Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Guidance on mushroom products

Complying with therapeutic goods advertising requirements

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Contents

About this mushroom products guidance

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care and is responsible for administering the regulation of therapeutic goods.

This guidance relates to the advertising of mushroom products that are used for therapeutic purposes and are therapeutic goods. Commonly, these are products containing mushroom extracts that are advertised with therapeutic claims, including claims about the treatment or prevention of disease.

The advertising and supply of therapeutic goods must comply with the:

- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods Regulations 1990* (the Regulations)
- Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Advertising Code).

In Australia, there are differences in the way foods and therapeutic goods are regulated. Foods and therapeutic goods have separate standards and regulatory controls for safety, quality, efficacy, labelling, and claims made about the product.

This guidance explains when mushroom products used for therapeutic purposes are likely to be considered foods, and when they are likely to be considered therapeutic goods under the Act.

If therapeutic claims are made about a mushroom product, then it is likely to be a therapeutic good. Mushroom products that are therapeutic goods must be entered in the Australian Register of Therapeutic Goods (the ARTG) before they are advertised for use or supply in Australia. Restricted and prohibited representations cannot be made about therapeutic goods without prior approval or permission from the TGA.

What are therapeutic goods?

Therapeutic goods are defined in the Act[1] as goods that are represented to be, or are likely to be taken to be, for:

- therapeutic use
- use in, or in connection with, preventing, diagnosing, curing, or alleviating a disease, ailment, defect or injury in a person
- use in, or in connection with, influencing, inhibiting or modifying a physiological process in a person.

Therapeutic goods pose a higher risk to consumers than ordinary consumer goods and are regulated by the TGA. They must be entered in the ARTG to ensure a level of safety, quality and efficacy. When therapeutic goods are supplied outside of the regulatory framework, there are no such assurances which poses an unacceptable risk to consumer health.

[1] Please refer to the definition in subsection 3(1) of Act for full context https://www.legislation.gov.au/Series/C2004A03952

What is a food?

Generally, a product is considered a food when it:

- is traditionally used in Australia or New Zealand as a food for human consumption, in the form that it is presented in
- has an applicable food standard
- is consumed orally
- is not a medicine
- does not make therapeutic claims.

State and territory food agencies regulate food in accordance with both state/territory and national food legislation, including food standards set by the statutory body Food Standards Australia New Zealand (FSANZ). The TGA does not regulate foods.

Generally, when a food standard applies to a product, that product cannot also be regulated as a therapeutic good under the Act.

How to tell if a mushroom product is a food or a therapeutic good

Mushroom products come in a variety of forms, from whole mushrooms to liquid and powdered extracts. Whether the products are foods or therapeutic goods can be nuanced and involves a consideration of the product ingredients, product presentation and, in some cases, the method of manufacture.

Advertisers and suppliers must assess their products carefully to determine whether they are regulated as foods or therapeutic goods because different regulatory requirements apply.

Information about food and medicine regulation is available on the TGA website. The Food-Medicine Interface Guidance Tool can be used to work out whether particular products are likely to be therapeutic goods or not.

Advertisers and suppliers who are unsure of their regulatory obligations are encouraged to seek independent legal advice or the assistance of a regulatory affairs consultant.

Therapeutic goods

Products that contain mushroom extracts (often supplied in the form of a liquid or powder) are likely to be therapeutic goods, and regulated by the TGA, particularly if they:

- are supplied in capsule or tablet form
- contain concentrated or isolated compounds which are intended for, and presented for, therapeutic use (whether on the product label or in other advertising)
- are manufactured using processing methods, such as alcohol extraction, which are consistent with therapeutic goods rather than food processing
- are used and advertised to be used in traditional medicine
- make therapeutic claims, on the product label or in other advertising. For example, the product is:
  - described as ‘medicinal’, a ‘traditional medicine’ or a ‘tincture’

- intended to be used for (makes claims about) the treatment or prevention of disease
- presented with dosage information like medicines
  - ‘Take 1ml per day, with or without food’
  - ‘Take 2 capsules in the morning’.
- presented with a warning such as those on medicines but are not prescribed by a relevant food standard in relation to the product
  - ‘Not to be taken by children under 15 years of age’
  - ‘Do not take if pregnant or breastfeeding’.

The above list is not exhaustive. Suppliers and advertisers must assess their individual products carefully.

Mushroom products supplied in capsule form or manufactured by way of extraction processes (such as using alcohol) are likely to be therapeutic goods.

Foods

Typically, whole or dried mushrooms are traditionally used in Australia or New Zealand as food for human consumption. In this form, they are considered and regulated as foods, for example, mushroom pate or mushroom chips.

Food products must comply with the relevant food regulation, for example Food Standard 2.3.1 – Fruit and vegetables.

Claims which are therapeutic in nature must not be made about food products unless those claims are specifically permitted in a relevant food standard.

Novel foods

Novel foods, such as lions mane mushrooms (*Hericium erinaceus*), are prohibited from retail sale unless included in the list of permitted novel foods under the Food Standards Code or schedule. See the FSANZ website for information.

Psilocybin

- Psilocybin is a psychedelic substance extracted from mushrooms. Mushrooms that contain psilocybin are included in the Australia New Zealand Food Standards Code - Schedule 23 - Prohibited plants and fungi, usually under the species name Psylocybe spp. Mushrooms containing psilocybin cannot be used in or sold as food in Australia.
- From 1 July 2023, psilocybin-containing products will be permitted to be prescribed as a prescription only medicine by authorised psychiatrists under strict conditions.

- Prescription medicines, including products containing psilocybin, are prohibited from being advertised to the public through any channel.
- Further information on psilocybin can be found at Re-scheduling of psilocybin and MDMA in the Poisons Standard: questions and answers.

Regulatory requirements for mushroom products regulated as therapeutic goods

We see a spectrum of potentially non-compliant behaviour in relation to mushroom products, such as therapeutic claims being made and that are directed at vulnerable consumers.

Advertisers and suppliers of mushroom products that are therapeutic goods must comply with the Act, the Regulations and the Advertising Code as outlined above at About this mushroom guidance.

Mushroom based therapeutic goods must be entered in the ARTG

Mushroom products that are therapeutic goods must be entered in the ARTG unless exempt from being entered in the ARTG, or otherwise authorised by the TGA.

In Australia, if not entered in the ARTG and no exemptions apply, these products cannot be:

- advertised
- imported
- exported
- manufactured, or
- supplied / sold.

TGA permission is required for restricted and prohibited representations

Even if therapeutic goods are entered in the ARTG, advertising (including product labels) must not refer to restricted or prohibited representations without prior permission or approval by the TGA.

Restricted representations are representations that refer to serious forms of diseases, conditions, ailments, or defects which require a suitably qualified health professional to diagnose and/or treat them.

Prohibited representations are representations that refer to specific serious conditions, such as cancer, sexually transmitted diseases and mental illness.

These representations require prior approval of the TGA before being used in advertising.

Advertisers are responsible for all their advertising material, including testimonials by customers that are published on their websites and social media platforms. Advertisers must ensure that unapproved restricted and prohibited representations do not appear in customer reviews or testimonials in advertising of therapeutic goods on their websites as these must

comply with the advertising requirements. Guidance on social media advertising can be found on the TGA website.

Consequences of advertising unapproved mushroom therapeutic goods

The TGA will take appropriate regulatory action when:

- therapeutic goods that are required to be entered in the ARTG are imported or supplied in Australia without being entered in the ARTG
- advertising does not comply with therapeutic goods advertising requirements.

Compliance actions in response to non-compliance with the requirements can include the issue of infringement notices or commencement of court proceedings. The TGA publishes advertising enforcement and outcomes on its website.

The TGA may refer cases about non-compliant foods to the relevant state and territory regulator. This includes when therapeutic claims are made about the food or if there are issues with ingredients.

Further information

Therapeutic Goods

- The *Therapeutic Goods Act 1989*
- The *Therapeutic Goods Regulations 1990*
- The Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021
- The Australian Register of Therapeutic Goods (ARTG) | Therapeutic Goods Administration (TGA)
- Information on the definition of 'therapeutic goods'
- Information on the use of restricted representations or prohibited representations in the advertising of therapeutic goods
- Guidance on advertising via social media

Foods

- The Australia New Zealand Food Standards Code
- Standard 2.3.1 of the Australia New Zealand Food Standards Code for fruit and vegetables
- Information on novel foods under the Food Standards Code
- Permitted novel foods under Schedule 25 of the Australia New Zealand Food Standards Code
- Australia New Zealand Food Standards Code – Schedule 23 – Prohibited plants and fungi

Version history

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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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