Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Determining if your product is a cosmetic or therapeutic good

This guidance will assist you in determining if a product is a cosmetic or a therapeutic good and how to comply with Australian regulatory requirements and advertising rules for therapeutic goods.

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Purpose

In Australia, products for external use or inside the mouth may be regulated as either cosmetics or therapeutic goods, depending on their precise circumstances. Cosmetics are typically used to change the body's odour or appearance, cleanse it, keep it in good condition or protect it. By contrast, therapeutic goods are for a therapeutic use. Cosmetics and therapeutic goods have separate standards and regulatory frameworks for safety, quality, efficacy, labelling and claims.

It may not be initially clear whether a product is a cosmetic or a therapeutic good. There are some products that may appear to fall within more than one definition and require further analysis to determine which regulatory scheme applies.

This guidance is designed to assist you in determining if a product is a cosmetic or a therapeutic good, and how to comply with the regulatory requirements for therapeutic goods in Australia, including the advertising requirements.

This guidance is not intended to provide definitive advice on whether any particular product is a cosmetic or a therapeutic good, or to substitute for a careful analysis of those products and the application of the relevant legislation.

Products can be classified as either cosmetics or therapeutic goods based on the following factors:

- the claims made about the product
- the product ingredients or composition
- how the product is administered or used

- whether the product is an Excluded Good or product declared not to be a therapeutic good.

Products that are therapeutic goods based on the above factors must be entered in the Australian Register of Therapeutic Goods (the ARTG) before they are imported, supplied or advertised in Australia, unless they are specifically excluded, or are the subject of an approval or authority.

Businesses are responsible for determining whether their product is a cosmetic or a therapeutic good, and then complying with the relevant regulatory requirements.

> This information is provided for guidance only and should not be relied on to address every aspect of the relevant legislation. It provides our interpretation of requirements based on current knowledge of the subject matter.
>
> It is the responsibility of each sponsor, advertiser and supplier to understand and comply with the regulatory requirements contained in the Act and supporting legislation.
>
> You are encouraged to seek your own independent legal advice on how therapeutic goods legislation and other applicable laws apply to you.

Legislation

Therapeutic Goods Act 1989

Therapeutic Goods (Declared Goods) Order 2019

Therapeutic Goods (Excluded Goods) Determination 2018

Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

Industrial Chemicals Act 2019

Regulation of cosmetics

The regulation of cosmetic ingredients or products involves a suite of controls that are the responsibility of:

- the Australian Industrial Chemicals Introduction Scheme (AICIS)
- the Australian Competition and Consumer Commission (ACCC), and
- the Poisons Standard.

Australian Industrial Chemicals Introduction Scheme

The Australian Industrial Chemicals Introduction Scheme (AICIS) regulates the introduction of ingredients used in cosmetics under the *Industrial Chemicals Act 2019*.

Cosmetic ingredients are recognised as industrial chemicals and are subject to the requirements of the AICIS.

AICIS does not regulate cosmetic products, product safety, labelling or advertising for cosmetics.

For more information, visit the AICIS website.

Australian Competition and Consumer Commission

The Australian Competition and Consumer Commission (ACCC) is the primary regulator for products for general sale, including cosmetics, and is responsible for product safety, ingredient labelling, and the claims made about those products.

The ACCC also administers the Australian Consumer Law found in Schedule 2 of the *Competition and Consumer Act 2010*, which requires that advertising about cosmetics is not false, misleading, or deceptive.

For more information, visit the ACCC website.

The Poisons Standard

The Poisons Standard is a legislative instrument that we administer, which recommends the classification of medicines and poisons into Schedules according to their risk-benefit profile. The Poisons Standard is principally adopted by the relevant legislation of the States and Territories that control the supply of medicines and poisons.

The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on medicines and poisons.

Ingredients in cosmetic products and therapeutic goods may be subject to limits or requirements under the Poisons Standard.

Regulation of therapeutic goods

The regulation of therapeutic goods in Australia, including in relation to the import, supply, export, manufacture and advertising of therapeutic goods, is provided for by:

- the *Therapeutic Goods Act 1989* (the Act)
- the Therapeutic Goods Regulations 1990 (the Regulations),
- the Therapeutic Goods (Medical Devices) Regulations 2002 and
- Various legislative instruments made under the Act, including for instance the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Advertising Code).

We are responsible for administering the above legislation, and for evaluating, assessing and monitoring the safety, quality and efficacy or performance of therapeutic goods and their ingredients, product labelling and advertising.

Subject to a limited number of exceptions, therapeutic goods that are not on the ARTG cannot be manufactured, imported, exported, supplied or advertised in Australia. See our webpage regarding unapproved goods for more information.

We may pursue regulatory actions including sanctions and penalties against those who import, supply, manufacture or export therapeutic goods not entered on the ARTG, or do not comply with therapeutic goods advertising and other applicable regulatory requirements (see also Consequences of advertising unapproved therapeutic goods).

Definitions

What is a cosmetic?

A cosmetic is a substance intended to be placed in contact with any external part of the body, or inside the mouth, with a view to changing its odour or appearance, cleansing it, keeping it in good condition or protecting it.

The definition of cosmetic in the *Industrial Chemicals Act 2019* (section 9) explicitly excludes therapeutic goods as defined under the *Therapeutic Goods Act 1989* (see below). This definition, including examples, can be viewed at the AICIS Cosmetics webpage.

Examples of cosmetics may include:

- bath salts
- some face creams, body lotions and hand creams
- some deodorants and antiperspirants
- hair dye
- some makeup including lipstick and mascara
- nail polish
- perfume
- some shampoos and conditioners
- shaving cream
- some soaps.

For examples of cosmetic and therapeutic claims used on products see the claims made about the product.

Please note this guidance document does not cover the distinction between advertising health services and advertising therapeutic goods. For further information on this distinction please see the Advertising health services webpage on our website.

What is a therapeutic good?

Therapeutic goods are defined in section 3 of the Act and include products that are represented in any way to be, or that are, likely to be taken for therapeutic use, whether because of the way in which the goods are presented, or for any other reason.

Therapeutic goods also include goods that are part of a class of goods, the sole or principal use of which is, or ordinarily is, a therapeutic use.

Therapeutic use is also defined in section 3 of the Act, and broadly means that the product is used in or in connection with, among other things:

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

Therapeutic goods comprise a wide range of products including:

- prescription, complementary, or over-the-counter medicines
- some sunscreens
- medical devices
- biologicals.

See our webpage What are 'therapeutic goods'? for more information.

In some instances, it may be unclear whether a product is a therapeutic good or a cosmetic. We have determined that certain products are, or are not, therapeutic goods when used, advertised or presented for supply in a particular way.

> Products for therapeutic use are therapeutic goods and must be regulated as such, unless the product is an excluded good or declared not to be a therapeutic good.

Generally, where a product is an excluded good or is declared not to be a therapeutic good and is presented and/ or advertised for use on any external part of the body, or inside the mouth, it will be regulated as a cosmetic.

How to tell the difference between a cosmetic and a therapeutic good

It is important for businesses to correctly determine if a product is a therapeutic good or a cosmetic, as the regulatory requirements differ. To determine whether a product is a cosmetic or therapeutic good you must consider the following:

- the claims made about the product
- product ingredients or composition
- how the product is administered or used
- whether the product is an excluded good or product declared not to be a therapeutic good.

A description of each of these factors is provided below.

The factors should not be considered in isolation. An assessment of whether a product is a therapeutic good or a cosmetic needs to be undertaken on a case-by-case basis and, in most cases, can only be determined based on an overall consideration the factors and the characteristics of the product.

We have developed the Is my product a therapeutic good? tool, which can be used to assist advertisers in determining whether or not particular products are likely to be therapeutic goods.

AICIS has a similar tool to assist advertisers: Is my product a cosmetic?

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

The claims made about the product

This factor relates to the claims made about a product through statements, images or designs that communicate the intended use and benefits of a product to consumers. Claims can be found on the product label (including the product name) or package insert, and in advertising.

It is important to consider the nature and purpose of a claim when determining if a product is a therapeutic good or cosmetic.

Cosmetics are intended to be used on the body or in the mouth, and their promotional claims are limited to those that are consistent with the meaning and intent of changing the body's odour or appearance, cleansing it, keeping it in good condition or protecting it.

Therapeutic goods generally make claims that represent them to be, or likely to be, for therapeutic purposes, which includes use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment or defect or
- influencing, inhibiting or modifying a physiological process in persons.

Questions to consider include:

- Does the product claim to change look or appearance, such as by adding colour or smoothing skin texture by adding a layer of product?
- Does the product claim to change an underlying physiological process to achieve a different appearance?

Consider the following examples as comparisons of similar claims made about a cosmetic versus a therapeutic good:

- 'Helps your skin look even and smooth' (cosmetic – changing its appearance) vs 'Reduces skin pigmentation and uneven skin tone' (therapeutic good - physiological change)
- 'Helps skin look firm' (cosmetic – changing its appearance) vs 'Improves skin's internal structure for firmer skin' (therapeutic good - physiological change).

It is also important to consider the impact images and context can have on a product's presentation and its claims. For example, a claim such as 'soothes dry skin' in relation to a moisturiser may be considered cosmetic, however, using this claim alongside pictures of severe dry or irritated skin (such as psoriasis), or including that advertisement on a patient support website for chronic psoriasis sufferers, may reasonably give a consumer the impression the product has therapeutic uses in relation to psoriasis.

Example: Moisturising claims

Cosmetic claim: 'our body lotion contains aloe to help hydrate and moisturise your skin'

Therapeutic claim: 'our body lotion contains aloe to help hydrate dry skin, soothing and repairing psoriasis patches'.

Example: Collagen products

Cosmetic claim: 'our facial oil contains collagen to smooth the appearance of fine lines'

Therapeutic claim: 'our facial oil stimulates collagen production to repair skin at the cellular level. This will enhance skin elasticity and smooth out wrinkles from within'.

Example: Essential oils

Essential oils are liquid extracts obtained from raw plant materials. They are commonly used as fragrances and are promoted for a wide range of uses. They may be used as ingredients in cosmetics or therapeutic goods, or they may be a raw material or finished product for general sale. For example, orange oil is also sold as a general purpose cleaning product.

If a product containing essential oils makes therapeutic claims, it will be considered a therapeutic good and must comply with therapeutic goods legislation.

Essential oils that make therapeutic claims must not be supplied, imported, or advertised in Australia unless they are entered into the ARTG, and comply with all relevant regulatory requirements.

Examples of product types with therapeutic claims

The list below provides examples of commonly used products which would likely be considered therapeutic goods unless otherwise excluded (see information on excluded goods and products declared to not be therapeutic goods below). This list is not exhaustive and should only be used as a guide.

- Hair care health
    - Medicated shampoos including:
        - anti-fungal
        - control or prevent dandruff
        - promote hair growth or decrease/reduce hair loss/alopecia.
- Personal hygiene
    - medicated antiperspirants.
- Face and skin care with references to:
    - healing or repairing damaged or dry skin through regenerating skin cells
    - antiviral, antibacterial or antiseptic activity
    - treating or relieving skin diseases, conditions or ailments, such as:
        - pimples and acne
        - scarring
        - rosacea
        - eczema and psoriasis
        - burns or sunburn
        - pain and inflammation.
- Oral care and hygiene
    - With references to:
        - gum or oral disease, or periodontal conditions, such as gingivitis
        - antiseptic or antiviral activity

    - pain, sensitivity or irritation.
  - Desensitising toothpastes.
- Sun protection
  - Primary sunscreens (products with a primary use of sun protection)
  - Some Secondary sunscreens (products with a primary use other than sun protection).

AICIS has published a list of examples of products that would likely be considered to be making cosmetic claims (see Cosmetics and therapeutics).

Product ingredients or composition

A product's ingredients, and the concentration of those ingredients (i.e. whether the concentration of ingredient influences, inhibits or modifies a physiological process), may also influence whether a product is likely to be a therapeutic good or a cosmetic.

If a product contains an ingredient that is known to have a therapeutic use, it may be more likely to be taken to be a therapeutic good.

Example: Skin whitening products

Skin-whitening lotions that contain ingredients such as hydroquinone, known to inhibit the physiological process of melanin production, are regulated as therapeutic goods.

A product will also likely be considered to be a therapeutic good if it contains ingredients that are included in Schedules 2, 3, 4 or 8 of the Poisons Standard. These ingredients are principally included in classes of goods, the sole or principal use of which is, or ordinarily is, a therapeutic use.

Example: Ingredient concentration

Some cosmetics, including certain soaps, contain etidronic acid and may be regulated as prescription medicines (included in Schedule 4) under the Poison Standard.

If a product contains etidronic acid for use other than topical only, or more than 1% etidronic acid, the product is considered a therapeutic good (a prescription medicine) and must comply with therapeutic goods legislation. When the etidronic acid content does not result in inclusion within Schedule 4, products may be non-prescription therapeutic goods or cosmetics pending on other factors outlined in this guidance.

If a product does not contain an ingredient included in Schedules 2, 3, 4 or 8 of the Poisons Standard it does not necessarily mean that it is not a therapeutic good.

Products that do not contain ingredients mentioned in a schedule to the Poisons Standard may be regulated as a cosmetic or a therapeutic good depending on the circumstances, including their effect on the body, how they are used or administered (e.g. topically or in injectable form) and the nature of any claims made in connection with the product. For more information see the claims made about the product above.

Example: Shae butter moisturizer

Cosmetic claim: 'Contains shae butter to moisturise and hydrate the skin.

Administration/use: intended for topical application (to the skin) only

Product ingredients and composition: does not contain any ingredients included within Schedules 2, 3, 4 or 8 to the Poisons Standard.

When considering the ingredients of the product, in combination with how it is intended to be administered and the claims made, this product is likely to be regulated as a cosmetic.

How the product is administered or used

This factor relates to how the product is taken or applied to the body.

- Cosmetics are only for use on any external part of the body or inside the mouth.
- Therapeutic goods can be administered in a range of different ways, including:
    - topically (applied to the external part of the body), including as a cream, ointment or transdermal patch
    - orally (ingested), including as a tablet, powder or liquid
    - by injection, including subcutaneously (beneath the skin), intramuscularly (into the muscle) or intravenously (into a vein).

Products for topical use or for use on teeth or in the mouth may be regulated as a cosmetic or a therapeutic good depending on the circumstances, including the type of product, ingredients and the claims made. For more information see The claims made about the product above.

Products labelled or promoted for cosmetic purposes, and are orally ingested, are declared to be therapeutic goods under the Therapeutic Goods (Declared Goods) Order 2019.

Products taken orally that make cosmetic claims

In Australia, orally ingested supplements containing vitamins, minerals, or other nutritive substances and that are labelled or promoted for cosmetic purposes, such as to improve the appearance of skin, hair and nails, are legally declared to be therapeutic goods under the Therapeutic Goods (Declared Goods) Order 2019 These products cannot be regulated as foods or cosmetics, and must comply with therapeutic goods legislation when:

- they are labelled or promoted for cosmetic claims, and
- they are used, advertised or presented for supply for oral consumption.

These products are usually included in the ARTG as low risk listed medicines and can only use claims included in the Therapeutic Goods (Permissible Indications) Determination.

Excluded Goods and products declared to not be therapeutic goods

Certain categories of products may be either *excluded* from being therapeutic goods for the purposes of the Act or be *declared* to not be therapeutic goods because the Secretary is satisfied that they do not meet the 'therapeutic goods' definition. The lists below provide examples of products covered by each aspect of legislation. These lists may not be exhaustive and you should read the relevant item within

the legislation for full details of any requirements.

Goods excluded from being therapeutic goods

The Therapeutic Goods (Excluded Goods) Determination 2018 outlines particular circumstances where products are excluded from being therapeutic goods for the purposes of the Act.

It is important to note that if a product does not comply with all relevant requirements in the Determination, it is not an excluded good, and therefore must comply with all applicable therapeutic goods regulatory requirements. Please note not all requirements are listed below, you must check individual requirements within the Determination for your product.

- Personal hygiene
    - Non-medicated antiperspirant preparations that are derived from specific ingredients.
    - Non-medicated soaps and detergents for cleaning skin or hair.
    - Menstrual pads other than tampons and menstrual cups.
- Oral health
    - Dental bleaches and dental whiteners.
    - Some oral hygiene products for the care of the teeth and the mouth including for the prevention of tooth decay. These must not make claims about diseases such as gum disease or periodontal conditions.
- Hair care health
    - Hair bleaches, hair dyes, hair-colorants and hair-perming preparations.
    - Anti-dandruff hair care products for controlling or preventing dandruff only through cleansing, moisturising, exfoliating or drying the scalp.

- Skin care
    - Some anti-acne skin care products for preventing acne only through cleansing, moisturising, exfoliating or drying the skin.
    - Antibacterial skin care products that meet particular requirements.
- Secondary sunscreens (has a primary use other than sun protection)
    - Lip balms that meet certain requirements.
    - Tinted bases and foundations that meet certain requirements.
    - Moisturisers that meet certain requirements (also must not claim SPF greater than 15).
    - Sunbathing skin care products (such as oils, creams, gels, tanning products without sun and after-sun care products) that meet certain requirements (also must not claim SPF greater than 15).

Goods declared to not be therapeutic goods

The Therapeutic Goods (Declared Goods) Order 2019 declares that particular products are not therapeutic goods when used, advertised or presented in particular ways, such as for:

- Personal hygiene
    - Deodorant preparations when used for dermal application.
    - Unmedicated soaps and detergents when used for cleansing skin or hair.
    - Unmedicated dental chewing gum when the only benefits claimed are consequential on improvements to oral hygiene.

Regulatory requirements for therapeutic goods

Any product categorised as a therapeutic good must be entered in the ARTG unless exempt from this requirement, or subject to an approval or authorisation not to be entered in the ARTG. In Australia, if not entered in the ARTG and no exemptions apply, these products cannot be:

- advertised
- imported
- exported
- manufactured
- supplied.

For information on how to add a medicine or medical device to the ARTG and how to legally supply different types of therapeutic goods in Australia see our webpage Supply a therapeutic good.

Advertising regulations

There are strict rules on how therapeutic goods can be promoted and advertised in Australia.

Under these rules an advertiser must not:

- advertise unapproved therapeutic goods - those not included on the ARTG but required to be - to Australian audiences
- advertise goods containing substances in Schedules 3, 4 or 8 of the Poisons Standard (but excluding substances listed in Appendix H of the Poisons Standard). This includes prescription

medicines unless an exceptional permission from us applies, for example in relation to registered COVID-19 vaccines
- make unrealistic or misleading claims
- promote a product using therapeutic claims that are not consistent with the indications on its ARTG entry
- refer to restricted or prohibited representations without prior permission or approval by us.

The Advertising Code sets out minimum requirements for the marketing and advertising of therapeutic goods to the public. Under these rules, advertising must:

- be accurate and balanced, and not be misleading
- only make claims that are consistent with the advertised indication or intended purpose of the product as stated in the ARTG entry
- contain mandatory warning statements that are applicable to each therapeutic good being advertised
- only use testimonials that comply with the requirements of the Advertising Code
- ensure that unapproved restricted and prohibited representations do not appear in customer reviews or testimonials in advertising of therapeutic goods on their websites or social media.

For more information on how to advertise therapeutic goods compliantly visit the Advertising Hub on our website.

> Advertisers requiring support for specific matters are encouraged to pursue independent legal advice or assistance from a regulatory affairs consultant.

Consequences of not complying with requirements

The Act provides for civil and criminal penalties for non-compliant conduct, which includes:

- supplying or importing therapeutic goods that are not entered in the ARTG and which are not subject to one of the limited exceptions
- advertising therapeutic goods in a way that does not comply with advertising requirements.

The maximum amount payable under an infringement notice issued for a single contravention of the Act by a corporation is 60 penalty units ($18,780 as of 1 July 2023), and the maximum civil penalty that can be awarded by a court for a single contravention by a corporation is 50,000 penalty units ($15.65 million as of 1 July 2023). The value of a penalty unit is updated periodically and therefore these penalties will change accordingly.

We also have the power to cancel registered or listed medicines from the ARTG if there is non-compliance with advertising requirements in certain circumstances.

We will consider the proportionality of a particular penalty when determining the appropriate regulatory action for alleged non-compliance of the Act.

For more information about the types of actions we can take, visit our webpage Compliance actions and outcomes.

Further information

- Consumer Goods (Cosmetics) Information Standard 2020 - Federal Register of Legislation

- Cosmetics ingredients labelling- ACCC website
- Advertising and Selling Guide - ACCC website
- False or misleading statements - ACCC website
- Industrial Chemicals Categorisation Guidelines - AICIS, Department of Health and Aged Care website
- Cosmetics and soap - AICIS, Department of Health and Aged Care website
- Cosmetic injections checklist
- TGA social media advertising guide
- How we manage advertising compliance
- Advertising health services vs advertising therapeutic goods
- Regulation of platelet-rich plasma (PRP), platelet-rich fibrin (PRF) and conditioned serum

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Topics: Advertising Cosmetics Regulatory compliance Therapeutic goods regulation

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