natural' with safety or efficacy include:

- ✗ 'protect your child's health by choosing natural'
  - ✗ 'nature knows best'
  - ✗ 'no synthetic ingredients - you can rest assured'
  - ✗ 'you can trust [product name], it's all natural'
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## Footnotes

[1] Part 2 of the *Therapeutic Goods Advertising Code (No. 2) 2018*

(#f  
n1  
s)

[2] See the ACCC's food and beverage guidelines for further information at

(#f <https://www.accc.gov.au/publications/food-and-beverage-industry-food-descriptors-guideline-to-the-trade-practices-act> (<https://www.accc.gov.au/publications/food-and-beverage-industry-food-descriptors-guideline-to-the-trade-practices-act>).

[3] Made by human skill and labour (opposed to natural) <https://www.macquariedictionary.com.au> (<https://www.macquariedictionary.com.au>).

n3  
s)

[4] ∞ denoting or relating to chemical compounds, resins, rubbers, etc., formed by chemical reaction in a laboratory or chemical plant, as opposed to those of natural origin.

(#f <https://www.macquariedictionary.com.au> (<https://www.macquariedictionary.com.au>).

n4  
s) [5] D.A. Goldstein, J.A. Thomas, Biopharmaceuticals derived from genetically modified plants, *QJM: An International Journal of Medicine*, Volume 97, Issue 11, November 2004, Pages 705-716,

n5 <https://doi.org/10.1093/qjmed/hch121> (<https://doi.org/10.1093/qjmed/hch121>).

s) [6] Section 4(1)(b) of the 2015 Code required that an advertisement for therapeutic goods *must* contain only correct and balanced statements only and claims which the sponsor has already verified.

n6  
s)

[7] Section 4(2)(c) of the 2015 Code required that an advertisement for therapeutic goods *must not* mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions.

n7  
s)

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### Topics:

[Advertising \(https://www.tga.gov.au/how-we-regulate/advertising\)](https://www.tga.gov.au/how-we-regulate/advertising)

[Biologicals \(https://www.tga.gov.au/products/biologicals-blood-and-tissues-and-advanced-therapies/biologicals\)](https://www.tga.gov.au/products/biologicals-blood-and-tissues-and-advanced-therapies/biologicals)

[Medical devices \(https://www.tga.gov.au/products/medical-devices\)](https://www.tga.gov.au/products/medical-devices)

[Medicines \(https://www.tga.gov.au/products/medicines\)](https://www.tga.gov.au/products/medicines)

[Other therapeutic goods \(https://www.tga.gov.au/products/other-therapeutic-goods\)](https://www.tga.gov.au/products/other-therapeutic-goods)



